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The President

Proclamation 10497 of November 16, 2022

National Rural Health Day, 2022

By the President of the United States of America

A Proclamation

On National Rural Health Day, we recommit to delivering quality, affordable health care to every zip code in America by making insurance and prescription drugs more affordable, expanding mental health and substance use disorder services, and by keeping rural facilities open and staffed with dedicated doctors, nurses, and other health professionals.

We have made progress, but challenges remain. For too long, rural hospitals and clinics have been closing, resulting in trauma patients in rural areas often needing to travel twice as far for care and experiencing a higher rate of fatality compared to Americans living in urban areas. These closures are also damaging to rural economies, where hospitals are often the biggest employers in town. Hunger and diet-related diseases are also more common in rural areas, deepening health inequities. And the COVID–19 pandemic further strained an already strapped system.

My Administration is fighting to change this. The American Rescue Plan directed $8.5 billion to help rural providers cover soaring costs associated with COVID–19—keeping rural hospitals and clinics open and contributing to nearly 700,000 previously uninsured rural Americans gaining health care coverage. To continue this progress, we established a new Rural Emergency Hospital designation with additional Medicare reimbursement to help improve access to emergency and outpatient care. We have provided $1.5 billion in scholarships and student loan assistance for rural clinicians and nurses, including over 20,000 National Health Service Corps members working in underserved areas. In addition, we launched an innovative program to train rural providers through the Department of Veterans Affairs to better serve the nearly five million veterans who live in rural areas. We are also helping to build and renovate rural facilities while boosting access to telehealth—a lifeline in remote areas—with historic investments in rural broadband and expansion of services that can be delivered via telehealth to providers serving Medicare beneficiaries. Meanwhile, the Inflation Reduction Act is lowering health insurance premiums under the Affordable Care Act and capping drug costs for seniors on Medicare at $2,000 a year and insulin at $35 per prescription per month.

At the same time, we are expanding mental health and substance use disorder services, supporting community health centers, training specialists, and sponsoring initiatives that reduce the stigma often associated with those conditions. Addressing the mental health crisis and beating the drug overdose epidemic, which cuts short so many lives in rural America, are urgent priorities for the Nation and key pillars of my Administration's Unity Agenda.

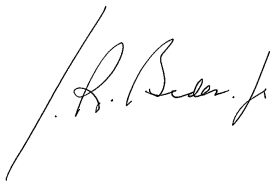
Finally, we are also improving rural health by making sure no child in America goes to bed hungry and no family has to second-guess the safety of the water they drink. In September, I convened the first White House Conference on Hunger, Nutrition, and Health in over 50 years, and released a national strategy to combat hunger and improve nutrition for every American. As part of the strategy, we are carving a pathway for all children to get free and healthy school meals and expanding efforts to increase access to local foods. This will benefit rural families as well as local farmers.

Through the Bipartisan Infrastructure Law, we are working with State, local, and Tribal partners to replace lead pipes, get rid of lead paint, and deliver clean water to every home nationwide.

We all benefit from the work rural Americans do to feed and fuel the Nation. Rural families deserve to pursue their dreams without worrying that the nearest hospital is too far or that their children and jobs will move away because health care is just too hard to find at home. Health care is a right, not a privilege, and I will never quit fighting for rural Americans.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 17, 2022, as National Rural Health Day. I call upon the people of the United States to reaffirm our dedication to the health and well-being of rural America.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of November, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-seventh.



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BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1091

[Docket No. CFPB–2022–0024]

Supervisory Authority Over Certain Nonbank Covered Persons Based on Risk Determination; Public Release of Decisions and Orders

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: The Consumer Financial Protection Bureau (Bureau) has procedures for establishing supervisory authority over a nonbank covered person based on a risk determination, which the Bureau recently amended in April 2022 (Updated Procedural Rule). The Updated Procedural Rule added a new process to the procedures, for the Bureau to consider making final decisions and orders in these proceedings public, in whole or in part. While the Bureau strongly believes in supervisory confidentiality, these particular decisions and orders present unique circumstances that implicate important public interests in transparency. The Updated Procedural Rule did not affect the confidentiality of supervisory examinations or other aspects of the supervisory process. The Bureau is making specific changes to that rule in response to comments, in order to clarify the standard that will govern whether a decision or order will be publicly released, as well as to give respondents in proceedings additional time to provide input on that issue.

DATES: This rule is effective on November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Shelton, Senior Counsel, Legal Division, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

Among other sources of supervisory authority, the Bureau can supervise a nonbank covered person that the Bureau ''has reasonable cause to determine, by order, after notice to the covered person and a reasonable opportunity for such covered person to respond . . . is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.'' [1] The Bureau issued a procedural rule in 2013 to govern these proceedings, which is codified at 12 CFR part 1091.[2] Under the original procedures, the Director's final decision or order in the proceeding generally could not be publicly released.

The Updated Procedural Rule that the Bureau issued in April 2022 amended these procedures, creating a process for the Director to consider whether to publicly release a final decision or order.[3] The Updated Procedural Rule was exempt from the notice-and-comment requirements of the Administrative Procedure Act (APA), because it was a rule of agency organization, procedure, and practice. Consequently, it was effective upon publication. However, the Bureau invited the public to submit comments.

The Bureau received nineteen comments. Many of the comments raised substantive issues regarding the entities that commenters believe the Bureau should designate, or how the Bureau should approach the ''risks to consumers'' standard. These comments are welcome, but the Bureau is not addressing those substantive issues in this procedural rulemaking.

After considering the comments on the Updated Procedural Rule, the Bureau is making two changes. First, as urged by several commenters, the Bureau is codifying a standard in the rule to govern the determination of whether to publicly release a decision or order. Second, at the request of one commenter, the Bureau is extending the time period that the rule gives to respondents to file a submission on the issue of public release. Part II of this preamble discusses in more detail the significant comments that the Bureau received.

II. Discussion

A. General Comments on Public Release of Decisions and Orders

The preamble to the Updated Procedural Rule explained that a central principle of the supervisory process is confidentiality. At the same time, final decisions and orders in part 1091 proceedings present unique considerations compared to other supervisory activity. There is a public interest in transparency when it comes to these potentially significant rulings by the Director as head of the agency. Also, if a decision or order is publicly released, it would be available as a precedent in future proceedings. Accordingly, the Bureau found that there should be a procedural mechanism to determine whether all or part of a decision or order should be publicly released.

Several trade associations and a credit union supported this approach. One association stated that public release would benefit all financial institutions by providing more clear examples of the types of acts and practices that pose risks to consumers. Another association noted that it was opposed to any erosion of confidentiality in the supervisory process itself, but it agreed with the Bureau that public release in this unique context could be insightful for both the public and other stakeholders. Similarly, a third association supported the change but emphasized that examinations should be confidential.

Other trade associations, a law firm, and an individual opposed any public release. One trade association expressed concern that public release would harm the Bureau's subsequent supervisory relationship with respondents. Several comments argued that public release would harm the reputations of companies. Relatedly, some commenters argued that the Bureau's risk determinations would be based on incomplete information about the respondent's practices, so there may be uncertainty about what specific practices the Bureau would find unlawful after a full investigation. According to these commenters, this

[1] 12 U.S.C. 5514(a)(1)(C). The Bureau must base such reasonable-cause determinations on complaints collected by the Bureau under 12 U.S.C. 5493(b)(3), or on information collected from other sources. *Id.*

[2] 78 FR 40351 (July 3, 2013); *see also* 85 FR 75194 (Nov. 24, 2020) (updating certain cross-references to 12 CFR part 1070). The 2013 procedural rule discussed the background and legal authority for 12 CFR part 1091 in more detail.

[3] 87 FR 25397 (Apr. 29, 2022).

could create uncertainty in the market and discourage lawful conduct and/or products that are beneficial to consumers. One comment also argued that the possibility of public release of the final decision could discourage the respondent from being candid when responding to a notice of reasonable cause issued by the Bureau. Some comments asserted that the approach the Updated Procedural Rule takes to respondents in risk-designation proceedings is inconsistent with the approach the Bureau takes to other supervised entities. Finally, some commenters argued that the rule was inconsistent with the approach of other financial regulators, although these comments did not cite specific examples.

After considering these comments, the Bureau continues to believe that there should be a process to publicly release final decisions and orders, in whole or in part, under appropriate circumstances. As the preamble to the Updated Procedural Rule explained, the public has an interest in understanding these consequential decisions. It can also be important for both the Bureau and the respondent in a risk-determination proceeding to be able to cite publicly available precedents from previous proceedings and assess whether or not they are analogous. This promotes consistency and predictability.[4] And the Bureau is not persuaded that public release—subject to the Director's authority to withhold or redact information when appropriate—would be harmful, for the reasons explained below.

First, public release of decisions and orders should generally cause no harm to the supervisory process, and those situations where there is a risk of harm can be addressed on a case-specific basis by withholding or redacting the relevant details. As background, the D.C. Circuit has explained that supervisory examinations are an informal process, where ''bank management must be open and forthcoming in response to the inquiries of bank examiners, and the examiners must in turn be frank in expressing their concerns about the bank.'' [5] That informal give and take requires confidentiality. However, a final decision or order by the Bureau's Director, which requires a respondent to submit to supervision, is very different in character from the collaborative back-and-forth between examiners and company employees that is the heart of the supervisory process.

Nonetheless, after considering the comments, the Bureau does foresee one circumstance where the need for supervisory confidentiality could potentially counsel against releasing information. Hypothetically, if the Director's decision or order were to include information about specific potential violations of law by the respondent, or specific potential compliance management deficiencies, and if that information were not otherwise publicly available (such as in a prior enforcement action by the Bureau or another regulator), that could be a situation where the risk of harm to the supervisory process potentially outweighs the public interest in transparency. That is because publicly revealing this information might signal the specific focus of subsequent confidential examinations. Accordingly, redactions may be warranted in that circumstance, as discussed further in part II.C of this preamble, below.

At the same time, the Bureau notes that Congress authorized the Bureau to make a risk designation when it has ''reasonable cause to determine'' that there are ''risks to consumers.'' [6] Congress did not require the Bureau to make findings that a respondent has violated the law or has compliance management deficiencies—instead, that is part of the purpose of subsequent examinations of the respondent.

The Bureau's risk-designation authority gives the Bureau's supervision program the ability to move as quickly as the marketplace. For instance, fast-growing companies in nontraditional areas of the consumer finance market may be engaged in novel activities that warrant supervisory attention because of their risks to consumers. And there can also be supervisory gaps in more traditional areas of the market that ought to be filled. Through the supervisory process, CFPB examiners can work with the company in question to fully understand and manage its risks. This preferably would occur before there has been any violation of law or consumer harm, rather than after.

Accordingly, the Bureau does not anticipate that most decisions and orders would include the kind of specific information about potential violations of law or compliance management deficiencies that warrant redactions.

With respect to commenters' concerns about reputational harm, there is no reason to believe that proceedings under part 1091—which provide a fair opportunity for the respondent to present its position to the agency and which are subject to judicial review—are more likely than any other legal proceeding to result in inaccurate findings the release of which would unfairly harm the respondent's reputation. In addition, to the extent the Bureau redacts nonpublic information about specific potential violations of law or specific potential compliance management deficiencies, for the supervisory reasons discussed above and in part II.C below, any reputational concerns would be attenuated.[7]

The Bureau emphasizes that the mere fact that the Bureau designates a nonbank covered person for supervision is not an allegation of wrongdoing. As a comparison, Congress decided that insured depository institutions and insured credit unions with more than $10 billion in assets would be subject to Bureau supervision, and the Bureau has published a list of those institutions on its website, for informational purposes, since the transfer of authority to the Bureau in 2011.[8] The fact that those depository institutions and credit unions are subject to Bureau supervision does not mean that they are engaged in violations of law. Similarly, an order designating a nonbank covered person for supervision only means that the Bureau believes that supervision is warranted, based on the statutory standard for those designations. Like with all institutions that it supervises, the Bureau will then use the confidential supervisory process to, among other things, assess the nonbank covered person's compliance with Federal consumer financial law.

The Bureau is also not persuaded by the comments arguing that public release would create uncertainty in the market. These comments assume that market participants would misunderstand the nature of the Bureau's findings, and so they would be

[4] One trade association asserted that the relevant decisions or orders have no precedential value because they would not be binding in a future proceeding, and also that each case is unique. The Bureau disagrees that precedents are only relevant when they are binding. The Bureau agrees that cases may or may not be analogous to one another, and some cases may turn on unique facts, but that can be true in any body of precedent.

[5] *In re Subpoena Served upon the Comptroller of the Currency,* 967 F.2d 630, 634 (D.C. Cir. 1992).

[6] 12 U.S.C. 5514(a)(1)(C).

[7] Relatedly, a law firm argued that respondents would have to expend substantial resources preparing for and addressing the reputational impact of public release. The Bureau agrees that respondents may choose to incur some public-relations-management and other costs to publicly respond to a public decision or order, but that is true of any adverse government decision and not an appropriate rationale, in itself, for keeping such decisions secret from the public.

[8] *See* Institutions Subject to the Bureau's Supervisory Authority, *https://www.consumerfinance.gov/compliance/supervision-examinations/institutions/.*

better off having no information about the Bureau's views. But the comments do not explain why market participants cannot be trusted to read the Bureau's decisions for themselves, to assess what significance those decisions may or may not have. It seems doubtful that a regulated entity would achieve greater certainty by remaining uninformed of its regulator's activities, or that the market as a whole functions more effectively when it has to guess about the market regulator's activities.[9]

The Bureau also does not believe that it is necessary, as a general matter, for the final order to be confidential in order for the initiating official to formulate a notice of reasonable cause under part 1091 and for a respondent to effectively respond to that notice. It is conceivable that a complete guarantee of confidentiality might result in respondents providing some amount of additional information in their responses. But a proceeding under part 1091 does not depend to the same degree as an examination on complete confidentiality. The Bureau believes that the public interest in transparency regarding the Director's decision or order will generally outweigh this consideration.

There is also no inconsistency between the approach that the Bureau is taking to respondents in risk-designation proceedings compared to other supervised entities. As noted above, the Bureau publicly releases a list of the insured depository institutions and insured credit unions that meet the $10 billion asset threshold to be subject to its supervisory authority. The Bureau does not currently publish such a list for the categories of nonbank covered persons that fall under its supervisory authority by statute or rule. A principal reason is that there is no available process to definitely establish whether a nonbank covered person engages in business activities that bring the nonbank covered person within those categories, other than when the Bureau initiates a specific confidential examination. That difficulty does not arise when the Bureau's Director has issued a final decision or order in a part 1091 proceeding. The Bureau emphasizes that it is committed to protecting examination confidentiality for all categories of entities that it supervises, in accordance with its confidentiality rules.[10]

Finally, there is no inconsistency between the Bureau and other financial regulators in this context. Generally, the prudential regulators supervise institutions based on their status as banks or credit unions, so the role that Congress assigned to the Bureau in extending supervision to nonbank covered persons based on their risks to consumers is unique. A roughly analogous situation is when the Secretary of the Treasury, the Chair of the Federal Reserve Board, the Director of the Bureau, and the other members of the Financial Stability Oversight Council make a determination that a nonbank financial company will become subject to Federal Reserve supervision, because that company ''could pose a threat to the financial stability of the United States.'' [11] The Council normally publishes a detailed explanation of its reasons. Any member of the public can read those reasons on the Council's web page.[12]

In summary, the Bureau is not persuaded by these commenters' arguments that public release of decisions and orders, in appropriate circumstances, would be harmful. However, as discussed in part II.C below, the Director will consider arguments that there are reasons why a particular decision or order should be withheld or redacted.[13]

B. Alternatives to Public Release Proposed by Commenters

Some commenters who opposed public release advocated for alternatives. These included: releasing only the names of supervised nonbanks but not the final decisions and orders themselves; relying on potential lawsuits seeking judicial review of decisions and orders to make information about them publicly available; adding anonymized summaries of decisions and orders to the Bureau's *Supervisory Highlights* publication; or including anonymized findings from subsequent exams of designated entities in *Supervisory Highlights.*

Ultimately, these alternatives would be inadequate to meet the goals of the Updated Procedural Rule. Releasing only the names of designated entities, or allowing only those proceedings that are challenged in court to enter the public domain, would provide the public with much less insight into the Bureau's use of its risk-designation authority and much less in the way of precedents to inform future risk-designation proceedings. Similarly, summarizing the Director's decisions and orders in an anonymized form in *Supervisory Highlights* would involve removing all potentially identifying information, which would likely deprive the public of information and context to understand the Director's decision regarding whether the individual entity satisfies the statutory standard for risk designation.

The Bureau does agree with commenters that significant findings from exams of designated entities, like significant findings from other Bureau exams, will be eligible for potential inclusion in *Supervisory Highlights* if that is appropriate under the circumstances and can be done while maintaining the entities' anonymity. Anonymity is important in that circumstance, because exam findings for an individual entity are part of the collaborative back-and-forth of the supervisory process and do not represent a final Director decision. The Director's final decision and order is different, for the reasons explained above. And although using *Supervisory Highlights* to release public summaries of significant exam findings is valuable, doing so would provide no direct insight into the Director's original decision to make a risk designation, so it is not a substitute for releasing the decision.

[9] On a similar note, a trade-association comment expressed concern that public release could inspire private lawsuits against respondents. It is true that Congress has chosen to make several of the laws that the Bureau administers privately enforceable by consumers. Such litigation may be meritorious or non-meritorious. There is no reason to believe that the Bureau's considered findings, informed by a fair administrative process, will increase the proportion of non-meritorious litigation.

[10] 12 CFR part 1070. In a related vein, one trade association argued that the Bureau's approach to final orders in risk-designation proceedings is inconsistent with the fact that it treats civil investigative demands (CIDs) issued by the Office of Enforcement as generally confidential. This objection overlooks the fact that when the Director as head of the agency rules on petitions to modify or set aside CIDs, the Bureau normally posts the Director's orders on its website in the interest of transparency. 12 CFR 1080.6(g).

[11] 12 U.S.C. 5323(a)(1), (b)(1).

[12] Financial Stability Oversight Council, Designations, *https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/fsoc/designations.* Of course, many features of the Council's determinations are dissimilar to the Bureau's risk determinations because of differences between the financial-stability and consumer-protection contexts, so the Bureau does not intend to suggest they are analogous in all respects. The Bureau further notes that, even if the Bureau's approach were different from other agencies (which it is not), the Bureau is free to pursue the approach that best achieves its view of its own statutory mission.

[13] A trade association argued that a decision highlighting a respondent's need to enhance cybersecurity could invite cybercrime. This kind of case-specific concern is properly analyzed on a case-by-case basis, under the standard discussed later in this preamble.

C. Standard for When the Bureau Would Publicly Release a Decision or Order

In the preamble to Updated Procedural Rule, the Bureau noted that rule did not codify a standard to govern public release. However, the preamble explained that the Bureau generally anticipated applying Exemptions 4 and 6 of the Freedom of Information Act to information submitted by respondents that is reflected in final decisions and orders.[14] Exemption 4 applies to ''trade secrets and commercial or financial information obtained from a person and privileged or confidential,'' while Exemption 6 applies to ''personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.'' [15] The Bureau stated that it would also consider (in the context of making individual determinations regarding public release) whether there are other reasons to not publicly release the decision or order, in whole or in part.

The Bureau specifically invited comments on whether it should amend the rule to codify a standard for determinations regarding public release. Commenters generally supported doing so, although there was disagreement among commenters about the best standard. One trade association stated that FOIA Exemptions 4 and 6 could reasonably apply to a wide variety of sensitive information and would give respondents ample means to limit the contents of a public order. Other commenters argued that FOIA Exemptions 4 and 6 are too limited, might not cover certain sensitive data, and are uncertain in scope.

After considering the comments, the Bureau is codifying a standard in the rule, which is that the Director will not release information in a decision or order to the extent it would be exempt from disclosure under FOIA Exemptions 4 and 6 or the Director determines there is other good cause. This standard is similar to the approach that the Bureau articulated in the preamble to the Updated Procedural Rule and requested comment upon. This approach will provide assurance to respondents that the Bureau will protect the categories of information included in those two FOIA exemptions, while not foreclosing respondents from raising, or the Director from invoking, other grounds that may arise. The Bureau disagrees with some commenters that the scope of Exemptions 4 and 6 is too uncertain, given that these exemptions are routinely applied by agencies and courts, or that the exemptions are too narrow, given that they are the method Congress has chosen to protect commercial interests and personal privacy interests in the FOIA context.[16] However, the standard adopted by the Bureau does not foreclose respondents from arguing that information not within those exemptions ought to be withheld for ''good cause.''

A potential example of ''good cause'' is the supervisory considerations noted in part II.A above. The Bureau generally expects to redact information about specific potential violations of law, or specific potential compliance management deficiencies, where the information is not otherwise publicly available, and where the Bureau concludes there is a risk of harm to the supervisory process that outweighs the public interest in transparency.

D. Input by Respondents Into the Determination Regarding Public Release

Section 1091.115(c)(2) of the Updated Procedural Rule provided that, within seven business days [17] of service of the decision or order, the respondent had the option of filing a submission on the issue of public release, and then the Director would determine whether the decision or order would be released on the Bureau's website, in whole or in part.[18]

A law firm argued that the Bureau should conduct a formal adjudicatory process when deciding whether to publicly release a decision or order—separate from and in addition to the substantive part 1091 proceeding—in which a decisionmaker other than the Director would conduct a hearing. The Bureau believes that the process established by the rule provides respondents with a full opportunity to raise any concerns regarding public release. The process proposed by the law firm would be cumbersome and disproportionate, resulting in excessive delay, unnecessary costs for the government, and additional legal fees for respondents.[19]

The law firm argued, in the alternative, that the seven-business-day interval for respondents to file their submissions regarding public release should be extended. The law firm cited some examples where other agencies provide companies with ten business days to address confidentiality issues in those agencies' programs. While the Bureau believes that the burden on a respondent to assess whether the text of a single decision or order contains confidential information is likely to be limited, it will err on the side of caution by extending the interval to ten business days.

E. Discussion of Impacts of the Rule

The preamble to the Updated Procedural Rule explained that it will have limited effects on the public. Nonbank covered persons that are respondents may incur incidental costs, if they choose to prepare submissions on the issue of public release. The preamble stated that the rule itself did not trigger public release of decisions and orders, since it simply established a procedure to consider that issue. It further noted that, if the Bureau does ultimately decide to release a decision or order, that should generally benefit covered persons, consumers, and other members of the public by giving them

[14] 5 U.S.C. 552(b)(4), (b)(6).

[15] *Id.*

[16] A law firm argued that the Bureau should add FOIA Exemption 3 to the list of exemptions, but the Bureau concludes that would create confusion. Exemption 3 resolves potential conflicts between FOIA disclosure and certain other federal statutes. 5 U.S.C. 552(b)(3). It contains requirements that may not be appropriate in a non-FOIA context. For instance, if a federal statute is ''enacted after the date of enactment of the OPEN FOIA Act of 2009,'' such a statute can only provide a basis for withholding records from a FOIA requester under Exemption 3 if it ''specifically cites to'' Exemption 3. 5 U.S.C. 552(b)(3)(B). But placing such a condition on applicable statutes is not necessarily appropriate in this non-FOIA context. Any statutory requirements are best addressed within the category of ''good cause,'' since compliance with an applicable statute would necessarily be ''good cause,'' rather than by relying on Exemption 3.

[17] Under the general rule for counting days in part 1091, the seven-day interval does not include intermediate Saturdays, Sundays, and Federal holidays. 12 CFR 1091.114(a). This preamble uses the term ''business days'' for convenience.

[18] The preamble to the Updated Procedural Rule also noted two other features of how § 1091.115(c)(2) operates. First, the Director's authority regarding public release can be delegated to a designee of the Director under existing § 1091.101. Second, the Updated Procedural Rule did not extend the staff separation-of-functions requirement in § 1091.109(c), which applies to the Director's final decision and order, to the Director's subsequent determination regarding public release. Doing so would not be required by law, and the routine determination of whether to post material on the Bureau's website is not sufficiently significant to warrant doing so. The Bureau did not receive comments opposing these two features of the rule, and the Bureau is retaining them. Some commenters, although not appearing to oppose the latter feature, disputed the description of the determination as routine. However, it is routine for federal agencies to decide whether to release or withhold information regarding regulated entities.

[19] The same comment cites examples of other agencies' practice that appear to be inconsistent with its argument that a formal adjudicatory process with a hearing is necessary. The comment cites, with approval, three agencies' processes for deciding whether to release business information under FOIA. Under those three agencies' FOIA regulations, like the Bureau's FOIA regulations, the agency generally provides notice to the submitter of the business information and an opportunity for the submitter to file an objection to the potential FOIA disclosure, and the regulations do not reference any trial-type hearing. 29 CFR 1610.19; 31 CFR 1.5; 45 CFR 5.42; 12 CFR 1070.20.

a better understanding of the Bureau's decisionmaking. This discussion from the Updated Procedural Rule remains applicable to this rule, which adds a standard for making the determination on public release and extends the interval for respondents to make submissions on that issue.

One trade association responded to the Bureau's observation that the Updated Procedural Rule did not itself trigger public release of decisions and orders, arguing that the Bureau was ignoring the consequences of the rule. However, the statement with which this trade association took issue is accurate: the Updated Procedural Rule did not cause public release by itself. The Bureau agrees that the procedures in that rule and this rule enable public release, and in both rules the Bureau has considered the consequences of such public release.

Other comments that relate to the impacts of public release of decisions and orders are addressed in part II.A above.

F. Interagency Consultation

In formulating both the Updated Procedural Rule and this rule, the Bureau has consulted the prudential regulators and the Federal Trade Commission.

III. Regulatory Requirements

The preamble to the Updated Procedural Rule explained that, as a rule of agency organization, procedure, or practice, it was exempt from the notice-and-comment rulemaking requirements of the APA.[20]

Because no notice of proposed rulemaking was required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[21] Moreover, the Bureau's Director certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, an analysis is also not required for that reason.[22] As a result of the rule, respondents in the relevant proceedings may choose to make submissions on the issue of public release. Some of these respondents may be small entities under the Regulatory Flexibility Act, but they would represent a very small fraction of small entities in consumer financial services markets. Accordingly, the number of small entities affected is not substantial.

The Bureau has also determined that this rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[23]

List of Subjects in 12 CFR Part 1091

Administrative practice and procedure, Consumer protection, Credit, Trade practices.

Authority and Issuance

Accordingly, the rule that amended 12 CFR part 1091, which was published at 87 FR 25397 on April 29, 2022, is adopted as final with the following changes:

PART 1091—PROCEDURAL RULE TO ESTABLISH SUPERVISORY AUTHORITY OVER CERTAIN NONBANK COVERED PERSONS BASED ON RISK DETERMINATION

■ 1. The authority citation for part 1091 continues to read as follows:

Authority: 12 U.S.C. 5512(b)(1), 5514(a)(1)(C), 5514(b)(7).

■ 2. In § 1091.115, revise paragraph (c)(2) to read as follows:

§ 1091.115 Change of time limits and confidentiality of proceedings.

* * * * *

(c) * * *

(2) *Publication of final decisions and orders by the Director.* The Director will make a determination regarding whether a decision or order under § 1091.103(b)(2), 1091.109(a), or 1091.113(e) will be publicly released on the Bureau's website, in whole or in part. The respondent may file a submission regarding that issue, within ten days after service of the decision or order. The Director will not release information in a decision or order to the extent it would be exempt from disclosure under 5 U.S.C. 552(b)(4) or (b)(6) or the Director determines there is other good cause. The Director may also decide that the determination regarding public release will itself be released on the website, in whole or in part. Section 1091.109(c) is not applicable to determinations under this paragraph.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2022–25139 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AM–P

[20] 5 U.S.C. 553(b).

[21] 5 U.S.C. 603, 604.

[22] 5 U.S.C. 605(b).

[23] 44 U.S.C. 3501–3521.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 11, 91, and 111

[Docket No. FAA–2022–1546]

Expunction Policy for Certain Civil Penalty Actions, Military Referrals, and Foreign Referrals

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Policy statement.

SUMMARY: The FAA will expunge records of civil penalty actions against individuals settled with no finding of violation, referrals of apparent violations by U.S. service members to the U.S. Armed Forces, and referrals of apparent violations by individual foreign certificate users to foreign aviation authorities.

DATES: This notification of enforcement policy is effective December 1, 2022.

FOR FURTHER INFORMATION CONTACT: Cole R. Milliard, Attorney, Enforcement Division, AGC–300, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3452; *Cole.Milliard@faa.gov;* or James Barry, Manager, Policy/Audit/Evaluation, AGC–300, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–8198; *James.Barry@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In 1991, the FAA adopted a policy of expunging records of certain closed legal enforcement actions against individuals.[1] The policy provided for the expunction of certain legal enforcement action records for individuals who hold airman certificates and those who do not, such as passengers. In 2011, the FAA suspended the expunction policy[2] based on the Airline Safety and Federal Aviation Administration Extension Act of 2010 (''Act'').[3] The Act amended the Pilot Records Improvement Act by requiring the FAA to create a pilot records database (''PRD'') for air carriers to use for pilot background checks. The Act further required the FAA to

[1] *See* FAA Enforcement Records; Expunction Policy, 56 FR 55788 (Oct. 29, 1991).

[2] *See* FAA Policy Statement on Expungement of Certain Enforcement Actions, 76 FR 7893 (Feb. 11, 2011).

[3] Public Law 111–216, 124 Stat. 2348 (2010).

maintain in the PRD ''summaries of legal enforcement actions resulting in a finding by the Administrator of a violation of this title or a regulation prescribed or order issued under this title that was not subsequently overturned.'' [4] The FAA is required to retain these records until the individual is deceased.[5] The FAA, therefore, determined that continuing its expunction policy was inconsistent with the Act and proceeded to implement the PRD through rulemaking.[6]

On June 10, 2021, the FAA published the final rule for the PRD in the **Federal Register**.[7] As stated in the final rule preamble, the Act ''requires the FAA to maintain records in the PRD for the life of the pilot and does not provide the FAA with discretion to expunge records outside of that timeframe.'' [8] However, records without a finding of violation are not included in the PRD.[9] When the FAA suspended the expunction policy in 2011, it stated it would determine the full effect of the PRD on the expunction policy and amend the policy accordingly.[10] The FAA has therefore reviewed all types of legal enforcement actions it issues to determine which records the FAA may expunge consistent with the Act and the PRD final rule.

Under 49 U.S.C. 46101(b), the Administrator must refer a complaint involving an apparent violation of a statute or regulation the FAA administers by a member of the U.S. Armed Forces while performing official duties to the secretary of the department concerned for action. The FAA calls these ''military referrals.'' In addition, the FAA refers an apparent violation of a statute or regulation it administers by an individual while exercising a foreign certificate or license (or other approval or authorization) to the appropriate foreign aviation authority for action. The FAA calls these ''foreign referrals.'' The FAA does not make a finding of violation as part of the military or foreign referral process. The FAA also may issue compromise orders, which involve no finding of violation, in settlement of civil penalty assessment actions and may compromise civil penalties of amounts greater than $50,000 against individuals without a finding of violation.[11]

Policy Statement

The FAA will begin expunging records of military and foreign referrals two years after the FAA closes those actions in the Enforcement Information System (''EIS'').[12] The FAA will close records of military and foreign referrals in EIS after (1) the FAA receives a response stating the action taken; or (2) 180 days from the date of the referral, whichever comes first. A two-year period before expunging military and foreign referrals comports with Privacy Act requirements that the agency maintain in its records only such information about an individual as is relevant and necessary to accomplish a statutory purpose of an agency.[13] The FAA will also expunge records of civil penalty actions against individuals settled with no finding of violation from EIS. Specifically, the FAA will expunge no-finding civil penalty actions five years after the date an individual subject to the civil penalty action or his or her representative: (1) pays the civil penalty; or (2) provides a promissory note for payment of the civil penalty to the FAA. If, at the time a record of a civil penalty action is due to be expunged, a subsequent enforcement action against the individual has been opened, the first civil penalty action record will be expunged if and when the subsequent enforcement action is expunged. This is consistent with the 1991 FAA expunction policy. If an individual who owes a civil penalty cannot be located, the FAA will maintain the record of the civil penalty action indefinitely unless or until the individual is located and the criteria in this policy statement for expunging the civil penalty action are satisfied. If a civil penalty is deemed ''uncollectable,'' the record will not be expunged until the civil penalty is satisfied.

The FAA will apply this expunction policy both prospectively and retrospectively, allowing for the expunction of EIS records of past actions that meet the criteria in this policy statement.

Issued in Washington, DC, on November 10, 2022.

Cynthia A. Dominik,

Assistant Chief Counsel for Enforcement.

[FR Doc. 2022–24982 Filed 11–18–22; 8:45 am]

BILLING CODE 4910–13–P

[4] 49 U.S.C. 44703(i)(2)(A)(iii).

[5] 49 U.S.C. 44703(i)(5).

[6] 76 FR 7894.

[7] 86 FR 31006. The PRD notice of proposed rulemaking (''NPRM'') is at 85 FR 17660 (Mar. 30, 2020).

[8] 86 FR 31017. Consistent with the Act's requirement, the FAA will expunge records when a pilot reaches ninety-nine years of age or upon receiving a notification of death. *Id.; see also* 14 CFR 111.40.

[9] *See* 49 U.S.C. 44703(i)(2)(A)(iii).

[10] 76 FR 7894.

[11] *See* 14 CFR 13.16(n)(2) & 13.18(i)(2); FAA Order 2150.3C, ch. 8, para. 20.f.(2). The provision in § 13.16(n) is not used in hazmat cases as a matter of policy. FAA Order 2150.3C, ch. 8, para. 19.g.(2).

[12] If conduct underlying the referral also gives rise to a legal enforcement action with a finding of violation, the record of that separate action will be maintained in accordance with 49 U.S.C. 44703(i)(2)(A)(iii) and 14 CFR part 111. *See, e.g.,* FAA Order 2150.3C, ch. 8, para. 29.b. (FAA is authorized to take legal enforcement action against any foreign person who violates U.S. statutes or regulations and may do so in the exercise of prosecutorial discretion); ch. 9, para. 10 (FAA may take action against a member of the U.S. Armed Forces if circumstances of the military referral demonstrate or raise a question as to a lack of qualification to hold an FAA-issued certificate).

[13] 5 U.S.C. 552a(e)(1).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1481; Project Identifier MCAI–2022–01442–R; Amendment 39–22248; AD 2022–24–08]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bell Textron Canada Limited Model 505 helicopters. This AD was prompted by the discovery of a potential fouling condition between the rotating swashplate outer ring and the non-rotating collective lever. This AD requires inspecting the collective control system rigging and depending on the results, rigging the collective and cyclic control systems, as specified in a Transport Canada emergency AD, which is incorporated by reference. This AD also requires reporting certain information. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective December 6, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 6, 2022.

The FAA must receive comments on this AD by January 5, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–

30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–1481; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For Transport Canada material incorporated by reference (IBR) in this final rule, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* internet *tc.canada.ca/en/aviation.* You may find this IBR material on the Transport Canada website at *tc.canada.ca/en/aviation.*

• You may view this service information at the FAA, FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–1481.

Other Related Service Information: For Bell service information identified in this final rule, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *bellflight.com/support/contact-support.* You may view this service information at the FAA contact information under *Material Incorporated by Reference* above.

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–1481; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the Transport Canada emergency AD, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada Emergency AD CF–2022–62, dated November 9, 2022 (Transport Canada Emergency AD CF–2022–62), to correct an unsafe condition for certain serial-numbered Bell Textron Canada Limited Model 505 helicopters. Transport Canada considers its emergency AD an interim action and stated that further AD action may follow.

This AD was prompted by the discovery of a potential fouling condition between the rotating swashplate outer ring and the non-rotating collective lever. The FAA is issuing this AD to address improper clearances in the collective control system installation. See Transport Canada Emergency AD CF–2022–62 for additional background information.

Related Service Information Under 1 CFR Part 51

Transport Canada Emergency AD CF–2022–62 requires accomplishing a collective control system rigging check and, depending on the results, rigging the collective control system and then the cyclic control system.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA also reviewed Bell Alert Service Bulletin 505–22–33, dated November 3, 2022. This service information specifies procedures for a one-time rigging check of the collective control system for minimum clearances and flight control rigging.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its emergency AD. The FAA is issuing this AD after evaluating all pertinent information and determining that the unsafe condition exists and is likely to exist or develop on other helicopters of the same type design.

Requirements of This AD

This AD requires accomplishing the actions specified in Transport Canada Emergency AD CF–2022–62, described previously, as IBRed, except for any differences identified as exceptions in the regulatory text of this AD. This AD also requires reporting certain information to Bell Product Support Engineering if any of the minimum clearance parameters are not met as a result of the collective control system rigging inspection (check).

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, Transport Canada Emergency AD CF–2022–62 is IBRed in this FAA final rule. This AD, therefore, requires compliance with Transport Canada Emergency AD CF–2022–62 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in Transport Canada Emergency AD CF–2022–62 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the sections titled ''Compliance'' and ''Corrective Actions'' in Transport Canada Emergency AD CF–2022–62. Service information referenced in Transport Canada Emergency AD CF–2022–62 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2022–1481 after this final rule is published.

Interim Action

The FAA considers this AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies

to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because the affected parts are critical to maintaining controlled flight and failure of a part could occur as a result of the unsafe condition during any phase of flight without any previous indications. In light of this, the initial action required by this AD must be accomplished within 10 hours time-in-service or 30 days, whichever occurs first. This compliance time is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1481; Project Identifier MCAI–2022–01442–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 118 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Inspecting the collective control system rigging takes about 1.5 work-hours for an estimated cost of $128 per helicopter and $15,104 for the U.S. fleet.

If required, rigging the collective and cyclic control systems takes about 4 work-hours and tooling costs about $29,000 for an estimated cost of $29,340 per helicopter. Reporting information takes about 1 work-hour for an estimated cost of $85 per helicopter.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–24–08 Bell Textron Canada Limited: Amendment 39–22248; Docket No. FAA–2022–1481; Project Identifier MCAI–2022–01442–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 6, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bell Textron Canada Limited Model 505 helicopters serial numbers 65011 through 65412 inclusive, 65414 through 65416 inclusive, 65419 through 65426 inclusive, 65428, 65430, and 65431, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6710, Main Rotor Control.

(e) Unsafe Condition

This AD was prompted by the discovery of a potential fouling condition between the rotating swashplate outer ring and the non-rotating collective lever. The FAA is issuing this AD to address improper clearances in the collective control system installation. The unsafe condition, if not addressed, could result in loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

(1) Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada Emergency AD CF–2022–62, dated November 9, 2022 (Transport Canada Emergency AD CF–2022–62).

(2) If any of the minimum clearance parameters are not met as a result of the actions required by paragraph A. of Transport Canada Emergency AD CF–2022–62, within 10 days after completing the actions required by paragraph A. of Transport Canada Emergency AD CF–2022–62, report the information identified in paragraphs (g)(2)(i) and (ii) of this AD by email to *productsupport@bellflight.com.*

(i) In the subject line of the email: The helicopter serial number and ''ASB 505–22–33.''

(ii) In the body of the email: Total hours time-in-service of the helicopter, and identify each clearance parameter that did not meet its minimum tolerance and the dimension of its measured parameter.

(h) Exceptions to Transport Canada Emergency AD CF–2022–62

(1) Where Transport Canada Emergency AD CF–2022–62 requires compliance in terms of air time, this AD requires using hours time-in-service.

(2) Where Transport Canada Emergency AD CF–2022–62 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph A. of Transport Canada Emergency AD CF–2022–62 requires a ''check,'' this AD requires an inspection.

(i) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199, provided that there are no known out of tolerance minimum clearance parameters.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

For more information about this AD, contact Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Transport Canada Emergency AD CF–2022–62, dated November 9, 2022.

(ii) [Reserved]

(3) For Transport Canada Emergency AD CF–2022–62, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* internet *tc.canada.ca/en/aviation.* You may find the Transport Canada material on the Transport Canada website at *tc.canada.ca/en/aviation.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 10, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–25404 Filed 11–17–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0460; Project Identifier AD–2021–00824–R; Amendment 39–22198; AD 2022–20–14]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Inc., Helicopters and Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters and various restricted category helicopters. This AD was prompted by reports of cracks found on the main transmission support case. This AD requires repetitive inspections of the main transmission housing assembly for cracks, pitting, and corrosion and depending on the results, corrective action. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2022.

ADDRESSES:

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0460; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Hye Yoon Jang, Aerospace Engineer, Delegation Oversight Section, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5190; email *hye.yoon.jang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters and restricted category Model HH–1K, SW205A–1, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P helicopters.

The NPRM published in the **Federal Register** on April 14, 2022 (87 FR 22146). The NPRM was prompted by reports of main transmission support cases found cracked at one of the lateral mounts. In the NPRM, the FAA proposed to require, within 3,000 hours time-in-service (TIS) accumulated by the main transmission after the effective date of the AD, and thereafter at intervals not to exceed 3,000 hours TIS accumulated by the main transmission, removing certain screws and washers and visually inspecting the upper and lower transmission support case lateral mount screws for corrosion and thread damage, washers for corrosion and pitting, bushings for corrosion and pitting, and lateral mount surfaces for corrosion and mechanical damage such as any crack or pitting. If there is any corrosion, thread damage, or mechanical damage, the NPRM proposed to require removing the affected parts from service before further flight.

The NPRM also proposed to require repetitive fluorescent penetrant inspections (FPIs) of all surfaces of the main transmission support case lateral mounts for a crack. For helicopters with a main transmission that has accumulated 6,000 or more total hours TIS, the initial FPI would be required before further flight after the effective date of the AD. For helicopters with a main transmission that has accumulated less than 6,000 total hours TIS, the initial FPI would be required before the main transmission accumulates 6,000 total hours TIS. For all helicopters, following the initial FPI, the NPRM proposed to require performing an FPI at intervals not to exceed 6,000 hours TIS accumulated by the main transmission. If there is any crack, the NPRM proposed to require removing the main transmission support case from service before further flight. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, Bell Textron Inc. The following presents the comments received on the NPRM and the FAA's response to each comment.

Comment Regarding the Unsafe Condition and Compliance With Service Information

Bell Textron Inc., commented that stress corrosion cracking of the support case that originates from a threaded hole used to secure the washer to the case lateral mount is not considered a safety of flight issue as changes to its maintenance manual and Component Repair and Overhaul (CR&O) manual address the issue. Bell Textron Inc., stated that it has revised its manuals to include a requirement to remove the washers at the scheduled 3000-hour Special Inspection for a detailed visual inspection and an FPI at the scheduled 6000-hour Overhaul to detect corrosion originating from a threaded hole under the washer that could result in cracking. Bell Textron Inc., also stated that its CR&O manual now specifies an improved washer installation procedure to minimize the risk of corrosion, as well as damage limits for the affected area.

The FAA acknowledges this comment; however, not all operators are required to accomplish a manufacturer's maintenance procedures. In order for procedures in service information, including procedures in manuals, to become mandatory when the FAA has determined the procedures are necessary to correct an identified unsafe condition, the FAA must issue an AD.

Request for Changes to the Required Actions

Request: Regarding the outcome of the visual inspections, Bell Textron Inc., recommended that rather than mandating the removal of parts that have any damage from service, which could ground several helicopters, the required actions of the proposed AD be revised to refer to the applicable CR&O manual for damage limits and repair procedure instead.

FAA Response: The FAA partially agrees. The FAA has revised the required actions in this final rule by specifying certain threshold limits and adding the option of repairing certain conditions in accordance with FAA-acceptable methods; however, the actions do not require referring to the CR&O manual for information.

Request: Regarding inspection and removal of hardware, Bell Textron Inc., requested the FAA revise the required actions of the proposed AD to require also determining if the case was previously repaired by Bell or a Bell Service Center (FAA or Bell approved repair with traceability), and if the case is found with a suspected unapproved repair, removing the case from service indefinitely.

FAA Response: The FAA disagrees with this request. The FAA currently has no information regarding repairs outside the scope of FAA-accepted methods having been accomplished on main transmission support cases affected by the proposed AD. Accordingly, the FAA has made no changes to this final rule based on that comment.

Request: Bell Textron Inc., requested the FAA revise the required actions of the proposed AD to require that if a case that has never been repaired exhibits corrosion on the bushing, lug face, or threaded hole(s) that is beyond repairable limits, contacting Bell Product Support for evaluation and a possible Bell approved Expanded Repair; Bell Textron Inc., added that the case can be returned to Bell or a Bell Service Center for evaluation and possible repair.

FAA Response: The FAA disagrees with this request. To require operators to contact the manufacture for repair instructions, as suggested by the commenter, would be delegating the FAA's rulemaking authority to that manufacturer. Additionally, the FAA does not have the authority to direct operators to return defective components to the manufacturer. However, operators may choose to contact Bell Product Support as this AD does not prohibit an operator from

contacting a manufacturer. Additionally, operators may request approval of any specific actions, including any specific corrective actions, as an alternative method of compliance (AMOC) under the provisions of paragraph (h) of this AD.

Recommendation To Allow Ferry Flights

Regarding the action to accomplish an FPI before further flight for helicopters with a main transmission that has accumulated 6,000 or more total hours TIS in paragraph (g)(2)(i) of the proposed AD, Bell Textron Inc., recommended the FAA allow a ferry flight to the nearest repair facility where the upper washers can be removed for a detailed 10X magnifying glass inspection. Bell Textron Inc., further stated that if a crack is suspected, to perform an FPI, and if a crack is found, to remove the affected support case from service. Bell Textron Inc., explained that the removal of all 8 washers for an FPI of the support case could be accomplished at the next scheduled overhaul as required by chapter 5 of the maintenance manual.

The proposed AD, as published, specifies no limitations for issuance of a special flight permit (SFP) (ferry flight). Accordingly, SFPs may be issued in accordance with 14 CFR 21.197 and 21.199. Additionally, the FAA has revised the initial action to accomplish an FPI on a main transmission that has accumulated 6,000 or more total hours TIS by extending the compliance time from ''before further flight'' to ''within 300 hours TIS'' and allowing credit if the action has previously been done within the last 6,000 hours TIS. Lastly, the FAA has revised the initial action to accomplish an FPI on a main transmission that has accumulated less than 6,000 total hours TIS from ''before accumulating 6,000 total hours TIS on the main transmission'' to ''before accumulating 6,300 total hours TIS on the main transmission.''

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for removing a note, minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Costs of Compliance

The FAA estimates that this AD affects up to 621 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Visually inspecting the main transmission mount assembly takes about 1 work-hour, for an estimated cost of $85 per helicopter and $52,785 for the U.S. fleet, per inspection cycle. Accomplishing an FPI of the main transmission support case lateral mounts will take about 1 work-hour for an estimated cost of $85 per helicopter, and $52,785 for the U.S. fleet, per inspection cycle.

The FAA has no way of determining the costs pertaining to necessary repairs that are required to be done in accordance with FAA-acceptable methods. Replacing the transmission support case assembly hardware parts including 8 washers, 8 screws, and 4 bushings will take about 1 work-hour and parts will cost up to $100 per part for an estimated cost of up to $2,085 per helicopter. Replacing the main transmission support case assembly will take up to 60 work-hours and parts will cost up to $54,501 for an estimated cost of up to $59,601 per helicopter.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–20–14 Bell Textron Inc., and Various Restricted Category Helicopters: Amendment 39–22198; Docket No. FAA–2022–0460; Project Identifier AD–2021–00824–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 27, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following:

(1) Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters, certificated in any category; and

(2) Various restricted category helicopters:

(i) Model HH–1K helicopters; current type certificate holders include, but are not limited to, Rotorcraft Development Corporation;

(ii) Southwest Florida Aviation International, Inc., Model SW205A–1 helicopters;

(iii) Model TH–1F helicopters; current type certificate holders include, but are not limited to, Robinson Air Crane Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(iv) Model TH–1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc. (type certificate previously held by JTBAM, Inc.); and Rotorcraft Development Corporation;

(v) Model UH–1A helicopters; current type certificate holders include, but are not limited to, Richards Heavylift Helo, Inc.;

(vi) Model UH–1B helicopters; current type certificate holders include, but are not limited to, International Helicopters, Inc.; Overseas Aircraft Support, Inc.; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and WSH, LLC (type certificate previously held by San Joaquin Helicopters);

Note 1 to paragraph (c)(2)(vi): Helicopters with an SW204 or SW204HP designation are Southwest Florida Aviation International, Inc., Model UH–1B helicopters.

(vii) Model UH–1E helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc.; Rotorcraft Development Corporation; Smith Helicopters; and West Coast Fabrications;

(viii) Model UH–1F helicopters; current type certificate holders include, but are not limited to, AST, Inc.; California Department of Forestry; Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(ix) Model UH–1H helicopters; current type certificate holders include, but are not limited to, Arrow Falcon Exporters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; JJASPP Engineering Services LLC; Northwest Rotorcraft, LLC; Overseas Aircraft Support, Inc.; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and Tamarack Helicopters, Inc.;

Note 2 to paragraph (c)(2)(ix): Helicopters with an SW205 designation are Southwest Florida Aviation International, Inc., Model UH–1H helicopters.

(x) Model UH–1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc.; and Rotorcraft Development Corporation; and

(xi) Model UH–1P helicopters; current type certificate holders include, but are not limited to, Robinson Air Crane, Inc.; and Rotorcraft Development Corporation.

(d) Subject

Joint Aircraft System Component (JASC) Code 6320, Main Rotor Gearbox.

(e) Unsafe Condition

This AD was prompted by reports of cracks found in the main transmission support case possibly due to corrosion. The FAA is issuing this AD to detect and address corrosion and other mechanical damage of the main transmission support case assembly. The unsafe condition, if not addressed, could result in cracking at the upper or lower surfaces of the lateral mounts, loss of load carrying capabilities of the main transmission, and subsequent loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within 3,000 hours time-in-service (TIS) accumulated by the main transmission after the effective date of this AD, and thereafter at intervals not to exceed 3,000 hours TIS accumulated by the main transmission, remove the screws and washers from the upper and lower surfaces of the main transmission support case lateral mounts and accomplish the following:

(i) Visually inspect each screw for corrosion and thread damage. If there is any corrosion or thread damage, before further flight, remove the screw from service.

(ii) Visually inspect each upper and lower washer for corrosion and pitting.

(A) If there is any corrosion or pitting that exceeds 10% of any surface or is deeper than 0.01 inch (0.3 mm), before further fight, remove the washer from service.

(B) If there is any corrosion or pitting that is 10% or less of any surface or has a depth of 0.01 inch (0.3 mm) or less, before further flight, remove the washer from service or repair the washer in accordance with FAA-acceptable methods.

(iii) Visually inspect each installed bushing for corrosion and pitting.

(A) If there is any corrosion or pitting inside the bushing bore that exceeds 10% of the surface or is deeper than 0.005 inch (0.13 mm), or if there is any corrosion or pitting on the bushing flange or chamfer that exceeds 10% of the surface or is deeper than 0.01 inch (0.3 mm), before further fight, remove the bushing from service.

(B) If there is any corrosion or pitting inside the bushing bore that is 10% or less of the surface or has a depth of 0.005 inch (0.13 mm) or less, or if there is any corrosion or pitting on the bushing flange or chamfer that is 10% or less of the surface or has a depth of 0.01 inch (0.3 mm) or less, before further fight, remove the bushing from service or repair the bushing in accordance with FAA-acceptable methods.

(iv) Visually inspect each upper and lower main transmission support case lateral mount machined surface adjacent to each washer and each lateral mount threaded screw hole for corrosion and mechanical damage. For the purposes of this AD, mechanical damage may be indicated by a crack or pitting.

(A) Before further flight, remove the main transmission support case assembly from service if any of the following exist:

(*1*) The depth of any pitting exceeds 0.03 inch (0.8 mm),

(*2*) The area of pitting for each pad surface exceeds 0.75 square inch (483.87 square mm) or exceeds 50% of any 0.50 inch (12.7 mm) diameter, or

(*3*) Any mechanical damage to the threaded holes (8–32 NC–2B x 0.62 deep) exceeds 1 thread depth.

(B) Before further flight, remove the main transmission support case assembly from service or repair the main transmission support case assembly in accordance with FAA-acceptable methods, if any of the following exist:

(*1*) The depth of any pitting is 0.03 inch (0.8 mm) or less.

(*2*) The area of pitting for each pad surface is 0.75 square inch (483.87 square mm) or less, or 50% or less of any 0.50 inch (12.7 mm) diameter, or

(*3*) Any mechanical damage to the threaded holes (8–32 NC–2B x 0.62 deep) has a depth of 1 thread or less.

(2) Fluorescent penetrant inspect (FPI) all surfaces of the main transmission support case lateral mounts for a crack at the compliance times identified in paragraph (g)(2)(i) or (ii) of this AD.

(i) For helicopters with a main transmission that has accumulated 6,000 or more total hours TIS, within 300 hours TIS after the effective date of this AD, unless already done within the last 6,000 hours TIS.

(ii) For helicopters with a main transmission that has accumulated less than 6,000 total hours TIS, before accumulating 6,300 total hours TIS on the main transmission.

(iii) If there is any crack, before further flight, remove the main transmission support case assembly from service.

(3) Thereafter following paragraph (g)(2) of this AD, at intervals not to exceed 6,000 hours TIS accumulated by the main transmission, FPI all surfaces of the main transmission support case lateral mounts for a crack. If there is any crack, before further flight, remove the main transmission support case assembly from service.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, DSCO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ASW-190-COS@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(i) Related Information

For more information about this AD, contact Hye Yoon Jang, Aerospace Engineer, Delegation Oversight Section, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5190; email *hye.yoon.jang@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on September 22, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–20914 Filed 11–18–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–837]

Schedules of Controlled Substances: Removal of [18F]FP–CIT From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration removes [18F]FP–CIT (chemical names: [18F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [18F]fluoropropylcarbomethoxy nortropane) from the schedules of the Controlled Substances Act. Prior to the effective date of this rule, [18F]FP–CIT was a schedule II controlled substance because it can be derived from cocaine, a schedule II substance, via ecgonine, also a schedule II substance. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, engage in research, import, export, conduct instructional activities or chemical analysis with, or possess) or propose to handle [18F]FP–CIT.

DATES: Effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause.[1] The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ''remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA).[2]

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party.[3] This action was initiated by a petition to remove [18F]FP–CIT from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle [18F]FP–CIT.

Background

[18F]FP–CIT (chemical names: [18F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [18F]fluoropropylcarbomethoxy nortropane) is described as a diagnostic substance that is used in assisting the evaluation of adult patients with suspected Parkinsonian syndromes. It is an entity used in the visualization of striatal dopamine transporters (DAT) using positron emission tomography (PET) imaging. [18F]FP–CIT is not yet approved by the United States Food and Drug Administration (FDA) and no New Drug Application (NDA) for [18F]FP–CIT or any [18F]FP–CIT-containing drug has been submitted to FDA.

[18F]FP–CIT is structurally similar to [123I]ioflupane, known as DaTscan or [123I]FP–CIT. Both [18F]FP–CIT and [123I]ioflupane were developed as clinical diagnostic substances to visualize DAT and contain the same tracer amount of the precursor, ecgonine. The only difference between these two compounds is the radiotracer (123I versus 18F). On January 14, 2011, FDA approved the NDA for [123I]ioflupane-containing drug product, DaTscan, for use to visualize striatal DAT in the brains of adult patients with suspected Parkinsonian syndromes using single photon emission computed tomography (SPECT) imaging. DEA removed [123I]ioflupane from schedule II of the CSA on September 11, 2015.[4]

The starting material for the synthesis of [18F]FP–CIT and [123I]ioflupane is *N*-nor-β-CIT (2β-carbomethoxy-3β -(4-iodophenyl) nortropane), which is derived from cocaine, a schedule II substance, via ecgonine (a schedule II substance). Thus, by definition[5] [18F]FP–CIT is currently controlled in schedule II of the CSA. On June 28, 2018, DEA received a petition from Advanced Imaging Projects to initiate proceedings to amend 21 CFR 1308.12(b)(4) so as to decontrol [18F]FP–CIT (proposed tradename Fluoroseek) from schedule II of the CSA. On October 6, 2018 and November 6, 2018, DEA received supplemental information from the Petitioner; DEA accepted the petition for filing on November 28, 2018.

DEA and HHS Eight-Factor Analyses

Pursuant to 21 U.S.C. 811(b), on May 2, 2019, DEA provided the necessary data on [18F]FP–CIT, along with the petition, to HHS with a request for a scientific and medical evaluation and scheduling recommendation for [18F]FP–CIT. On April 16, 2021, DEA received from HHS a scientific and medical evaluation, conducted by FDA[6], and a recommendation to remove [18F]FP–CIT from all schedules of the CSA. Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that [18F]FP–CIT be removed from all schedules of control of the CSA. In response, DEA conducted its own eight-factor analysis of [18F]FP–CIT pursuant to 21 U.S.C. 811(c). Both DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–837) at *https://www.regulations.gov* under ''Supporting and Related Material''.

Determination To Decontrol [18F]FP–CIT

On November 4, 2021, DEA published a notice of proposed rulemaking (NPRM) to remove [18F]FP–CIT from the schedules of the CSA. 86 FR 60785. The NPRM provided an opportunity for interested persons to file a request for a

[1] 21 U.S.C. 812.

[2] 28 CFR 0.100.

[3] 21 U.S.C. 811(a).

[4] 80 FR 54715.

[5] 21 CFR 1308.12(b)(4).

[6] As discussed in a memorandum of understanding entered into by FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

hearing in accordance with DEA regulations by December 6, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposal on or before December 6, 2021.

Comments Received

DEA received six comments on the NPRM to remove [^{18}F]FP–CIT from control.

Support for rulemaking: Five commenters supported decontrol of [^{18}F]FP–CIT. Four of these commenters noted the potential therapeutic benefit of this radiolabeled substance related to diagnosing Parkinson's disease.

DEA Response: DEA appreciates these comments in support of this rulemaking.

Opposition to rulemaking: One commenter opposed decontrol of [^{18}F]FP–CIT, suggesting rescheduling cocaine, or any cocaine derivative, is a safety concern and such rescheduling would wrongly signal that cocaine is less harmful than cannabis.

DEA Response: DEA does not agree with the commenter's concern about harm. [^{18}F]FP–CIT is derived from cocaine, a schedule II substance, via ecgonine, a schedule II substance. As described below [^{18}F]FP–CIT is manufactured as a radiopharmaceutical containing minute amounts of this radiolabeled substance in limited and specified places (*e.g.,* nuclear pharmacies) and distributed and handled under a highly regulatory environment.

As stated by FDA in its scientific and medical evaluation, radioligands in general are used in very dilute, or low dose formulations, and are unlikely to produce pharmacological effect and be abused, which is the case for the [^{123}I]ioflupane-containing drug product, DaTscan. Similar to [^{123}I]ioflupane, [^{18}F]FP–CIT is expected to be present in low concentration in the final drug product, thus it is unlikely that [^{18}F]FP–CIT will produce stimulant effects or be abused. Further, due to its radioactive nature and similar to the handling of [^{123}I]ioflupane, [^{18}F]FP–CIT will be restricted to nuclear medicine departments and radiopharmacies authorized to handle radioactive substances. Both nuclear medicine departments and radiopharmacies are highly regulated by multiple federal, state and local regulating agencies.

Based on the totality of the available scientific data, FDA stated that [^{18}F]FP–CIT does not conform with the findings for schedule II in 21 U.S.C. 812(b)(2) or in any other schedule as set forth in 21 U.S.C. 812(b). Based on FDA's scientific and medical review of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that [^{18}F]FP–CIT be removed from all schedules of the CSA. Pursuant to 21 U.S.C. 811(b), the recommendations of HHS shall be binding on DEA as to such scientific and medical matters and if the Secretary recommends that a drug or other substance not be controlled, DEA shall not control the drug or other substances. As stated in the NPRM, after careful review of all relevant data including HHS's scientific and medical evaluation and scheduling recommendation, DEA concurred with HHS's assessment that there is no evidence that [^{18}F]FP–CIT has a comparable potential for abuse relative to schedule V substances. DEA is therefore promulgating this final rule to remove [^{18}F]FP–CIT from control under the CSA and notes that non-radiolabeled FP–CIT remains a schedule II substance.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, the Administrator finds that these facts and all relevant data demonstrate that [^{18}F]FP–CIT does not meet the requirements for inclusion in any schedule. As such, DEA is removing [^{18}F]FP–CIT form control under the CSA.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for removing a drug or other substance from the list of controlled substances. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. This rule does not have substantial direct effects on the States, on the relationship between the Federal government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove [^{18}F]FP–CIT from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of [^{18}F]FP–CIT. Accordingly, it has the potential for some economic impact in the form of cost savings.

This rule will affect all persons who handle, or propose to handle, [^{18}F]FP–CIT. [^{18}F]FP–CIT is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of [^{18}F]FP–CIT, DEA is unable to determine the number of entities and small entities which might handle [^{18}F]FP–CIT. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether [^{18}F]FP–CIT is

expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle [18F]FP–CIT.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle [18F]FP–CIT will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements.

Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

DEA finds that good cause exists for adopting this rule as a final rule with an immediate effective date under 5 U.S.C. 553(d) because this final rule relieves a restriction.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[7]

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308— SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.12, revise paragraphs (b)(4)(i) and (ii) and add paragraph (b)(4)(iii) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(4) * * *

(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(ii) [123I]ioflupane; or

(iii) [18F]FP–CIT.

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25212 Filed 11–18–22; 8:45 am]

BILLING CODE 4410–09–P

[7] 44 U.S.C. 3501–3521.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–477]

Schedules of Controlled Substances: Placement of Zipeprol in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

DATES: Effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] Based on those

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

determinations, as appropriate, the Secretary of HHS (Secretary) shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to 21 U.S.C. 811(a) and (b).[3] The CSA also stipulates that in certain circumstances where the permanent section 811(a) scheduling will not be completed in time as required by the 1971 Convention, the Attorney General shall, after satisfying other specified conditions, issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under the 1971 Convention.[4]

In the event that the Secretary did not so consult with the Attorney General to make a determination about the existing legal controls, and the Attorney General did not issue a temporary order, the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).[5]

Background

Zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol) is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On May 20, 2013, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 3, 2009 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for zipeprol. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *http://www.regulations.gov* under docket number DEA–477.

Notice of Proposed Rulemaking To Schedule Zipeprol

On May 14, 2020, DEA published a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of zipeprol in schedule I.''[6] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before June 15, 2020. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before July 13, 2020.

Comments Received

DEA received eight comments on the proposed rule to control zipeprol in schedule I of the CSA.

Support for Rulemaking

Comments: Three commenters recognized zipeprol's high potential for abuse and adverse health effects, including reports of hallucinations, seizures, overdoses, and deaths. Thus, these commenters supported the placement of zipeprol in schedule I.

DEA Response: DEA appreciates these comments in support of this rulemaking.

Dissent for Rulemaking

Five commenters opposed the placement of zipeprol in schedule I, and provided various reasons as discussed below.

Comment: One commenter contended that it is not appropriate for DEA to schedule zipeprol as health experts, not law enforcement, should regulate and oversee all schedules I through III substances, and specifically that the Secretary of HHS is responsible for adding new substance to the CSA schedules.

DEA Response: DEA disagrees. Congress through the enactment of the CSA provided specific roles and procedures for both law enforcement (DEA) and the medical community (HHS) in controlled drugs with potential for abuse.[7] These procedures were followed in promulgating this final rule.

Comment: One commenter stated that all drugs need to be deregulated and decriminalized, and the focus of the law enforcement should be directed towards addressing social and non-drug related public health matters such as violent crime, unsolved murders, and control of obesity.

DEA Response: This comment is outside the scope of this rule insofar as it addresses drugs other than zipeprol. Regarding zipeprol, however, DEA maintains that control of zipeprol is needed and is appropriate. As stated in the background section, zipeprol is an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention. As a party to the 1971 Convention, the United States is taking action to place appropriate controls on zipeprol by scheduling it under the CSA.

Comment: One of two commenters mistakenly believe that zipeprol is a schedule II controlled substance under the CSA and that the proposed rule would reclassify zipeprol from schedule II to schedule I. The first commenter stated that reclassifying zipeprol to schedule I control does not warrant priority as it is not currently being used in the United States nor is it being actively manufactured or used in other countries, and there is a need for reclassification of many other drugs. This commenter added that marijuana needs to be reclassified from its current schedule I control.

DEA Response: DEA emphasizes to these commenters that zipeprol is not currently scheduled under the CSA. Perhaps the commenters are thinking of zipeprol's control status under the 1971 Convention. As noted in the background section, the Committee on Narcotic Drugs added zipeprol to Schedule II of the 1971 Convention in March 1995. DEA further notes that classification of a drug under the 1971 Convention, and its relevant schedules, is different from that of the CSA.[8]

[3] Id.

[4] 21 U.S.C. 811(d)(4)(A).

[5] 28 CFR 0.100.

[6] 85 FR 28899.

[7] 21 U.S.C. 811(a) and (b).

[8] The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States. See

Regarding the comment about reclassifying marijuana, this current rulemaking pertains only to the scheduling of zipeprol. Therefore, this comment is outside the scope of this rule.

Comment: A commenter noted that zipeprol and dextromethorphan (DXM, unscheduled under the CSA) are both cough suppressants with potential for abuse; however, adding control of DXM should take priority over reclassifying control of zipeprol as DXM is available and ''wildly abused'' in the United States.

DEA Response: This current rulemaking pertains only to the scheduling of zipeprol. Therefore, this comment is outside the scope of this rule.

Comment: One commenter recognized zipeprol's high potential for abuse and dependence but expressed that zipeprol has an accepted medical use as a cough suppressant. The commenter noted that schedule I, by definition, is only for drugs with both no accepted medical use and a high potential for abuse. Therefore, the commenter contends that zipeprol should instead be placed in schedule II.

DEA Response: DEA does not agree. While zipeprol was previously marketed and used in other countries in the 1980s and 1990s as a cough suppressant (antitussive), hallucinations, convulsions, and opioid-like tolerance, along with both a psychological and physical dependence, have been reported following its ingestion. As discussed in HHS's eight-factor analysis, zipeprol is not approved by the Food and Drug Administration for use in the United States. As explained in the NPRM, the medical and scientific evaluation and scheduling recommendation issued by the Assistant Secretary for Health of HHS (Assistant Secretary for HHS) concludes that zipeprol has no currently accepted medical use in treatment in the United States, has high potential for abuse, and lacks accepted safety for use under medical supervision. Following DEA's proposed determination to place zipeprol in schedule I, as outlined in the NPRM, the Administrator maintains the appropriateness of that schedule placement and concludes that zipeprol warrants control in schedule I of the CSA.[9] Further, regarding the appropriateness of placing zipeprol in schedule I of the CSA, DEA notes that Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. As a party to the 1971 Convention, the United States is taking action to place appropriate controls on zipeprol by scheduling it under the CSA.

DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c) and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the NPRM, after careful review of all relevant data, DEA concurred with HHS' assessment that zipeprol has a high potential for abuse with no currently accepted medical use in treatment the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.''[10] The other four schedules require the drug or other substance to have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions (schedule II) or a currently accepted medical use in treatment in the United States (schedules III through V).[11] DEA is therefore promulgating this final rule placing zipeprol in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of zipeprol. As such, DEA is permanently scheduling zipeprol as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V.[12] The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[13] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Zipeprol has a high potential for abuse. This potential is comparable to certain schedule II substances (*e.g.,* morphine);

(2) Zipeprol has no currently accepted medical use in treatment in the United States;[14] and

(3) There is a lack of accepted safety for use of zipeprol under medical supervision.

Based on these findings, the Administrator concludes that zipeprol, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, warrants control in schedule I of the CSA.[15]

Requirements for Handling Zipeprol

Effective as of December 21, 2022, zipeprol will be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) zipeprol, or who desires to handle zipeprol, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles zipeprol and is not registered with DEA must submit an application for registration and may not continue to handle zipeprol after the effective date of this rule, unless DEA has approved that application, pursuant to 21 U.S.C.

21 U.S.C. 812(b). In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention, and altered in accordance with Article 2.

[9] 21 U.S.C. 812(b)(1).

[10] 21 U.S.C. 812(b).

[11] Id.

[12] 21 U.S.C. 812(a).

[13] 21 U.S.C. 812(b).

[14] Although there is no evidence suggesting that zipeprol has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[15] 21 U.S.C. 812(b)(1).

822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of zipeprol as of the effective date of this rule, or may transfer all such quantities of currently held zipeprol to a person registered with DEA. Zipeprol is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Zipeprol is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling zipeprol must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of zipeprol must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture zipeprol in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of zipeprol must take an inventory of zipeprol on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including zipeprol) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including zipeprol) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to zipeprol, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding zipeprol to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes or orders zipeprol must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of zipeprol must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving zipeprol not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance zipeprol, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that zipeprol has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for zipeprol in the United States. Therefore, DEA estimates that no United States entity currently handles zipeprol and does not expect any United States entity to handle zipeprol in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding paragraph (b)(92) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(92) Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl) piperazin-1-yl]-1-phenylpropan-2-ol) 9873

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25206 Filed 11–18–22; 8:45 am]

BILLING CODE 4410–09–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 212

RIN 0412–AA97

Implementation of the Freedom of Information Act

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This regulation updates certain procedures and standards USAID follows in processing requests for records under the Freedom of Information Act (FOIA).

DATES: Effective December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher A. Colbow, Bureau for Management, Office of Management Services, Information Records Division, U.S. Agency for International Development, 1300 Pennsylvania Avenue, USAID Annex, Room 2.4.0A, Washington, DC 20523; tel. 202–916–4661; *foia@usaid.gov.*

SUPPLEMENTARY INFORMATION: This rule makes revisions to 22 CFR part 212, USAID's regulations under the Freedom of Information Act (FOIA) and the Privacy Act. The Agency is revising its regulations to update several procedural provisions, including methods for submitting requests under the FOIA, and initial appeals of denials of requests, for records of the Office of the USAID Inspector General (OIG). The Inspector General Act of 1978, as amended (5 U.S.C. App. 3) was enacted to, ''create independent and objective units,'' to perform investigative and monitoring functions within Executive Departments and Agencies of the Federal Government, including USAID. These revisions will further the OIG's independence and streamline the processing of requests that seek OIG records.

List of Subjects in 22 CFR Part 212

Freedom of Information.

For the reasons stated in the preamble, USAID revises 22 CFR part 212 to read as follows:

PART 212—PUBLIC INFORMATION

Subpart A—General Provisions

Sec.
212.1 Purpose and scope.
212.2 Policy.
212.3 Records available on the Agency's website.

Subpart B—Proactive Disclosures of Agency Records

212.4 Materials available for public inspection and in election format.

Subpart C—Requirements for Making Requests

212.5 How to make a request for records.

Subpart D—Responsibility for Responding to Requests

212.6 Designation of authorized officials.
212.7 Processing of request.

Subpart E—Timing of Responses to Requests

212.8 Time limits.

Subpart F—Responses to Requests

212.9 Responsibility for responding to requests.

Subpart G—Confidential Commercial Information

212.10 Policy and procedures.

Subpart H—Administrative Appeals

212.11 Appeal procedures.
212.12 Mediation and dispute services.

Subpart I—Preservation of Records

212.13 Policy and procedures.

Subpart J—Fees

212.14 Fees to be charged—general.
212.15 Fees to be charged—requester categories.

Subpart K—FOIA Definitions

212.16 Glossary.

Subpart L—Other Rights and Services

212.17 Rights and services qualified by the FOIA statute.

Subpart M—Privacy Act Provisions

212.18 Purpose and scope.
212.19 Privacy definitions.
212.20 Request for access to records.
212.21 Request to amend or correct records.
212.22 Request for accounting of record disclosures.
212.23 Appeals from denials of PA amendment requests.
212.24 Specific exemptions.

Authority: Pub. L. 114–185, 130 Stat. 538.

Subpart A—General Provisions

§ 212.1 Purpose and scope.

This subpart contains the rules that the United States Agency for International Development (hereinafter ''USAID'' or ''the Agency'') follows in processing requests for records under the Freedom of Information Act (''FOIA''), 5 U.S.C. 552. The rules in this subpart should be read in conjunction with the text of the FOIA. Requests made by individuals for records about themselves under the Privacy Act of 1974, are processed under Subpart O. Definitions of FOIA terms are referenced in subpart L of this part.

§ 212.2 Policy.

(a) As a general policy, USAID follows a balanced approach in administering the FOIA. USAID recognizes the right of the public to access information in the possession of the Agency. USAID also recognizes the legitimate interests of organizations or persons who have submitted records to the Agency or who would otherwise be affected by release of records. USAID has no discretion to release certain records, such as trade secrets and confidential commercial information, prohibited from release by law. USAID's policy calls for the fullest responsible disclosure consistent with those requirements of administrative necessity and confidentiality which are recognized under the FOIA.

(b) For purposes of subparts A through K, M, and O of this part, *record* means information regardless of its physical form or characteristics including information created, stored, and retrievable by electronic means that is created or obtained by the Agency and under the control of the Agency at the time of the request, including information maintained for the Agency by an entity under Government contract for records management purposes. It does not include records that are not already in existence and that would have to be created specifically to respond to a request. Information available in electronic form shall be searched and compiled in response to a request unless such search and compilation would significantly interfere with the operation of the Agency's automated information systems.

§ 212.3 Records available on the Agency's website.

Information that is required to be published in the **Federal Register** under 5 U.S.C. 552(a)(1) is regularly updated by the Agency and found on its public website, *https://www.usaid.gov/foia-requests,* or for records of the Office of the USAID Inspector General (OIG), on the FOIA page of OIG's public website, *https://oig.usaid.gov/FOIA.* Records required by FOIA to be made available for public inspection in an electronic format under 5 U.S.C. 552(a)(2) are available on the Agency's and OIG's public websites.

Subpart B—Proactive Disclosures of Agency Records

§ 212.4 Materials available for public inspection and in electronic format.

(a) In accordance with this subpart, the Agency shall make the following materials available for public inspection in an electronic format:

(1) Operational policy in USAID's Automated Directives System (ADS) which have been adopted by the Agency and are not published in the **Federal Register**;

(2) Administrative staff manuals and instructions to staff that affect any member of the public; and

(3) Copies of all records, regardless of form or format, which have been released pursuant to a FOIA request, and which have been requested three (3) or more times, or because of the nature of their subject matter, have become or are likely to become the subject of subsequent requests for substantially the same records. The Agency shall decide on a case by case basis whether records fall into this category, based on the following factors:

(i) Previous experience with similar records;

(ii) The particular characteristics of the records involved, including their nature and the type of information contained in them; and

(iii) The identity and number of requesters and whether there is widespread media, historical, academic, or commercial interest in the records.

(b) [Reserved].

Subpart C—Requirements for Making Requests

§ 212.5 How to make a request for records.

(a) USAID has a de-centralized system for responding to FOIA requests for all USAID records. The USAID FOIA operations are broken down into two component FOIA Offices: The Bureau for Management, Office of Management Services, Information and Records Division (M/MS/IRD) and the Office of the USAID Inspector General (OIG).

(b) The Bureau for Management, Office of Management Services, Information and Records Division (M/MS/IRD) is the central processing point for requests for USAID records contained in Washington, DC and its overseas missions. All FOIA requests for USAID records (other than OIG records) must be submitted to this office. To make a request for the Agency's records, a requester may send request via one of the following mediums:

(1) *By Email: foia@usaid.gov.* Please include your mailing address, email address, phone number, and fee category with your request. While our FOIA Specialists are happy to answer questions about the FOIA Program and/or help you formulate your request over the phone, please be advised that FOIA requests cannot be accepted by phone.

(2) *Online Portal:* To submit your request online, please click the subsequent link: *https://foiarequest.usaid.gov/index.aspx.*

(3) *By U.S. Postal Mail:* United States Agency for International Development Bureau for Management, Office of Management Services Services, Information and Records Division USAID Annex, Room 2.4.0A, Washington, DC 20523.

(4) By Telephone: (202) 916–4661.

(5) By Fax: (202) 916–4990.

(c) The Inspector General has received delegated authority from USAID's Administrator to process requests and issue determinations with respect to requests, and appeals of initial denials of requests, for the OIG's records. To make a request for OIG records, a requester may send a request via one of the following mediums:

(1) *By email: foiaoig@usaid.gov.* Please include your mailing address, email address, phone number, and fee category with your request.

(2) *Online Portal:* Please submit a request online via the OIG website at *https://oig.usaid.gov/FOIA.*

(3) *By U.S. Postal Mail:* United States Agency of International Development Office of Inspector General, Office of General Counsel 1300 Pennsylvania Avenue NW, Suite 6.06–D, Washington, DC 20523.

(4) *By Telephone:* (202) 712–1150.

(d) Where a request for records pertains to a third party, a requester may receive greater access by submitting either a notarized consent form signed by the person who is the subject of the records, or a signed declaration by that person, made under penalty of perjury pursuant to 28 U.S.C. 1746, authorizing disclosure of the records to the requester, or by submitting proof that the individual is deceased (*e.g.,* a copy of a death certificate or an obituary). In addition, requesters may present an argument that there exists an overriding public interest in disclosure of the information related to official misconduct by producing evidence that alleged Government impropriety occurred. As an exercise of administrative discretion, the component's FOIA office can require a requester to supply additional information if necessary in order to verify that a particular individual has consented to disclosure.

(e) Requesters must describe the records sought in sufficient detail to enable the component's FOIA office personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may assist in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number. In general, requesters should include as much detail as possible about the specific records or the types of records that they are seeking. Before submitting their requests, requesters may contact the component FOIA office's FOIA contact or FOIA Public Liaison to discuss the records they are seeking and to receive assistance in describing the records. If, after receiving a request, the component's FOIA office determines that it does not reasonably describe the records sought, the component's FOIA office shall inform the requester what additional information is needed or why the request is otherwise insufficient. Requesters who are attempting to reformulate or modify such a request may discuss their request with the component FOIA office's designated

FOIA Specialist or its FOIA Public Liaison, each of whom is available to assist the requester in reasonably describing the records sought. If a request does not reasonably describe the records sought, the component FOIA office's response to the request may be delayed or denied.

Subpart D—Responsibility for Responding to Requests

§ 212.6 Designation of authorized officials.

(a) The Assistant Administrator for the Bureau for Management(M) serves as the USAID Chief FOIA Officer. The Chief FOIA Officer has overall responsibility for USAID compliance with the FOIA. The Chief FOIA Officer provides high level oversight and support to USAID's FOIA programs, and recommends adjustments to agency practices, personnel, and funding as may be necessary to improve FOIA administration, including through an annual Chief FOIA Officers Report submitted to the U.S. Department of Justice. The Chief FOIA Officer is responsible for offering training to agency staff regarding their FOIA responsibilities; serves as the primary liaison with the Office of Government Information Services and the Office of Information Policy; and reviews, not less frequently than annually, all aspects of the Agency's administration of the FOIA to ensure compliance with the FOIA's requirements.

(b) The Bureau for Management, Office of Management Services, Information and Records Division (M/MS/IRD) is the component FOIA office that receives, tracks, and processes all of USAID's FOIA requests, other than requests for OIG records, to ensure transparency within the Agency.

(c) The Deputy Director, Bureau for Management, Office of Management Services (M/MS/OD) serves as the USAID FOIA Appeals Officer for requests for all USAID records other than OIG records. The FOIA Appeals Officer is responsible for receiving and acting upon appeals from requesters whose initial FOIA requests for USAID records (other than OIG records) have been denied, in whole or in part.

(d) The Deputy Inspector General serves as the USAID OIG FOIA Appeals Officer for appeals of requests for OIG records.

(e) The Chief, Bureau for Management, Office of Management Services, Information and Records Division (M/MS/IRD) serves as USAID's FOIA Officer and USAID's FOIA Public Liaison. The FOIA Officer is responsible for program direction, original denials, and policy decisions required for effective implementation of USAID's FOIA program. The FOIA Public Liaison serves as a supervisory official to whom a FOIA requester can raise concerns about the services received, following an initial response from the FOIA staff. In addition, the FOIA Public Liaison assists, as appropriate, in reducing delays, increasing transparency and understanding of the status of requests, and resolving disputes.

(f) The General Counsel to the Inspector General serves as the OIG's FOIA Officer and FOIA Public Liaison.

(g) The Supervisory FOIA Team Lead is the Principal Operations Officer within the component's FOIA office for the processing of FOIA requests and release determinations.

(h) The FOIA Specialist also known as the Government Information Specialist (GIS) is responsible for processing requests and preparing records for release when such releases are authorized by the FOIA. They do not have the authority to make denials, including ''no records'' responses.

(i) The General Counsel (GC), FOIA Backstop Attorney Advisor has responsibility for providing legal advice on all USAID matters regarding or resulting from the FOIA (other than OIG matters). Upon request, GC advises M/MS/IRD on release and denial decisions, and apprises the FOIA Office of all significant developments with respect to the FOIA.

(j) OIG attorneys have responsibility for providing legal advice on all requests and appeals related to OIG records.

(k) Each Attorney Advisor designated to provide legal advice to USAID Bureaus/Independent Offices (B/IOs) is responsible for providing, at M/MS/IRD's request, legal advice on FOIA requests assigned to those B/IOs.

(l) The designated FOIA Liaison Officer (FLO) in each USAID Bureau and Office is responsible for tasking and facilitating the collection of responsive records and monitoring the production of records to M/MS/IRD.

§ 212.7 Processing of request.

(a) *In general.* In determining which records are responsive to a request, the component's FOIA office ordinarily will include only records in its possession as of the date that it begins its search. If any other date is used, the component's FOIA office shall inform the requester of that date.

(b) *Authority to grant or deny requests.* The FOIA Officer is authorized to grant or to deny any requests for records that are maintained by the Agency (other than OIG records). The OIG FOIA Officer is authorized to grant or to deny any requests for records maintained by OIG.

(c) *Consultation, referral, and coordination.* When reviewing records located by the Agency in response to a request, the component's FOIA office shall determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. All consultations and referrals received by the Agency will be handled according to the date that the first agency received the perfected FOIA request. As to any such record, the component's FOIA office shall proceed in one of the following ways:

(1) *Consultation.* When records originated with USAID, but contain within them information of substantial interest to another agency, or other Federal Government office, the component's FOIA office should consult with that other agency prior to making a release determination.

(2) *Referral.* (i) When a component's FOIA office believes that a different Department, agency, or component, is best able to determine whether to disclose the record, the component's FOIA office will refer the responsibility for responding to the request regarding that record, as long as the referral is to an agency that is subject to the FOIA. Ordinarily, the agency that originated the record will be presumed to be best able to make the disclosure determination. However, if the component's FOIA office and the originating agency jointly agree that the former is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever the component's FOIA office refers any part of the responsibility for responding to a request to another agency, it shall document the referral, maintain a copy of the record that it refers, and notify the requester of the referral and inform the requester of the name(s) of the agency to which the record was referred, including that agency's FOIA contact information.

(iii) Where a component's FOIA office determines that a request was misdirected within the agency, the receiving component's FOIA office must route the request to the FOIA office of the proper component within the agency.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. In

such instances, in order to avoid harm to an interest protected by an applicable exemption, the component's FOIA office will coordinate with the originating agency to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination will then be conveyed to the requester by the component's FOIA office.

(d) *Classified information.* On receipt of any request involving classified information, the component's FOIA office must determine whether the information is currently and properly classified in accordance with applicable classification rules. Whenever a request involves a record containing information that has been classified or may be appropriate for classification by another agency under any applicable executive order concerning the classification of records, the component's FOIA office must refer the responsibility for responding to the request regarding that information to the agency that classified the information, or that should consider the information for classification. Whenever USAID's record contains information that has been derivatively classified (for example, when it contains information classified by another agency), the component's FOIA office must refer the responsibility for responding to that portion of the request to the agency that classified the underlying information.

(e) *Furnishing records.* The component's FOIA office shall furnish copies only of records that the Agency has in its possession. The Agency is not compelled to create new records. The Agency is not required to perform research for a requester. The component's FOIA office is required to furnish only one copy of a record. If information exists in different forms, the component's FOIA office will provide the record in the form that best conserves government resources. Requests may specify the preferred form or format (including electronic formats) for the records sought by the requester. The component's FOIA office will accommodate the form or format request if the record is readily reproducible in that form or format.

(f) *Archival records.* The Agency ordinarily transfers records in accordance with its retirement authority, included in ADS 502, to the National Archives and Records Administration. These records become the physical and legal custody of the National Archives. Accordingly, requests for retired Agency records should be submitted to the National Archives by mail addressed to Special Access and FOIA Staff (NWCTF), 8601 Adelphi Road, Room 5500, College Park, MD 20740 by fax to (301) 837¬1864 or by email to *specialaccess_foia@nara.gov.*

(g) *Poor copy.* If USAID cannot make a legible copy of a record to be released, the Agency is not required to reconstruct it. Instead, the component's FOIA office will furnish the best copy possible and note its poor quality in the component's FOIA office reply.

Subpart E—Timing of Responses to Requests

212.8 Time limits.

(a) *In general.* The component's FOIA office ordinarily will respond to requests according to their order of receipt.

(b) *Multitrack processing.* (1) The component's FOIA office shall designate a specific track for requests that are granted expedited processing, in accordance with the standards set forth in paragraph (e) of this section. The component's FOIA office may designate additional processing tracks that distinguish between simple and more complex requests based on the estimated amount of work or time needed to process the request. Among the factors the component's FOIA office may consider are, the number of pages involved in processing the request and the need for consultations or referrals. The component's FOIA office shall advise requesters of the track into which their request falls and, when appropriate, shall offer the requesters an opportunity to narrow their request so that it can be placed in a different processing track.

(2) The component's FOIA office shall generally process requests in each track on a ''first-in, first-out'' basis.

(c) *Unusual circumstances.* Whenever the statutory time limit for processing a request cannot be met because of ''unusual circumstances,'' as defined in the FOIA, and the component's FOIA office extends the time limit on that basis, the component's FOIA office shall, before expiration of the 20-day period to respond, notify the requester in writing of the unusual circumstances involved and of the date by which processing of the request can be expected to be completed. Where the extension exceeds 10 working days, the component's FOIA office shall, in the written notice, notify the requester of the right to contact the component's FOIA office's FOIA Public Liaison, or seek dispute resolution services from the Office of Government Information Services (OGIS). In addition, the component's FOIA office shall, as described by the FOIA, provide the requester with an opportunity to modify the request or arrange an alternative time period for processing.

(d) *Aggregating requests.* For the purposes of satisfying unusual circumstances under the FOIA, the component's FOIA office may aggregate requests in cases where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances. The component's FOIA office shall not aggregate multiple requests that involve unrelated matters.

(e) *Expedited processing.* (1) Requests and appeals shall be processed on an expedited basis whenever it is determined that they involve:

(i) Circumstances in which the lack of expedited processing could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged Federal Government activity, if made by a person who is primarily engaged in disseminating information;

(iii) The loss of substantial due process rights; or

(iv) A matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity that affect public confidence.

(2) A requester who seeks expedited processing must submit a statement, certified to be true and correct, explaining in detail the basis for making the request for expedited processing. For example, under paragraph (e)(1)(ii) of this section, a requester who is not a full-time member of the news media must establish that the requester is a person whose primary activity or occupation is information dissemination, though it need not be the requester's sole occupation. Such a requester also must establish a particular urgency to inform the public about the government activity involved in the request—one that extends beyond the public's right to know about government activity generally. The existence of numerous articles published on a given subject can be helpful in establishing the requirement that there be an ''urgency to inform'' the public on the topic. As a matter of administrative discretion, the component's FOIA office may waive the formal certification requirement.

(3) The component's FOIA office shall notify the requester within 10 calendar days of the receipt of a request for expedited processing of its decision whether to grant or deny expedited

processing. If expedited processing is granted, the request shall be given priority, placed in the processing track for expedited requests, and shall be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision shall be acted on expeditiously.

Subpart F—Responses to Requests

§ 212.9 Responsibility for responding to requests.

(a) *In general.* The component's FOIA office should, to the extent practicable, communicate with requesters having access to the internet using electronic means, such as email or web portal.

(b) *Acknowledgments of requests.* The component's FOIA office shall acknowledge the request and assign it an individualized tracking number. The component's FOIA office shall include in the acknowledgment a brief description of the records sought to allow requesters to more easily keep track of their requests.

(c) *Grants of requests.* Once the component's FOIA office makes a determination to grant a request in full or in part, it shall notify the requester in writing. The component's FOIA office also shall inform the requester of any fees charged and shall disclose the requested records to the requester promptly upon payment of any applicable fees.

(d) *Consultations and referrals.* Whenever the component's FOIA office consults with another Federal Government office over the releasability of a record, the component's FOIA office shall notify the requester of the consultation and inform the requester of the name(s) of the agency or office with which the consultation is taking place. Whenever the component's FOIA office refers any part of the responsibility for responding to a request to another Federal Government office, the component's FOIA office shall document the referral, maintain a copy of the record that it refers, notify the requester of the referral, and inform the requester of the name(s) of the agency to which the record was referred, including that agency's FOIA contact information.

(e) *Adverse determinations of requests.* If the component's FOIA office has made an adverse determination denying a request in any respect, the component's FOIA office shall notify the requester of that determination in writing, and provide the contact information for the FOIA Public Liaison, as well as a description of the requester's right to seek mediation services from the Office of Government Information Services (OGIS). Adverse determinations, or denials of requests, include decisions that: the requested record is exempt, in whole or in part; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester. A response will provide an estimate of the volume of any records or any information withheld. Adverse determinations also include denials involving fees or fee waiver matters or denials of requests for expedited processing.

(f) *Information furnished.* All denials are in writing and describe in general terms the material withheld; state the reasons for the denial, including, as applicable, a reference to the specific exemption of the FOIA authorizing the withholding; explain your right to appeal the decision and identify the official to whom you should send the appeal; and are signed by the person who made the decision to deny all or part of the request. Records disclosed in part must be marked clearly to show the amount of information deleted and the exemption under which the deletion was made unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted must also be indicated on the record, if technically feasible.

(g) *Conducting searches.* USAID performs a diligent search for records to satisfy your request. Nevertheless, the Agency may not be able to find the records requested using the information provided, or the records may not exist.

Subpart G—Confidential Commercial Information

§ 212.10 Policy and procedures.

(a) *Definitions*—(1) *Confidential commercial information* means commercial or financial information obtained by the Agency from a submitter that may be protected from disclosure under Exemption 4 of the FOIA, 5 U.S.C. 552(b)(4).

(2) *Business submitter* means any person or entity, including a corporation, State, or foreign government, but not including another Federal Government entity, that provides information, either directly or indirectly to the Federal Government.

(b) *Designation of confidential commercial information.* A submitter of confidential commercial information must use good faith efforts to designate by appropriate markings, either at the time of submission or within a reasonable time thereafter, any portion of its submission that it considers to be protected from disclosure under Exemption 4. These designations shall expire 10 years after the date of the submission unless the submitter requests and provides justification for a longer designation period.

(c) *When notice to business submitters is required.* (1) The component's FOIA office shall promptly provide written notice to a business submitter of confidential commercial information whenever records containing such information are requested under the FOIA if, after reviewing the request, the responsive records, and any appeal by the requester, the component's FOIA office determines that it may be required to disclose the records, provided:

(i) The requested information has been designated in good faith by the business submitter as information considered protected from disclosure under Exemption 4; or

(ii) The component's FOIA office has a reason to believe that the requested information may be protected from disclosure under Exemption 4, but has not yet determined whether the information is protected from disclosure under that exemption or any other applicable exemption.

(2) The notice shall either describe the commercial information requested or include a copy of the requested records or portions of records containing the information. In cases involving a voluminous number of submitters, notice may be made by posting or publishing the notice in a place or manner reasonably likely to accomplish it.

(d) *Exceptions to business submitter notice requirements.* The notice requirements of this section shall not apply if:

(1) The component's FOIA office determines that the information is exempt under the FOIA;

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by a statute other than the FOIA or by a regulation issued in accordance with the requirements of Executive Order 12600 of June 23, 1987; or

(4) The designation made by the business submitter appears obviously frivolous, except that, in such a case, the component's FOIA office shall give the business submitter written notice of any final decision to disclose the information and must provide that

notice within a reasonable number of days prior to a specified disclosure date.

(e) *Opportunity to object to disclosure.* (1) The component's FOIA office shall specify a reasonable time period within which the business submitter must respond to the notice referenced in paragraph (c) of this section. If a business submitter has any objections to disclosure, the business submitter should:

(i) Provide the component's FOIA office with a detailed written statement that specifies all grounds for withholding the particular information under any exemption of the FOIA. In order to rely on Exemption 4 as basis for nondisclosure, the business submitter must explain why the information constitutes a trade secret or commercial or financial information that is privileged or confidential.

(ii) [Reserved].

(2) A business submitter who fails to respond within the time period specified in the notice shall be considered to have no objection to disclosure of the information. Information received by the component's FOIA office after the date of any disclosure decision shall not be considered by the component's FOIA office. Any information provided by a business submitter under this subpart may itself be subject to disclosure under the FOIA.

(f) *Analysis of objections.* The component's FOIA office shall consider a business submitter's objections and specific grounds for nondisclosure in deciding whether to disclose the requested information.

(g) *Notice of intent to disclose.* Whenever the component's FOIA office decides to disclose information over the objection of a business submitter, the component's FOIA office shall provide the business submitter written notice, which shall include:

(1) A statement of the reasons why each of the business submitter's disclosure objections was not sustained;

(2) A description of the information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time subsequent to the notice.

(h) *Notice of FOIA lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of confidential commercial information, the component's FOIA office shall promptly notify the business submitter.

(i) *Requester notification.* The component's FOIA office shall notify the requester whenever it provides the submitter with notice and an opportunity to object to disclosure; whenever it notifies the submitter of its intent to disclose the requested information; and whenever a submitter files a lawsuit to prevent the disclosure of the information.

Subpart H—Administrative Appeals

§ 212.11 Appeal procedures.

The component's FOIA office must inform the requester of the reasons for the denial and the requester's right to appeal the denial to the FOIA Appeals Officer whenever a FOIA request is denied.

(a) *What a requester can appeal.* A requester may appeal the withholding of a document or denial of a fee waiver request. A requester may contest the type or amount of fees that were charged, or may appeal any other type of adverse determination under the FOIA. A requester may also appeal because USAID failed to conduct an adequate search for the documents requested. However, a requester may not file an administrative appeal for the lack of a timely response. A requester may administratively appeal any portion denied when their request is granted in part and denied in part.

(b) *Requirements for making an appeal.* A requester may appeal any adverse determinations to the component's FOIA office. The requester must make the appeal in writing. To be considered timely, the appeal must be postmarked, or in the case of electronic submissions, transmitted, within 90 calendar days after the date of the response. The appeal should clearly identify the component FOIA office's determination that is being appealed and the assigned request number. To facilitate handling, the requester should mark both the appeal letter and envelope, or subject line of the electronic transmission, ''Freedom of Information Act Appeal.''

(c) *Adjudication of appeals.* (1) The Deputy Director of the Bureau for Management Services or designee will conduct de novo review and make the final determination on the appeals related to all Agency records other than OIG records. The Deputy Inspector General will conduct *de novo* review and make the final determination on the appeals relating to OIG records.

(2) An appeal ordinarily will not be adjudicated if the request becomes a matter of FOIA litigation.

(d) *Decisions on appeals.* A decision on an appeal must be made in writing. A decision that upholds the component FOIA office's determination will contain a statement that identifies the reasons for the affirmance, including any FOIA exemptions applied. The decision will provide the requester with notification of the statutory right to file a lawsuit and will inform the requester of the mediation services offered by the Office of Government Information Services of the National Archives and Records Administration (OGIS) as a non-exclusive alternative to litigation. Mediation is a voluntary process. If the component's FOIA office agrees to participate in the mediation services provided by OGIS, it will actively engage as a partner to the process in an attempt to resolve the dispute. If the component FOIA office's decision is remanded or modified on appeal, the requester will be notified of that determination in writing. The component's FOIA office will thereafter further process the request in accordance with that appeal determination and respond directly to the requester.

(e) *When appeal is required.* Before seeking review by a court of the component FOIA office's adverse determination, a requester generally must first submit a timely administrative appeal.

(f) *Where to file an appeal.* An appeal (other than appeals related to OIG records) may be filed by sending a letter to: FOIA Appeals Officer, Bureau for Management, Deputy Director, Office of Management Services, U.S. Agency for International Development, USAID Annex, M/MS, Room 10.8 OD, Washington, DC 20523; or by email at *foia@usaid.gov.* An appeal relating to OIG records may be filed by sending a letter to: Deputy Inspector General, Office of Inspector General, U.S. Agency for International Development, Suite 6.06–D, RRB, 1300 Pennsylvania Avenue NW, Washington, DC 20523–4601; or by email at *foiaoig@usaid.gov.* There is no charge for filing an administrative appeal.

§ 212.12 Mediation and dispute services.

(a) The Office of Government Information Services of the National Archives and Records Administration (OGIS) is a Freedom of Information Act (FOIA) resource for the public and the government. Congress has charged OGIS with reviewing FOIA policies, procedures and compliance of Federal agencies and to recommend changes to the FOIA. OGIS' mission also includes providing dispute resolution services between Federal agencies and requesters. OGIS works as a non-exclusive alternative to litigation.

(b) When the component's FOIA office makes a determination on a request, the component's FOIA office shall offer the services of the FOIA Public Liaison, and will notify requesters of the mediation services

provided by OGIS. Specifically, the component's FOIA office will include in the component's FOIA office's notification to the requester:

(1) The right of the requester to seek assistance from the FOIA Public Liaison of the component's FOIA office, and in the case of an adverse determination;

(2) The right of the requester to seek dispute resolution services from the FOIA Public Liaison of the component's FOIA office or the Office of Government Information Services.

Subpart I—Preservation of Records

§ 212.13 Policy and procedures.

The component's FOIA office shall preserve all correspondence relating to the requests it receives under this subpart, and all records processed pursuant to such requests, until such time as the destruction of such correspondence and records is authorized pursuant to title 44 of the United States Code or the General Records Schedule 4.2 of the National Archives and Records Administration (NARA). Under no circumstances shall records be sent to a Federal Records Center, transferred to the permanent custody of NARA, or destroyed while they are the subject of a pending request, appeal, or civil action under the FOIA.

Subpart J—Fees

§ 212.14 Fees to be charged—general.

(a) *In general.* The component's FOIA office shall charge for processing requests under the FOIA in accordance with the provisions of this section and with the Office of Management and Budget (OMB) Guidelines. In order to resolve any fee issues that arise under this section, the component's FOIA office may contact a requester for additional information. The component's FOIA office shall ensure that search, review, and duplication are conducted in the most efficient and the least expensive manner. The component's FOIA office ordinarily will collect all applicable fees before sending copies of records to a requester. Requesters must pay fees by check or money order made payable to the Treasury of the United States.

(b) *Definitions.* For purposes of this section:

(1) *Commercial use request* is a request that asks for information for a use or a purpose that furthers a commercial, trade, or profit interest, which can include furthering those interests through litigation. The component FOIA office's decision to place a requester in the commercial use category will be made on a case-by-case basis based on the requester's intended use of the information.

(2) *Direct costs* are those expenses that the Agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

(3) *Duplication* is reproducing a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, audiovisual materials, or electronic records, among others.

(4) *Educational institution* is any school that operates a program of scholarly research. A requester in this fee category must show that the request is made in connection with his or her role at the educational institution. Agencies may seek verification from the requester that the request is in furtherance of scholarly research.

(5) *Fee waiver* is a waiver or reduction of processing fees if a requester can demonstrate that certain statutory standards are satisfied, including that the information is in the public interest and is not requested for a commercial interest.

(6) *Noncommercial scientific institution* is an institution that is not operated on a ''commercial'' basis, as defined in paragraph (b)(1) of this section and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. A requester in this category must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are sought to further scientific research and are not for a commercial use.

(7) *Representative of the news media* is any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast ''news'' to the public at large and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the internet. A request for records supporting the news-dissemination function of the requester shall not be considered to be for a commercial use. ''Freelance'' journalists who demonstrate a solid basis for expecting publication through a news media entity shall be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however, components shall also consider a requester's past publication record in making this determination.

(8) *Requester category* is one of the three categories that agencies place requesters in for the purpose of determining whether a requester will be charged fees for search, review, and duplication. The three categories are: commercial requesters; non-commercial scientific or educational institutions or news media requesters; and all other requesters.

(9) *Review* is the examination of a record located in response to a request in order to determine whether any portion of it is exempt from disclosure. Review time includes processing any record for disclosure, such as doing all that is necessary to prepare the record for disclosure, including the process of redacting the record and marking the appropriate exemptions. Review costs are properly charged even if a record ultimately is not disclosed. Review time also includes time spent both obtaining and considering any formal objection to disclosure made by a confidential commercial information submitter, but it does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(10) *Search* is the process of looking for and retrieving records or information responsive to a request. Search time includes page-by-page or line-by-line identification of information within records and the reasonable efforts expended to locate and retrieve information from electronic records.

(c) *Charging fees.* In responding to FOIA requests, the component's FOIA office shall charge the following fees unless a waiver or reduction of fees has been granted under paragraph (k) of this section.

(1) *Search.* Requests made by educational institutions, noncommercial scientific institutions, or representatives of the news media are not subject to search fees. Search fees shall be charged for all other requesters, subject to the restrictions of paragraph (d) of this section. The component's FOIA office may properly charge for time spent searching even if they do not locate any responsive records or if they determine that the records are entirely exempt from disclosure.

(2) *Duplication.* Duplication fees shall be charged to all requesters, subject to the restrictions of paragraph (d) of this section. The component's FOIA office shall honor a requester's preference for receiving a record in a particular form or format where it is readily reproducible by the component's FOIA office in the form or format requested. Where photocopies are supplied, the component's FOIA office shall provide one copy per request at a cost of ten cents per page. For copies of records produced on tapes, disks, or other media, the direct costs of producing the copy, including operator time shall be charged. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester shall pay the direct costs associated with scanning those materials. For other forms of duplication, the component's FOIA office shall charge the direct costs.

(3) *Review.* Review fees shall be charged to requesters who make commercial use requests. Review fees shall be assessed in connection with the initial review of the record, *i.e.,* the review conducted by the component's FOIA office to determine whether an exemption applies to a particular record or portion of a record. No charge will be made for review at the administrative appeal stage of exemptions applied at the initial review stage. However, if a particular exemption is deemed to no longer apply, any costs associated with the component's FOIA office re-review of the records in order to consider the use of other exemptions may be assessed as review fees.

(d) *Restrictions on charging fees.* (1) No search fees will be charged for requests by educational institutions, noncommercial scientific institutions, or representatives of the news media, unless the records are sought for commercial use.

(2) When the component's FOIA office determines that unusual circumstances apply to the processing of a request, and the component's FOIA office has provided timely written notice to the requester, the delay is excused for an additional 10 days. If the component's FOIA office fails to comply with the extended time limit, it may not charge search fees (or for requesters with preferred fee status, may not charge duplication fees) except as provided in paragraphs (d)(2)(i) and (ii) of this section.

(i) *Exception.* If unusual circumstances apply and more than 5000 pages are necessary to respond to the request, the component's FOIA office may charge search fees (or, for requesters in preferred fee status, may charge duplication fees) if timely written notice has been made to the requester and the component's FOIA office has discussed with the requester via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request.

(ii) *Court Determination that exceptional circumstances exist.* If a court determines that exceptional circumstances exist, the component's FOIA office's failure to comply with a time limit shall be excused for the length of time provided by the court order.

(3) If the component's FOIA office fails to comply with the time limits in which to respond to a request, and if no unusual or exceptional circumstances, as those terms are defined by the FOIA, apply to the processing of the request, it may not charge search fees, or, in the instances of requests from requesters described in paragraph (d)(1) of this section, may not charge duplication fees.

(4) No search or review fees will be charged for a quarter-hour period unless more than half of that period is required for search or review.

(5) Except for requesters seeking records for a commercial use, the component's FOIA office shall provide without charge:

(i) The first 100 pages of duplication (or the cost equivalent for other media); and

(ii) The first two hours of search.

(6) When, after first deducting the 100 free pages (or its cost equivalent) and the first two hours of search, a total fee calculated under paragraph (c) of this section is $25.00 or less for any request, no fee will be charged.

(e) *Notice of anticipated fees in excess of $25.00.* (1) When the component's FOIA office determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, the component's FOIA office shall notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the component's FOIA office shall advise the requester accordingly. If the requester is a noncommercial use requester, the notice shall specify that the requester is entitled to the statutory entitlements of 100 pages of duplication at no charge and, if the requester is charged search fees, two hours of search time at no charge, and shall advise the requester whether those entitlements have been provided.

(2) In cases in which a requester has been notified that the actual or estimated fees are in excess of $25.00, the request shall not be considered received and further work will not be completed until the requester commits in writing to pay the actual or estimated total fee, or designates some amount of fees the requester is willing to pay, or in the case of a noncommercial use requester who has not yet been provided with the requester's statutory entitlements, designates that the requester seeks only that which can be provided by the statutory entitlements. The requester must provide the commitment or designation in writing, and must, when applicable, designate an exact dollar amount the requester is willing to pay. The component's FOIA office is not required to accept payments in installments.

(3) If the requester has indicated a willingness to pay some designated amount of fees, but the component's FOIA office estimates that the total fee will exceed that amount, the component's FOIA office shall toll the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. The component's FOIA office shall inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(4) The component's FOIA office shall make available their FOIA Public Liaison or other FOIA Specialists to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

(f) *Charges for other services.* Although not required to provide special services, if the component's FOIA office chooses to do so as a matter of administrative discretion, the direct costs of providing the service shall be charged. Examples of such services include certifying that records are true copies, providing multiple copies of the same document, or sending records by means other than first class mail.

(g) *Charging interest.* The component's FOIA office may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges shall be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the billing date until payment is received by the component's FOIA office. The component's FOIA office shall follow the provisions of the Debt Collection

Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(h) *Aggregating requests.* When the component's FOIA office reasonably believes that a requester or a group of requesters acting in concert is attempting to divide a single request into a series of requests for the purpose of avoiding fees, the component's FOIA office may aggregate those requests and charge accordingly. The component's FOIA office may presume that multiple requests of this type made within a 30-day period have been made in order to avoid fees. For requests separated by a longer period, the component's FOIA office will aggregate them only where there is a reasonable basis for determining that aggregation is warranted in view of all the circumstances involved. Multiple requests involving unrelated matters shall not be aggregated.

(i) *Advance payments.* (1) For requests other than those described in paragraph (i)(2) or (3) of this section, the component's FOIA office shall not require the requester to make an advance payment before work is commenced or continued on a request. Payment owed for work already completed (*i.e.,* payment before copies are sent to a requester) is not an advance payment.

(2) When the component's FOIA office determines or estimates that a total fee to be charged under this section will exceed $250.00, it may require that the requester make an advance payment up to the amount of the entire anticipated fee before beginning to process the request. The component's FOIA office may elect to process the request prior to collecting fees when it receives a satisfactory assurance of full payment from a requester with a history of prompt payment.

(3) Where a requester has previously failed to pay a properly charged FOIA fee to the component's FOIA office within 30 calendar days of the billing date, the component's FOIA office may require that the requester pay the full amount due, plus any applicable interest on that prior request, and the component's FOIA office may require that the requester make an advance payment of the full amount of any anticipated fee before the component's FOIA office begins to process a new request or continues to process a pending request or any pending appeal. If the component's FOIA office has a reasonable basis to believe that a requester has misrepresented the requester's identity in order to avoid paying outstanding fees, it may require that the requester provide proof of identity.

(4) In cases in which the component's FOIA office requires advance payment, the request shall not be considered received and further work will not be completed until the required payment is received. If the requester does not pay the advance payment within 30 calendar days after the date of the component FOIA office's fee determination, the request will be closed.

(j) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any statute that specifically requires an agency to set and collect fees for particular types of records. In instances where records responsive to a request are subject to a statutorily-based fee schedule program, the component's FOIA office shall inform the requester of the contact information for that program.

(k) *Requirements for waiver or reduction of fees.* (1) Records responsive to a request shall be furnished without charge or at a reduced rate below the rate established under paragraph (c) of this section, where the component's FOIA office determines, based on all available information, that the requester has demonstrated that:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) In deciding whether disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government, the component's FOIA office shall consider all four of the following factors:

(i) The subject of the request must concern identifiable operations or activities of the Federal Government, with a connection that is direct and clear, not remote or attenuated.

(ii) Disclosure of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public shall be considered. It shall be presumed that a representative of the news media will satisfy this consideration.

(iv) The public's understanding of the subject in question must be enhanced by the disclosure to a significant extent. However, the component's FOIA office shall not make value judgments about whether the information at issue is ''important'' enough to be made public.

(3) To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, the component's FOIA office shall consider the following factors:

(i) The component's FOIA office shall identify any commercial interest of the requester, as defined in paragraph (b)(1) of this section, that would be furthered by the requested disclosure. Requesters shall be given an opportunity to provide explanatory information regarding this consideration.

(ii) A waiver or reduction of fees is justified where the public interest is greater than any identified commercial interest in disclosure. The component's FOIA office ordinarily shall presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return shall not be presumed to primarily serve the public interest.

(4) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver shall be granted for those records.

(5) Requests for a waiver or reduction of fees should be made when the request is first submitted to the component's FOIA office and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester shall be required to pay any costs incurred up to the date the fee waiver request was received. A

requester may appeal the denial of a fee waiver.

§ 212.15 Fees to be charged—requester categories.

(a) The following specific fees are charged for services rendered:

(1) Commercial use:

(i) *Search:* $40.00 per hour. Search costs will be assessed even though no records may be found or even if, after review, there is no disclosure or records.

(ii) *Review:* $55.00 per hour.

(iii) *Duplication:* 10¢ per page.

(2) Educational & Non-Commercial Scientific Institutions:

(i) *Search:* No fee.

(ii) *Review:* No fee.

(iii) *Duplication:* 10¢ per page after the first 100 pages.

(3) Representatives of the News Media:

(i) *Search:* No fee.

(ii) *Review:* No fee.

(iii) *Duplication:* 10¢ per page after the first 100 pages.

(4) All Others:

(i) *Search:* Same as ''Commercial Users'' except the first two hours shall be furnished without charge.

(ii) *Review:* No fee.

(iii) *Duplication:* 10¢ per page after the first 100 pages.

(b) If copies of records are provided in other than paper format (such as on microfiche, video tape, or as electronic data files), or other than first-class mail is requested or required, the requester is charged the actual cost of providing these additional services.

Subpart K—FOIA Definitions

§ 212.16 Glossary.

As used in this part:

Administrative FOIA Appeal is an independent review of the initial determination made in response to a FOIA request. Requesters who are dissatisfied with the response made on their initial request have a statutory right to appeal the initial determination made by the component's FOIA office.

Agency is any executive agency, military agency, government corporation, government-controlled corporation, or other establishment in the executive branch of the Federal Government, or any independent regulatory agency. Thus, USAID is an agency.

Complex request is a request that typically seeks a high volume of material or requires additional steps to process such as the need to search for records in multiple locations.

Consultation is when USAID locates a record that contains information of substantial interest to another agency, and the component's FOIA office asks for the views of that other agency on the disclosability of the records before any final determination is made.

Discretionary disclosure is information that the component's FOIA office releases even though it could have been withheld under one of the FOIA's exemptions.

Duplication is reproducing a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, audiovisual materials, or electronic records, among others.

Electronic record is any information that is recorded in a form that only a computer can process and that satisfies the definition of a Federal record per the *Federal Records Act.* Federal electronic records are not necessarily kept in a ''recordkeeping system'' but may reside in a generic electronic information system or are produced by an application such as word processing or electronic mail.

Exemptions are nine categories of information that are not required to be released in response to a FOIA request because release would be harmful to a government or private interest. These categories are called ''exemptions'' from disclosures.

Expedited processing is the FOIA response track granted in certain limited situations, specifically when a FOIA request is processed ahead of other pending requests.

Freedom of Information Act or *FOIA* is a United States Federal law that grants the public access to information possessed by government agencies. Upon written request, U.S. Government agencies are required to release information unless it falls under one of nine exemptions listed in the Act.

Frequently requested records are records that have been requested three (3) or more times from the component's FOIA office.

Multi-track processing is a system that divides in-coming FOIA requests according to their complexity so that simple requests requiring relatively minimal review are placed in one processing track and more complex requests are placed in one or more other tracks. Requests granted expedited processing are placed in yet another track. Requests in each track are processed on a first-in/first-out basis.

Office of Government Information Services (OGIS) offers mediation services to resolve disputes between FOIA requesters and agencies as an alternative to litigation. OGIS also reviews agency FOIA compliance, policies, and procedures and makes recommendations for improvement. The Office is a part of the National Archives and Records Administration, and was created by Congress as part of the OPEN Government Act of 2007, which amended the FOIA.

Proactive disclosures are records made publicly available by agencies without waiting for a specific FOIA request. Agencies now post on their websites' material concerning their functions and mission. The FOIA itself requires agencies to make available certain categories of information, including final opinions and orders, specific policy statements, certain administrative staff manuals and frequently requested records.

Record means information regardless of its physical form or characteristics including information created, stored, and retrievable by electronic means that is created or obtained by the Agency and under the control of the Agency at the time of the request, including information maintained for the Agency by an entity under Government contract for records management purposes. It does not include records that are not already in existence and that would have to be created specifically to respond to a request. Information available in electronic form shall be searched and compiled in response to a request unless such search and compilation would significantly interfere with the operation of the Agency's automated information systems.

Referral occurs when an agency locates a record that originated with, or is of otherwise primary interest to another Department, agency, or component. It will forward that record to the other agency to process the record and to provide the final determination directly to the requester.

Simple request is a FOIA request that a component's FOIA office anticipates will involve a small volume of material or which will be able to be processed relatively quickly.

Subpart L—Other Rights and Services

§ 212.17 Rights and services qualified by the FOIA statute.

Nothing in this subpart shall be construed to entitle any person, as a right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

Subpart M—Privacy Act Provisions

§ 212.18 Purpose and scope.

This subpart contains the rules that the USAID follows under the Privacy Act of 1974 (PA), 5 U.S.C. 552a, as amended. These rules should be read together with the text of the statute,

which provides additional information about records maintained on individuals. The rules in this subpart apply to all records in systems of records maintained by the agency that are retrieved by an individual's name or personal identifier. They describe the procedures by which individuals may request access to records about themselves, request amendment or correction of those records, and request an accounting of disclosures of those records by the agency. If any records retrieved pursuant to an access request under the PA are found to be exempt from access under that Act, they will be processed for possible disclosure under the FOIA, as amended. No fees shall be charged for access to or amendment of PA records.

§ 212.19 Privacy definitions.

As used in this subpart, the following definitions shall apply:

(a) *Individual* means a citizen or a legal permanent resident alien (LPR) of the United States.

(b) *Maintain* includes maintain, collect, use, or disseminate.

(c) *Record* means any item, collection, or grouping of information about an individual that is maintained by the agency and that contains the individual's name or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or photograph.

(d) *System of records* means a group of any records under the control of the agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to an individual.

§ 212.20 Request for access to records.

(a) *In general.* Requests for access to records (other than OIG records) under the PA must be made in writing and mailed to the Bureau for Management Services, Information and Records Division at the address given in § 212.5. Requests for access to OIG records under the PA must be made in writing and mailed to the Office of General Counsel for the OIG at the address given in § 212.5.

(b) *Description of records sought.* Requests for access should describe the requested record(s) in sufficient detail to permit identification of the record(s). At a minimum, requests should include the individual's full name (including maiden name, if appropriate) and any other names used, current complete mailing address, (city, state and country). Helpful data includes the approximate time period of the record and the circumstances that give the individual reason to believe that the agency maintains a record under the individual's name or personal identifier, and, if known, the system of records in which the record is maintained. In certain instances, it may be necessary for the component's FOIA office to request additional information from the requester, either to ensure a full search, or to ensure that a record retrieved does in fact pertain to the individual.

(c) *Verification of personal identity.* The component's FOIA office will require reasonable identification of individuals requesting records about themselves under the PA's access provisions to ensure that records are only accessed by the proper persons. Requesters must state their full name, current address, citizenship or legal permanent resident alien status, and date (city, state, and country). The request must be signed, and the requester's signature must be either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746. If the requester seeks records under another name the requester has used, a statement, under penalty of perjury, that the requester has also used the other name must be included.

(d) *Third party access.* The component's FOIA office may process third party requests, as described in this section. In the absence of a request by, or prior written consent of, the individual to whom the records pertain, the component's FOIA office will process third party requests under the FOIA. The Agency's form, AID 507–1, may be used to certify the identity and provide third party authorization.

(1) *Parents and guardians of minor children.* Upon presentation of acceptable documentation of the parental or guardian relationship, a parent or guardian of a U.S. citizen or LPR minor (an unmarried person under the age of 18) may, on behalf of the minor, request records under the PA pertaining to the minor. In any case, U.S. citizen or LPR minors may request such records on their own behalf.

(2) *Guardians.* A guardian of an individual who has been declared by a court to be incompetent may act for and on behalf of the incompetent individual upon presentation of appropriate documentation of the guardian relationship.

(3) *Authorized representatives or designees.* Third-party access to an individual's records shall be granted pursuant to a written request by, or with the prior written consent of, the individual. The designated third party must submit identity verification information described in paragraph (c) of this section.

(e) *Referrals and consultations.* If the component's FOIA office determines that records retrieved as responsive to the request were created by another Department, agency, or component it ordinarily will refer the records to the originating agency for direct response to the requester. If the agency determines that records retrieved as responsive to the request are of interest to another agency, it may consult with the other agency before responding to the request. The component's FOIA office may make agreements with other agencies to eliminate the need for consultations or referrals for particular types of records.

(f) *Records relating to civil actions.* Nothing in this subpart entitles an individual to access to any information compiled in reasonable anticipation of a civil action or proceeding.

(g) *Time limits.* The component's FOIA office will acknowledge the request promptly and furnish the requested information as soon as possible thereafter.

§ 212.21 Request to amend or correct records.

(a) An individual has the right to request that the component's FOIA office amend a record pertaining to the individual that the individual believes is not accurate, relevant, timely, or complete.

(b) Requests to amend records must be in writing to the component's FOIA office, and mailed or delivered to the Bureau for Management, Office of Management Services, Information and Records Division (for non-OIG records), or the Office of the USAID Inspector General (for OIG records) at the addresses given in § 212.5, with ATTENTION: PRIVACY ACT AMENDMENT REQUEST written on the envelope. The component's FOIA office will coordinate the review of the request with the appropriate offices of the Agency. The component's FOIA office will require verification of personal identity before it will initiate action to amend a record. Amendment requests should contain, at a minimum, identifying information needed to locate the record in question, a description of the specific correction requested, and an explanation of why the existing record is not accurate, relevant, timely, or complete. The request must be signed, and the requester's signature must be either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746. The requester should submit as much pertinent documentation, other information, and explanation as

possible to support the request for amendment.

(c) All requests for amendments to records shall be acknowledged within 10 working days.

(d) In reviewing a record in response to a request to amend, the Agency shall review the record to determine if it is accurate, relevant, timely, and complete.

(e) If the Agency agrees with an individual's request to amend a record, it shall:

(1) Advise the individual in writing of its decision;

(2) Amend the record accordingly; and

(3) If an accounting of disclosure has been made, advise all previous recipients of the record of the amendment and its substance.

(f) If the Agency denies an individual's request to amend a record, it shall advise the individual in writing of its decision and the reason for the refusal, and the procedures for the individual to request further review. See § 171.25 of this chapter.

§ 212.22 Request for accounting of record disclosures.

(a) *How made.* Except where accountings of disclosures are not required to be kept, as set forth in paragraph (b) of this section, or where accountings of disclosures do not need to be provided to a requesting individual pursuant to 5 U.S.C. 552a(c)(3), an individual has a right to request an accounting of any disclosure that the component's FOIA office has made to another person, organization, or agency of any record about an individual. This accounting shall contain the date, nature, and purpose of each disclosure as well as the name and address of the recipient of the disclosure. Any request for accounting should identify each particular record in question and may be made by writing directly to the Appeals Officer, Bureau for Management, Office of Management Services at the address given in § 212.19.

(b) *Where accountings are not required.* The component's FOIA office is not required to keep an accounting of disclosures in the case of:

(1) Disclosures made to employees within the Agency who have a need for the record in the performance of their duties; and

(2) Disclosures required under the FOIA.

§ 212.23 Appeals from denials of PA amendment requests.

(a) If the component's FOIA office denies a request for amendment of such records, the requester shall be informed of the reason for the denial and of the right to appeal the denial to the Appeals Review Panel. Any such appeal must be postmarked within 60 working days of the date of the component FOIA office's denial letter and sent to: Appeals Officer, Bureau for Management, Office of Management Services (for non-OIG records), and Deputy Inspector General, Office of Inspector General (for OIG records) at the addresses given in § 212.11.

(b) Appellants should submit an administrative appeal of any denial, in whole or in part, of a request for access to the PA at the above address. The component's FOIA office will assign a tracking number to the appeal.

(c) The Appeals Review Panel will decide appeals from denials of PA amendment requests within 30 business days, unless the Panel extends that period for good cause shown, from the date when it is received by the Panel.

(d) Appeals Review Panel decisions will be made in writing, and appellants will receive notification of the decision. A reversal will result in reprocessing of the request in accordance with that decision. An affirmance will include a brief statement of the reason for the affirmance and will inform the appellant that the decision of the Panel represents the final decision of the Agency and of the right to seek judicial review of the Panel's decision, when applicable.

(e) If the Panel's decision is that a record shall be amended in accordance with the appellant's request, the Chairman—USAID'S FOIA Liaison Officer or their designee shall direct the office responsible for the record to amend the record, advise all previous recipients of the record of the amendment and its substance (if an accounting of previous disclosures has been made), and so advise the individual in writing.

(f) If the Panel's decision is that the amendment request is denied, in addition to the notification required by paragraph (d) of this section, the Chairman—USAID'S FOIA Liaison Officer or their designee-shall advise the appellant:

(1) Of the right to file a concise Statement of Disagreement stating the reasons for disagreement with the decision of the Agency;

(2) Of the procedures for filing the Statement of Disagreement;

(3) That any Statement of Disagreement that is filed will be made available to anyone to whom the record is subsequently disclosed, together with, at the discretion of the Agency, a brief statement by the component's FOIA office summarizing its reasons for refusing to amend the record;

(4) That prior recipients of the disputed record will be provided a copy of any statement of disagreement, to the extent that an accounting of disclosures was maintained.

(g) If the appellant files a Statement of Disagreement under paragraph (f) of this section, the component's FOIA office will clearly annotate the record so that the fact that the record is disputed is apparent to anyone who may subsequently access the record. When the disputed record is subsequently disclosed, the component's FOIA office will note the dispute and provide a copy of the Statement of Disagreement. The component's FOIA office may also include a brief summary of the reasons for not amending the record. Copies of the component FOIA office's statement shall be treated as part of the individual's record for granting access; however, it will not be subject to amendment by an individual under this part.

§ 212.24 Specific exemptions.

(a) Pursuant to 5 U.S.C. 552a(k), the Director or the Administrator may, where there is a compelling reason to do so, exempt a system of records, from any of the provisions of subsections (c)(3); (d); (e)(1); (e)(4) (G), (H), and (I); and (f) of the Act if a system of records is:

(1) Subject to the provisions of 5 U.S.C. 552(b)(1); (2) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of the Act: Provided, however, that if any individual is denied any right, privilege, or benefit to which he or she would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

(2) Maintained in connection with providing protective services to the President of the United States or other individuals pursuant to 18 U.S.C. 3056;

(3) Required by statute to be maintained and used solely as statistical records;

(4) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or

access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

(5) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process; or

(6) Evaluation material used to determine potential for promotion in the armed services, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

(b) Each notice of a system of records that is the subject of an exemption under 5 U.S.C. 552a(k) will include a statement that the system has been exempted, the reasons therefore, and a reference to the **Federal Register**, volume and page, where the exemption rule can be found.

(c) The systems of records to be exempted under section (k) of the Act, the provisions of the Act from which they are being exempted, and the justification for the exemptions, are set forth in paragraphs (c)(1) through (3) of this section:

(1) *Criminal Law Enforcement Records.* If the 5 U.S.C. 552a(j)(2) exemption claimed under § 215.13(c) of this chapter and on the notice of systems of records to be published in the **Federal Register** on this same date is held to be invalid, then this system is determined to be exempt, under 5 U.S.C. 552(a) and (k)(1) and (2) of the Act, from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f). The reasons for asserting the exemptions are to protect the materials required by executive order to be kept secret in the interest of the national defense or foreign policy, to prevent subjects of investigation from frustrating the investigatory process, to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques, to maintain the ability to obtain necessary information, to fulfill commitments made to sources to protect their identities and the confidentiality of information and to avoid endangering these sources and law enforcement personnel.

(2) *Personnel Security and Suitability Investigatory Records.* This system is exempt under U.S.C. 552a(k)(1), (2), and (5) from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f). These exemptions are claimed to protect the materials required by executive order to be kept secret in the interest of national defense or foreign policy, to prevent subjects of investigation from frustrating the investigatory process, to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information, to avoid endangering those sources and, ultimately, to facilitate proper selection or continuance of the best applicants or persons for a given position or contract. Special note is made of the limitation on the extent to which this exemption may be asserted.

(3) *Litigation Records.* This system is exempt under 5 U.S.C. 552(k)(1), (2), and (5) from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f). These exemptions are claimed to protect the materials required by executive order to be kept secret in the interest of national defense or foreign policy, to prevent subjects of investigation from frustrating the investigatory process, to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information.

Christopher A. Colbow,

Chief, Information and Records Division, FOIA Public Liaison/Agency Records Officer, U.S. Agency for International Development.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 201, 203, and 206

[Docket No. FR–6084–F–02]

RIN 2502–AJ43

Acceptance of Private Flood Insurance for FHA-Insured Mortgages

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Final rule.

SUMMARY: This final rule amends Federal Housing Administration (FHA) regulations to allow mortgagors the option to purchase private flood insurance on FHA-insured mortgages for properties located in Special Flood Hazard Areas (SFHAs), in satisfaction of the mandatory purchase requirement of the Flood Disaster Protection Act of 1973 (the FDPA). The FDPA, as amended, requires the owner of a property mapped in a SFHA, and located in a community participating in the National Flood Insurance Program, to purchase flood insurance as a condition of receiving a mortgage backed by the Government Sponsored Entities (GSEs), Department of Veterans Affairs (VA), U.S. Department of Agriculture (USDA), or Federal Housing Administration (FHA). In consideration of public comments, HUD's experience implementing the program, and HUD's goals of aligning with the Biggert-Waters Act while mitigating risk and protecting taxpayers' funds, this final rule adopts HUD's November 23, 2020, proposed rule with minor changes.

DATES: *Effective date:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Elisa Saunders, Director, Office of Single Family Program Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 9184, Washington, DC 20410–8000; telephone number 202–708–2121 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

National Flood Insurance Program Statutory Framework and the Biggert-Waters Act of 2012

The National Flood Insurance Act of 1968 (the 1968 Act) and the FDPA, as amended, govern the National Flood Insurance Program (NFIP).[1] The 1968 Act makes federally backed flood insurance available to owners of improved real estate or manufactured

[1] *See* Public Law 90–448 (1968); Public Law 93–234 (1973). These statutes are codified at 42 U.S.C. 4001 *et seq.*

homes located in special flood hazard areas (SFHAs) if their community participates in the NFIP.

Until the adoption of the FDPA in 1973, the purchase of flood insurance was voluntary. Section 102 of the FDPA made the purchase of flood insurance mandatory. Specifically, it provides that no Federal officer or agency may approve any financial assistance for acquisition or construction [2] in any area identified as having SFHAs and in which the sale of flood insurance has been made available under the 1968 Act, unless the building or mobile home and any personal property is covered by flood insurance. The National Flood Insurance Reform Act of 1994 [3] (Reform Act) requires the owner of a property located in a community participating in the NFIP, and mapped in a SFHA, to purchase flood insurance as a condition of receiving a mortgage backed by the Federal National Mortgage Association (Fannie Mae) or the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the government-sponsored enterprises or GSEs), VA, USDA, or FHA.

The Biggert-Waters Flood Insurance Reform Act of 2012, amended in 2014, (Biggert-Waters Act) [4] further amended the Federal flood insurance statutes to encourage private-sector participation. However, it does not impose requirements on FHA-insured loans. The Biggert-Waters Act requires the Federal entities for lending regulation (the Federal Reserve Board (FRB), the Federal Deposit Insurance Corporation (FDIC), the Office of the Comptroller of the Currency (OCC), the National Credit Union Administration (NCUA), and the Farm Credit Administration (FCA), and collectively, Federal regulators), to direct lenders to accept private flood insurance to satisfy the mandatory purchase requirement, instead of NFIP insurance, if the private flood insurance meets the conditions defined further in the statute at 42 U.S.C. 4012a(b)(7). In addition, the Biggert-Waters Act also requires Federal agency lenders and the GSEs to accept private flood insurance, as defined by the statute. The Biggert-Waters Act also mandates that federally regulated lenders, Federal agency lenders, and lenders who sell to or service loans on behalf of the GSEs must accept private flood insurance policies that meet the definition of ''private flood insurance'' in the Biggert Waters Act as satisfaction of mandatory purchase and flood insurance coverage requirements under the FDPA.[5] On February 20, 2019, the Federal regulators jointly issued a final rule, published at 84 FR 4953 in the **Federal Register**, implementing the private flood insurance provisions of the Biggert-Waters Act. For more information on the statutory framework for NFIP, see HUD's proposed rule published at 85 FR 74630 on November 23, 2020.

HUD's Proposed Rule

On November 23, 2020 (85 FR 74630), HUD proposed to amend FHA regulations at 24 CFR parts 201, 203, and 206, to allow owners the option to purchase private flood insurance on FHA-insured mortgages for properties located in SFHAs, consistent with the FDPA and in harmony with private flood insurance requirements under the Biggert-Waters Act. As explained in the proposed rule, mortgagee's acceptance of private flood insurance policies would provide borrowers with more flood insurance choices, promote consistency with industry standards, reduce the regulatory restrictions on flood insurance for FHA-insured loans, and harmonize FHA policies with the congressional intent expressed in the Biggert-Waters Act to encourage an expanded private flood insurance market.

HUD's proposed rule included a provision with a compliance aid designed to help mortgagees evaluate whether a flood insurance policy meets HUD's definition of ''private flood insurance.'' HUD's proposal provided, however, that a mortgagee may make its own determination and choose not to rely on this statement and that the provision would not relieve a mortgagee of the requirement to accept a policy that both meets the definition of ''private flood insurance'' and fulfills the flood insurance coverage requirement, even if the policy does not include the compliance aid statement. In other words, this provision would not permit mortgagees to reject policies solely because they are not accompanied by the compliance aid statement. Mortgagees that are regulated lending institutions may seek additional compliance aids on the policy.

HUD's proposed rule also sought public input on specific aspects of HUD's proposal. HUD sought public comment on whether FHA regulations should state that a mortgagee may accept a qualifying private flood insurance policy in lieu of an NFIP policy or that a mortgagee must accept a qualifying private flood insurance policy in lieu of an NFIP policy. Additionally, HUD sought public feedback on its proposed compliance aid. Specifically, HUD sought public comment on the language and option for the proposed HUD compliance aid for private flood insurance policies to demonstrate compliance with HUD's definition and requirements for private flood insurance.

HUD noted that its proposed rule differed from the Federal regulators' rule, published in the **Federal Register** at 84 FR 4953 on February 20, 2019, in several ways. Both rules offer a compliance aid to help mortgagees evaluate whether a flood insurance policy meets the definition of ''private flood insurance.'' However, as explained in HUD's proposed rule, HUD's compliance aid differs from the Federal regulators' compliance aid provided in their final rule. HUD explained that this is due to differences in authorities governing the Federal regulators and FHA. The Federal regulators rely on the governing authority of the Biggert-Waters Act, which does not cover FHA. Additionally, unlike the Federal regulators' joint rule, HUD did not propose to permit Mortgagees to exercise their discretion to accept flood insurance policies, provided by private insurers or mutual aid societies, that do not meet the definition and requirements for a private flood insurance policy as laid out in HUD's proposed rule. As stated in HUD's proposed rule, due to the differences between HUD's and the Federal regulators' rules, compliance with the Federal regulators' final rule should not be interpreted as compliance with HUD's requirements.

II. Changes Made at the Final Rule Stage

In consideration of the public comments, HUD's experience implementing the program, and HUD's goals of aligning with the Biggert-Waters Act while mitigating risk and protecting taxpayers' funds, this final rule adopts with minor changes HUD's proposal published on November 23, 2020 (85 FR 74630). What follows is a summary of HUD's changes to 24 CFR parts 201, 203, and 206 made by this final rule. See HUD's proposed rule for more detailed information.

§ 201.28 Flood and Hazard Insurance, and Coastal Barriers Properties

HUD revises § 201.28 to better align it with the requirements of 42 U.S.C. 4012a(a) and §§ 203.16a and 206.45. Specifically, the revision adds a reference to the statutory requirements

[2] Defined at 42 U.S.C. 4003(a)(4).

[3] Title V of the Riegle Community Development and Regulatory Improvement Act of 1994, Public Law 103–325 (1994).

[4] Public Law 112–141 (2012).

[5] *See id.*

for community participation in NFIP and NFIP's availability in that community. HUD is adding this language to ensure that prospective homeowners seeking homes in communities that do not participate in NFIP are aware that they will not be able to obtain a private flood insurance policy and still meet FHA insurance requirements. In addition, HUD is adding language to clarify that lenders may rely on the compliance aid statement as provided in § 203.16a(c).

§ 203.16a Mortgagor and Mortgagee Requirement for Maintaining Flood Insurance Coverage

This final rule makes two changes to § 203.16a as proposed. Initially, the final rule adds § 203.16a(a)(1)(iii), and addresses the applicability of § 203.16a if a mortgage is to cover property improvements that are not otherwise covered by the flood insurance standard for condominium projects established under § 203.43b(d)(6)(iii) or (i)(1). HUD makes this technical change for clarity given the scope of properties that may constitute a condominium project.

Second, HUD's proposed rule at § 203.16a(d) stated that flood insurance must be maintained during such time as the mortgage is insured in an amount at least equal to the lowest of three possible amounts, consistent with the statutory requirements in Section 102 of the FDPA. One option proposed by paragraph (d)(1) of this section was to use the statutory language providing for coverage in an amount equal to the ''Development or project cost less estimated land cost.'' This final rule revises paragraph (d)(1) to clarify the meaning of ''Development or project cost less estimated land cost''. HUD is now providing that paragraph (d)(1) is an amount equal to ''100 percent replacement cost of the insurable value of the improvements, which consists of the development or project cost less estimated land cost.'' This language is codified in HUD's Home Equity Conversion Mortgage (HECM) regulations at § 206.45(c)(3)(i). This final rule makes this technical change for clarity and consistency and alignment with HECM regulations.

§ 206.45 HECM Requirements for Private Flood Insurance Coverage

This final rule makes several minor revisions to § 206.45 as proposed. Initially, HUD is adding a restatement of the definition and requirements for flood insurance to § 206.45. HUD is also revising § 206.45(c)(2) to add for HECM mortgages the loss payee and compliance aid language that is in § 203.16a(c). This final rule adds paragraph (c)(4) to § 206.45 to restate the definition of private flood insurance in § 203.16a(e). HUD is amending § 206.45 by replacing the cross references to the definition in § 203.16a with cross references to § 206.45(c)(4). HUD has determined that greater clarity can be achieved by keeping private flood insurance requirements related to HECM in part 206. Additionally, this increases consistency between HECM and forward-facing mortgage regulations and affords the same benefits to both HECM and forward-facing mortgage mortgagors.

Second, similar to § 203.16a(a)(1)(iii), this final rule adds a paragraph to § 206.45. Under this new paragraph (c)(1)(i)(C), the requirements of § 206.45(c) apply if a mortgage is to cover property improvements that are not otherwise covered by the flood insurance standard for condominium projects established under § 203.43b(d)(6)(iii) or (i)(1). HUD makes this technical change for consistency within HUD's regulations and clarity given the scope of properties that may comprise a condominium project.

Finally, this final rule reorganizes the text of § 206.45(c)(1) into new paragraphs (c)(1) and (2) for clarity and structural consistency with § 203.16a and adds a header to paragraph (c)(3).

III. The Public Comments

The public comment period for the November 23, 2020, proposed rule closed on January 22, 2021. HUD received 31 (thirty-one) public comments in response to the proposed rule from brokers, homeowners, mortgagees, insurance agents, first-time home buyers, FHA borrowers, non-profit organizations, and other interested parties. This section presents the significant issues, questions, and suggestions submitted by public commenters, and HUD's responses to these issues, questions, and suggestions.

General Support and Benefits of HUD's Proposed Rule

Many commenters supported HUD's proposal to permit FHA borrowers to purchase private flood insurance. Many commenters cited how the proposed rule would save homeowners money, increase affordability and options for buyers, and offer broader insurance coverage at a lower price. Some commenters urged HUD to move forward with a final rule as soon as possible for FHA borrowers to realize the intended benefit.

One commenter noted that COVID–19 has presented obstacles of its own and the proposed rule will help families save money during the pandemic.

HUD Response: HUD appreciates the feedback and is publishing this rule to align with the intention of the Biggert-Waters Act. This rule allows borrowers the option to purchase private flood insurance in lieu of an NFIP policy, where flood insurance is required. Private flood insurance policies might offer borrowers greater coverage, less expensive rates, and lower deductibles.

Comments: Private Insurance Is Less Expensive and Offers More Coverage

Many commenters stated that Federal flood insurance policies are significantly more expensive than private insurance. Moreover, commenters stated that private insurance offered more coverage for lower premiums. One commenter stated that they considered refinancing their home into a conventional loan so they could buy private insurance because of the price of Federal flood insurance policies. Another commenter quoted the premium they received for Federal flood insurance at $5,500 with a $2,000 deductible, compared to the premium for private insurance at $1,100 with a $1,000 deductible for the same coverage. One commenter stated that even though their home has not had a flood in about 70 years the premiums for required insurance are ''still insanely high.'' Other commenters stated that each year the cost of Federal flood insurance continues to rise significantly. These commenters generally agreed that private flood insurance would help low to middle income families save money, expand homeownership to first time homeowners, and help homeowners stay in their homes rather than having to sell because of expensive NFIP flood insurance. Another commenter said that because private flood insurance typically provides more coverage than an NFIP policy, it is less likely that FHA insurance will be required after floods.

HUD Response: HUD is encouraged that borrowers will be offered greater choice in selecting a flood insurance policy, which will reduce differences between FHA-insured mortgages and other mortgage options, while maintaining fiscal responsibility to FHA borrowers and taxpayers.

The range of flood insurance rates and deductibles varies greatly based on the characteristics of each property. A private flood insurance policy might allow some borrowers to obtain a less expensive policy.

Comments: Offering Private Insurance Promotes Affordability and Buying Options and May Expand the Flood Insurance Market

Commenters stated that private flood insurance is more affordable and gives more individuals and families the opportunity to own or refinance homes, along with the ability to save money. For example, allowing private flood insurance for FHA-insured loans will give more consumers who do not have ''extra funds to afford the current flood insurance premiums'' the opportunity to become homeowners. One commenter stated that FHA-insured loans are supposed to represent ''affordable housing.'' The commenter continued, however by stating that borrowers are forced to get Federal flood insurance policies through FEMA which are double the cost of private flood insurance and which prohibit many prospective homeowners from buying due to costs. Another commenter noted that the high rates for Federal flood insurance could make a difference in someone being able to buy their dream home. Another commenter stated that their ''elderly clients are tired of having to sell their homes because their [Federal flood insurance policy] rates are so high.''

Several commenters supported the proposed rule because it could give homeowners and buyers financial breathing room and allow people to purchase homes without restrictions on purchasing power arising from the cost of flood insurance. One commenter noted the difficulty in advising clients that they are not eligible for a $500 private flood policy and are required to purchase a $3000 policy due to FHA requirements. The commenter also stated that in some cases the costs of FEMA insurance cause people to not be able to purchase a new home at all.

Another commenter stated that consumers should be allowed to choose their flood insurance policy, and that the current rule restricts consumer choice, creates inequities between FHA and more conventional loan holders, and raises barriers for FHA-insured loan products, which sometimes precludes first-time home buyers from closing on a home. One commenter stated, from the seller's point of view, that after potential buyers with an FHA-insured loan realize that they will be adding ''over $100 to their house payment for flood insurance,'' buyers choose not to go forward with the sale.

One commenter emphasized that the rule's proposal to permit private flood insurance is significant and critical to consumer choice because ''about 20 percent of home purchase first liens and about 15 percent of refinance transactions on 1–4 family dwelling are FHA-insured.'' The commenter stated that every year there are thousands of borrowers who are not able to choose private flood insurance that is more affordable.

One commenter supported the proposed rule explaining that it would give homeowners the option to purchase private flood insurance during periods where NFIP may lapse. Additionally, one commenter noted that the rule would grow the private flood insurance market to complement the NFIP and expand consumer flood insurance options.

HUD Response: Changes to HUD's flood insurance regulations to allow acceptance of private flood insurance policies offer access to a broader range of flood insurance options. Private flood insurance policies could provide potential cost savings to some borrowers compared to the cost of NFIP policies.[6] Additionally, in the event of a lapse in appropriations for NFIP, a private insurance option could be available to borrowers.

Comments: HUD's Proposed Rule Aligns With Industry Standards, Law, and Principles of Affordability, Consumer Choice, and Fiscal Responsibility

Some commenters stated that the proposed rule would more closely align HUD regulations with industry standards, statutory law, and principles of good governance, consumer choice, affordable housing, and fiscal prudence.

One commenter stated that the proposed rule will achieve HUD's stated goal of more closely aligning FHA regulations ''with industry standards and reduc[ing] the regulatory restrictions on flood insurance for FHA-insured loans.'' The commenter also stated that the proposed rule would reduce regulatory restrictions on flood insurance for FHA-insured loans, provide greater consumer choice, and enhance homeownership opportunities for its members.

Another commenter stated that HUD's rule aligns with the Biggert-Waters Act's clear direction to all Federal agency regulated mortgagees to accept certain private flood insurance. The commenter stated that, ''[d]rawing a distinction between agencies that 'insure' versus 'lend' is a hyper-technical legal reading of the statute that does not comply with the spirit—if not the exact letter—of the law.'' Similarly, the commenter stated that laws should be uniformly and consistently applied across the Federal Government, and that an ''agency should not exploit a technical drafting error to avoid compliance with a statute, especially when Congressional intent is clear.'' Finally, the commenter said HUD's rule is fiscally prudent because providing for FHA mortgagee acceptance of private policies not only bolsters the FHA Fund but also protects taxpayers.

HUD Response: HUD's intention is to align as much as possible with other Federal agencies, the intentions of the Biggert-Waters Act, and industry standards where appropriate, while issuing distinct regulations when necessary.

HUD is committed to removing barriers to affordable housing, supporting affordable housing opportunities, homeownership, and facilitating access to credit for borrowers. This rule could increase the entry-level housing supply in communities where flood insurance is required, while mitigating risk and protecting taxpayers' funds. This rule is not expected to have a substantial direct budgetary impact to FHA's Mutual Mortgage Insurance (MMI) Fund.

Mandatory Versus Permissive Requirement (Whether HUD's Rule Should State That Mortgagees ''May Accept'' or ''Must Accept'' Private Flood Insurance Policies That Meet the Definition Under HUD's Rule and the Biggert-Waters Flood Insurance Reform Act of 2012 (''Biggert-Waters Act''))

Comments: Support for a Permissive Requirement (Mortgagees ''May Accept'')

Some commenters agreed with HUD's decision to make optional mortgagees' acceptance of private flood insurance policies that meet the definition of private flood insurance under HUD's rule and the Biggert-Waters Flood Insurance Reform Act of 2012 (''Biggert-Waters Act'') (a mortgagee ''may accept'' a private flood insurance policy).

One commenter stated that ''it is more appropriate to give [mortgagees] discretion to accept private flood policies by saying that they 'may' accept a private flood policy if it meets all of the definitions. While we respect that the borrower has the freedom of choice to find a private policy (provided the policy fits all of the required definitions/parameters), it is also important that the mortgagee has a choice based on past experiences with providers and their own risk tolerance levels.''

[6] Please see the Regulatory Impact Analysis for the November 23, 2020, proposed rule for more information, at *https://www.regulations.gov/document/HUD-2020-0078-0040.*

Another commenter noted that mortgagees have greater expertise and a shared interest with borrowers in ensuring that the property is adequately covered by flood insurance. The commenter stated that directing mandatory acceptance could be warranted only in the presence of overwhelming policy reasons to do so, which are not present here. Another commenter explained that adding a mandatory acceptance requirement in HUD's regulations (''must accept'') could create additional burdens for those mortgagees and servicers that are not subject to the Biggert-Waters Act requirement to accept private flood insurance since they may have to develop new procedures and processes to review private flood insurance policies. The commenter also noted that requiring the acceptance of private flood insurance could mean that some mortgagees and servicers would continue not to accept private flood insurance which could result in higher costs and limited choices for FHA borrowers.

Comments: Support for a Mandatory Requirement (Mortgagees ''Must Accept'')

Some commenters supported a mandatory requirement that mortgagees accept private flood insurance policies that meet the definition and requirements for a private flood insurance policy under HUD's rule and the Biggert-Waters Act. One commenter stated that having consistency between HUD's rule and that of the Federal financial regulators is beneficial to the consumer because it ''provides consumer choice and prevents [mortgagees] from competing on underwriting guidelines.''

One commenter explained that mandating the acceptance of private flood insurance would help further FEMA's ''Moon Shot Initiative'' to double the number of properties covered by flood insurance.

Another commenter stated that mandating private insurance would ''harmonize FHA policies with Congressional intent to expand the private flood insurance market.''

Another commenter stated that changing the practice of denying property owners access to private flood insurance is long overdue and that a mortgagee should be required to accept qualifying private flood insurance in lieu of an NFIP policy.

HUD Response: HUD recognizes the value of consistency across the housing finance industry with respect to flood insurance and the importance of providing borrowers the option to select flood insurance coverage that best matches their needs.

HUD recognizes the importance of allowing mortgagees discretion to accept private flood insurance policies that meet HUD's requirements. This approach is similar to HUD's policy for accepting hazard insurance, where mortgagees have discretion to accept a policy. HUD requires the mortgagee to provide evidence of acceptable insurance coverage, where required, and does not prescribe which provider the mortgagee accepts. Under HUD's regulations for FHA-insured mortgages, HUD will not pay a claim to mortgagees for surchargeable damages that should have been covered by the required flood or hazard insurance; therefore, it is in the mortgagee's financial interest to ensure that the borrower has adequate coverage from a responsible insurance provider.

HUD does not anticipate this rule playing a role in furthering FEMA's ''Moonshot Initiative'' to increase the number of properties with flood insurance. Although FEMA has indicated its desire for more properties to carry flood insurance to help protect them against potential flood losses, FEMA's initiative seems targeted at homeowners who are not currently required to carry flood insurance, such as those who have paid off their mortgage. With this rule, HUD is not expanding the requirement for which FHA-insured mortgages are required to carry flood insurance.

Consideration of Whether HUD's Rule Should Offer a Discretionary Option for Mortgagees To Accept Policies That Do Not Meet the Definition of Private Flood Insurance Under HUD's Rule and the Biggert-Waters Act

Comments: Opposition to a Discretionary Option

One commenter applauded HUD for rejecting the ''discretionary acceptance'' option that was in the final joint rule published by the banking regulators. The Federal regulators' rule has a provision that provides that mortgagees may accept flood insurance that does not meet the definition of flood insurance in the banking regulator's joint final rule. The commenter stated the discretionary acceptance option ''runs counter to Congressional intent of NFIP reforms'' and that ''[i]t is quite clear by the definition of private flood insurance in Section 100239 of the Biggert-Waters Flood Insurance Reform Act of 2012, that Congress wanted clear sideboards on what qualified as a private flood insurance policy for the purposes of meeting the mandatory purchase requirement under the NFIP.'' The commenter found the Federal regulators' rule to circumvent ''Congressional sideboards by enacting failed legislative proposals from 2016 through rulemaking.'' The commenter continued that a discretionary acceptance option ''could lead to excessive deductibles'' which would lower premiums but increase out-of-pocket ''costs for the mortgagor to then ultimately recover when an event occurs.'' The commenter concluded that discretionary acceptance does not provide consumer protections and would result in taxpayers being forced to cover additional disaster losses.

Comments: Support for a Discretionary Option

Some commenters recommended that HUD provide a discretionary acceptance option. Commenters stated that if HUD does not provide FHA mortgagees with a discretionary acceptance provision, FHA borrowers effectively would be barred from the use of private insurance policies that may be available to non-FHA borrowers. This would undermine HUD's objectives of helping borrowers and providing more consumer choice in options for flood insurance products.

One commenter stated that following the Federal regulators' current framework, which includes a discretionary acceptance provision, will best protect the interest of insured borrowers and mortgagees by giving borrowers options to less expensive flood policies with the same or better coverage, and by giving mortgagees the flexibility to make their own determination of the adequacy of such policies.

Another commenter stated that without a discretionary acceptance provision, HUD's proposed rule may not actually afford consumers the options it seeks to provide because the proposal would only provide credit unions with the ability to accept private flood insurance in lieu of a Federal flood insurance policy if all the factors defining ''private flood insurance'' are present. The commenter stated that providing a discretionary acceptance provision would ease operations, minimize delays in the homebuying process, and enhance consumer choice. For example, without such a provision, credit unions may send private flood insurance policies to a specialist for review, if there is no expert on staff, to ensure the credit union may accept the policy. This may, in turn, lead to longer closing times and borrower frustration with the homebuying process.

One commenter pointed out that HUD's rule does not appear to allow

mortgagees to accept all residential policies offered by surplus line insurers, namely nonresidential commercial policies. The commenter explained that restricting acceptance to only commercial surplus lines coverage could hinder access to additional choices for residential flood insurance products. Surplus lines carriers may also be able to offer residential consumers additional coverage features or greater limits than the NFIP at a more affordable price.

Another commenter suggested that HUD ''should allow discretionary acceptance of a private flood insurance policy regardless of HUD's decision on whether accepting private flood insurance is a mandatory requirement or optional under its final regulations.'' The commenter explained that this would promote harmony with the Flood Disaster Protection Act and consumer choice for FHA borrowers. Most mortgagees already ''must'' accept private flood insurance that meets the Biggert-Waters Act definition, under the Federal regulators' rule. So, if HUD's definition is ''the same or substantially similar to the FDPA definition,'' from which the Federal regulators' definition derives, then ''[HUD's separate rule and definition] would appear to marginally help create the consistency and harmony with the FDPA that HUD is attempting to do.'' However, if HUD uses a permissive (*e.g.,* ''may accept''), then some mortgagees will continue to not accept private flood insurance, even if the policy meets the definition. ''This could result in higher costs and limited choices for FHA borrowers.'' Therefore, HUD should offer a discretionary option in either case to permit mortgagees to accept policies that do not strictly conform to the statutory, and derivative, definitions.

The commenter explained that a discretionary option is especially crucial if HUD makes it mandatory that mortgagees accept policies that meet the definitions. A discretionary option would address elements important to institutional risk and consumer protections. The commenter stated that the statutory definition of ''private flood insurance'' is imprecise or impractical when considering actual insurance contracts, existing state law, and state approval processes; and, therefore, the final rule ''can provide further detail'' by establishing discretionary acceptance criteria.

HUD Response: HUD has determined that discretionary acceptance of policies that do not meet HUD's requirements would not protect borrowers or FHA's MMI Fund. HUD appreciates the feedback but believes that permitting mortgagees the discretion to accept flood insurance policies that do not meet HUD's private flood insurance requirements would not sufficiently mitigate risk and protect taxpayers' funds.

HUD is concerned about the lack of deductible limits for discretionary acceptance of flood insurance policies in the Federal regulators' rule, which could open borrowers to significant costs. There is no requirement that a deductible under these policies be no greater than that of a comparable NFIP policy; therefore, a policy that seems less expensive may have significantly higher deductibles leading to potentially prohibitively costly out-of-pocket expenses for the borrower when an event occurs. HUD is concerned that having uncapped deductible limits could have a negative impact on the financial stability of FHA-insured borrowers, which could lead to higher risk of default and foreclosure. Furthermore, HUD does not believe that eliminating the option for discretionary acceptance will significantly reduce choice for most FHA-insured borrowers.

HUD appreciates the commenters' desire for uniformity and HUD has strived to align with other agencies' requirements where appropriate. While HUD aims to align with the Biggert-Waters Act, allowing mortgagees to permit a discretionary acceptance option does not align with the best interests of HUD's borrowers or the MMI Fund.

Comments Suggested Criteria for a Discretionary Option

Some commenters that recommended HUD add a discretionary acceptance option also contended that HUD should include provisions outlining discretionary acceptance criteria identical or similar to the Federal agencies' final regulation. One commenter offered suggested revisions to the regulatory text.

One commenter stated that HUD should allow mortgagees, specifically credit unions, ''to accept private flood insurance policies in lieu of NFIP policies on FHA-insured mortgages, if the compliance aid is present, if the policy meets the mandatory acceptance criteria under the definition of 'private flood insurance' or if the policy meets the discretionary acceptance criteria outlined in the [Federal regulators'] Interagency Rule.''

Commenters recommended that the regulations permit FHA mortgagees to accept private flood insurance policies that meet discretionary acceptance criteria, even where those policies may not necessarily satisfy the technical definition of ''private flood insurance'' in the Biggert-Waters Act. One commenter pointed to the Federal regulators' regulations, which ''require at least four criteria that must be satisfied before a mortgagee can exercise its discretion to accept [a] private flood insurance policy.'' [7] The commenter reasoned that the Biggert-Waters Act was meant to create a floor for policies that must be accepted or could not be rejected, and that it remains the province of the states to determine what constitutes acceptable insurance. This commenter also stated that a discretionary provision can be drafted in a manner that provides consumer choice while maintaining the safety and integrity of the Mutual Mortgage Insurance Fund, similar to the way that the Federal regulators' rule protects the associated Federal insurance programs.

Commenters provided an example of how these principles should inform HUD's addition of a discretionary acceptance option: Under the discretionary acceptance provision of the Federal regulators' final rules and, where permitted by state insurance law, a mortgagee has the discretion to accept a private flood insurance policy that contains a 30-day notice provision rather than a 45-day notice provision as required under the Biggert-Waters Act. Commenters recommended HUD use this example to help guide its creation of discretionary option criteria.

One commenter emphasized that it is important for mortgagees to understand whether a private policy requires a separate or included disclosure with a statement of the availability of Federal flood insurance policies. The commenter said that ''[Flood Disaster Protection Act] criteria require that a private policy must include a statement of the availability of flood insurance under the NFIP. In current practice this statement (when provided) is being provided by private carriers as a separate disclosure rather than embedded language in the actual policy contract. Discretionary acceptance criteria from FHA could exclude this as a required element or could clarify that this separate disclosure is satisfactory and meets the intent of the FDPA.''

HUD Response: HUD appreciates the specific feedback provided. However, HUD believes it is in the best interest of borrowers and HUD's fiduciary responsibility to the Mutual Mortgage Insurance Fund to not offer a discretionary option and to require all private flood insurance policies to meet

[7] See the four criteria explained at 84 FR 4953, 4962.

the definition of private flood insurance under this rule.

Consideration of Whether HUD Should Align Its Compliance Aid With the Federal Regulators' Compliance Aid

Comments: Support for HUD's Proposed Compliance Aid

Some commenters supported HUD's compliance aid or the inclusion of a compliance aid generally. Commenters supported HUD's compliance aid because it would assist mortgagees with the review of private flood insurance policies to ensure they are compliant with FHA's regulations, assist mortgagees in determining whether a policy meets the definition of ''private flood insurance'' without further review of the policy, and prove particularly helpful to smaller mortgagees that may lack resources or technical expertise to adequately review flood insurance policies.

Comments: Support for Making HUD's Compliance Aid Similar or Identical to the Federal Regulators'

Some commenters generally supported the addition of a compliance aid, but strongly recommended that HUD's compliance aid statement be identical or made more similar to Federal regulators' compliance aid language. Commenters wrote that this would ensure ''the policy meets the definition of 'private flood insurance' and fulfills the requirements of both the Federal regulators and HUD.'' Further, this would enable FHA borrowers to immediately benefit from work done by the industry on the Federal regulators' compliance aid since February 2019. The commenter explained, ''At this point, the specific language of the Federal regulators' compliance aid has already been incorporated into the state insurance legislative and regulatory infrastructure.'' The commenter provided an example from a state that enacted a new private flood insurance act in September 2020 that requires that a private flood policy must state that it meets the private flood insurance requirements specified in 42 U.S.C. 4012a(b) and may not contain provisions that, when taken as a whole, are not in compliance with that statutory provision. The commenter also explained that the Federal regulators' compliance aid language has been incorporated into legislation being developed by the National Council of Insurance Legislators (NCOIL), titled the Private Primary Residential Flood Insurance Model Act.[8]

Commenters stated that making HUD's compliance aid more similar or identical to the Federal regulators' will relieve compliance burden on FHA/HUD mortgagees and provide ''certainty'' and prevent confusion for both mortgagees and consumers that private flood insurance policies meet requirements and will or should be accepted ''without further analysis.''

One commenter suggested that HUD clarify ''at least as broad as'' when it comes to deductibles and coverages, ''specifically cautioning against excessive deductibles and ensuring the policy has an equivalent to Increased Cost of Coverage (ICC) that is found in an NFIP policy.'' The commenter explained their concern that the private sector's equivalent to ICC is ''often optional rather than mandatory as with NFIP policies.''

Some commenters pointed out that some insurers may choose not to include both HUD's and the Federal regulators' compliance aid statements, which would ''narrow the pool of available private flood insurance coverage the [proposed rule] is intended to provide to FHA borrowers.'' Even if insurers did include both compliance aid statements, commenters explained that the experience of implementing the Federal regulators' compliance aid demonstrates that including two sets of compliance aid language would not be a simple process. Using different language for an FHA compliance aid would require insurers and mortgagees to use different sets of insurance policies and other documentation for FHA-insured loans. Another commenter suggested that an ''FHA specific compliance aid is superfluous and will add an unnecessary cost to an already costly transaction.'' Similarly, another commenter explained that changes and procedures were put in place following the Federal regulators' 2019 rule and a second process for HUD's compliance aid would impose further burden.

One commenter recommended that if HUD does not adopt the Federal regulators' compliance aid, then HUD should clarify language in its compliance aid regarding the scope of coverage. This language should highlight limited utility in that the compliance aid only ensures compliance with HUD's regulations and not with the interagency rule. Placing this additional language into the compliance aid will provide clarity and put mortgagees on notice that, notwithstanding inclusion of HUD's compliance aid, if a separate compliance aid that conforms to the Federal regulators' rule is not present, they will have to review the private flood insurance policy to determine its compliance with the Federal regulators' rule.

HUD Response: HUD appreciates the feedback regarding the compliance aid. The intention of the compliance aid is to assist mortgagees in understanding when an insurance policy coverage meets the definition of private flood insurance. The compliance aid is a voluntary option that private flood insurance companies may choose to provide.

HUD believes providing a compliance aid is important to assist mortgagees to understand when a private flood insurance policy meets HUD's requirements. This will facilitate the closing process by allowing the mortgagee to rely on the compliance aid instead of the mortgagee taking the time and developing the technical expertise to review the details of each private insurance policy. This aid also ensures that lack of technical expertise regarding flood insurance does not becomes an obstacle to the implementation of this policy.

HUD recognizes the value of consistency across the housing finance industry with respect to flood insurance. However, HUD's legal authority and requirements are distinct from that of the Federal regulators. The Biggert Waters Act does not require HUD to provide a private flood insurance option; therefore, HUD cannot rely on the authority of the Biggert-Waters Act referenced in the Federal regulators' compliance aid and must rely on its own authority. Furthermore, this rule is distinct from the Federal regulators' rule regarding the ''may accept'' versus ''must accept'' requirement, the discretionary acceptance option, and mutual aid associations. Therefore, a different compliance aid is necessary to highlight this distinction; HUD's compliance aid will specify compliance with HUD's requirements.

HUD believes it is in the best interest of borrowers and HUD's fiduciary responsibility to protect taxpayers' funds to have a distinct compliance aid to help ensure the requirements in this rule are met.

Additional Concerns Related to Aligning HUD's Proposed Rule With the Federal Regulators' Rule

While generally in support of the proposed rule, some commenters offered recommendations to improve the proposed rule. These commenters

[8] *NCOIL Adopts Private Primary Residential Flood Insurance Model Act,* Nat'l Council of Insurance Legislators, Sept. 24, 2020, *https://ncoil.org/2020/09/24/ncoil-adopts-private-primary-residential-flood-insurance-model-act/.*

agreed that the proposed rule would substantially benefit FHA borrowers, but suggested HUD more closely align its regulations with the Federal regulators' rule.

Comments: Support for Permitting Mortgagees To Accept Coverage Provided by Mutual Aid Societies

Some commenters recommended HUD, like the Federal regulators, permit mortgagees to accept coverage provided by mutual aid societies consistent with the Biggert-Waters Act. Commenters wrote that if such provisions are excluded, ''individuals and families, whose religious beliefs, or other strictures conflict with the purchase of traditional NFIP or private flood insurance policies'' would be excluded from being able to take advantage of private flood insurance which was intended to benefit all Americans. One commenter recommended using a provision comparable to the Federal regulators' mutual aid society provision. This commenter cited 12 CFR 22.3(3), which was amended by the Federal regulators' joint interim rule and suggested HUD adopt similar language. The changes would conform HUD's proposed rule to the Federal regulators' joint rule and permit acceptance of coverage by mutual aid societies.

HUD Response: HUD appreciates the comments and recognizes the value of consistency across the housing finance industry and has strived to balance those interests as appropriate. Unlike the requirements for NFIP and other private flood insurance providers, mutual aid associations are not required to be licensed, admitted, or otherwise approved to engage in the business of insurance by the insurance regulator of the State or jurisdiction in which the property to be insured is located. FHA does not have the expertise or authority to evaluate the ability of mutual aid associations to fulfill their obligations with regards to their insurance policies or their demonstrated history of fulfilling the terms of agreements to cover losses to members' property caused by flooding. Without specific guidance from FHA, mortgagees would be forced to evaluate the financial soundness of mutual aid associations which might be interpreted differently, causing confusion as well as an undue burden to mortgagees.

Given that mutual aid associations, as defined in the Federal regulators' rule, are not regulated by a State Insurance Regulator and that HUD's role is not to regulate financial institutions, HUD has determined that accepting flood insurance policies provided by mutual aid associations could create a financial risk to borrowers and the MMI Fund.

Comments: Aligning HUD's Rule With the Federal Regulators' Rule Will Create Better Consistency in the Industry and Promote Correct Application of Regulations

One commenter noted that aligning HUD's rule with the Federal regulators' rule would allow borrowers and mortgagees to draw on the policies, documentation, and practices that mortgagees, flood insurance companies, and others have already adopted under the Federal regulators' requirements—which would reduce the risk of mortgagees misapplying FHA regulations. Other commenters recommended consistency throughout the lending process and within industry standards to maintain discretionary acceptance criteria.

Some commenters supported HUD's proposed definition of private flood insurance. However, one commenter recommended HUD better align its definition with the Federal regulators' definition in their joint final rule. The commenter reasoned that while some differences between the specific language in the two regulations are necessary and appropriate (*e.g.,* using ''FHA'' rather than ''regulated lending institution''), other differences create risk that a reader could make an incorrect inference that differences are intended to have substantive impact, which appears not to be the case.

Another commenter explained that ''[a]dopting identical language in [HUD's] regulation would be consistent with HUD's proposed approach to the acceptance of private flood insurance.'' Then the commenter referred to the definition of ''private flood insurance'' in the proposed FHA regulation and the Federal regulators' final regulations and explained that both explicitly incorporate the definition at 42 U.S.C. 4012a(b)(7). The commenter stated that HUD's proposed definition of ''private flood insurance'' is not materially different from the definitions of ''private flood insurance'' in the Federal agencies' final regulations, and HUD's proposed regulation could fairly be characterized as a ''corresponding regulation.''

One commenter stated it is critical that HUD implement regulations consistent with the Federal flood insurance regulations regarding the definition of ''private flood insurance,'' language used in the compliance aid statement, and a mortgagee's discretionary acceptance of a private flood insurance policy that is sufficient protection for the loan.

HUD Response: HUD appreciates the comments and recognizes the value of consistency across the housing finance industry and has strived to align with the other agency's requirements where possible and appropriate. The discretionary acceptance provision under the Federal regulators' rule creates financial risk for FHA borrowers and the MMI Fund.

Other Issues Raised by Commenters

Comments: Concerns About Continuous Coverage

One commenter expressed a concern for the loss of continuous coverage since private flood insurance is not seen as continuous coverage by the NFIP, meaning borrowers will lose subsidies they have with NFIP if they decide to go back after switching to private flood insurance. For example, homeowners who seek FHA mortgages may already be financially constrained and should they need to return to NFIP for flood insurance it could result in them having higher premiums. Additionally, even if the homeowner is informed of this risk, it may not prevent someone who is focused on cost savings from deciding to switch, putting them in a detrimental position that is long-term and may affect the sale of their property.

The commenter pointed out legislation that has already been introduced and seeks to ''amend the definition of continuous coverage to include the provision of private flood insurance.'' [9] The commenter expects this legislation to pass into law soon and to become a part of the comprehensive reform of the NFIP. The commenter stated that for these reasons, the rule is premature and should be postponed until legislation is adopted that will protect homeowners who choose to switch back to NFIP. The new legislation will ensure homeowners can have previous subsidized rates after having continuous coverage either through NFIP or private flood insurance.

HUD Response: HUD appreciates the comment and the commentator's desire to protect homeowners from increased prices under private flood insurance policies. HUD notes and appreciates commenters' concerns about proposed legislation. HUD is publishing this rule to align with the intention of the Biggert-Waters Act. HUD only has authority to act on current law; legislation cited by commenters was not signed into law. Other agencies' forthcoming rules may consider not only borrowers but all homeowners with federally backed mortgages who

[9] See H.R. 2874, 115th Cong. (2017); H.R. 1666, 116th Cong. (2019); S. 1313, 115th Cong. (2017).

have the option to purchase a private flood insurance policy in lieu of an NFIP policy, where one is required.

Comments: HUD's Regulatory Burden Analysis Is Flawed

One commenter stated that the regulatory burden analysis claims that most private flood insurance is sold on the surplus lines market as opposed to the admitted market and dominated by large international insurers. The commenter stated this is ''a complete misunderstanding of the surplus lines market and refuted in a closer reading of the report cited as the source of the information.'' [10]

HUD Response: HUD appreciates the feedback and concern regarding data sourcing. As stated, there is limited data regarding flood insurance companies. HUD utilized a peer reviewed study published in professional risk industry journals, which is considered a reliable source of data.

This data was taken from Kousky et al. (2018). The authors' paper is among the limited existing studies on residential private flood insurance. The authors stated that ''more policies are written by surplus lines carriers than by admitted carriers. . . . This is unsurprising, since surplus lines firms tend to cover new or catastrophic risks for which consumers may have trouble finding coverage in the admitted market.'' [11] In addition, ''the largest US homeowners insurance companies have generally been hesitant to enter the flood [insurance] market, although a few have begun to enter through subsidiaries.'' [12]

HUD expects that more private insurers—either admitted carriers or surplus lines carriers, and of any company size—will be offering flood insurance soon or have already started offering flood insurance, especially after the Federal regulators passed their rule on the acceptance of private flood insurance. ''As insurers' familiarity with flood catastrophe models grows, as underwriting experience develops, and as state regulatory structures evolve, the number of private flood policies in force could continue to grow, including among admitted carriers.'' [13]

Comments: HUD's Rule Would Address Issues Raised in a Recent HUD OIG Report

Some commenters stated that the proposed rule would help address an issue raised by HUD's Office of Inspector General (OIG) in a report issued January 5, 2021.[14] The recent report found that at least 3,870 FHA-insured loans totaling $940 million ''had private flood insurance coverage instead of the required national flood insurance program coverage, coverage that did not meet the minimum required amount, or no coverage at the time the loan was closed and endorsed.'' [15] Every other Federal lending authority now allows, and in many cases requires, the acceptance of private flood insurance, leaving FHA mortgagees with an untenable choice: follow their regulator's private flood insurance requirement and risk the FHA insurance down the road, or walk away from FHA loan products entirely. The commenters stated that this is an unacceptable situation.

HUD Response: HUD agrees that this rule should help reduce confusion for borrowers and mortgagees, who may not have realized that HUD did not previously accept private flood insurance policies in lieu of NFIP policies, although other Federal agencies did. This issue was identified in a recent HUD OIG audit.[16] This rule should remove that source of confusion and non-compliance by allowing FHA borrowers to purchase a flood insurance policy that meets HUD's requirements.

IV. Findings and Certifications

Executive Order 12866 and Executive Order 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.

This rule was determined to be a ''significant regulatory action'' under section 3(f) of Executive Order 12866 (but not an economically significant action under section 3(f)(1) of the Executive order).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained in HUD's November 23, 2020, proposed rule, supervised mortgagees are among FHA-approved lenders. These mortgagees are supervised by the Federal regulators. Based on the analysis developed by the Federal regulators and published as part of their final rule (see 84 FR 4953), the Federal regulators determined that allowing private flood insurance in mortgage transactions conducted by these mortgagees would not have a significant economic impact on a substantial number of small entities they supervised. This finding is also true for the share of regulated lending institutions supervised by the Federal regulators that are FHA-approved lenders.

Small entities also include small businesses, small not-for-profit organizations, and small governmental jurisdictions. This rule, however, offers a benefit to all FHA-approved mortgagees regardless of the size of the firm. Allowing private insurers to compete provides business opportunities to those private insurers. The rule provides a compliance aid which will allow all mortgagees, including small mortgagees that may

[10] The commenter cited Carolyn Kousky, et al., *The Emerging Private Residential Flood Insurance Market in the United States, Risk Management and Decision Processes Center, Wharton, University of Pennsylvania* (2018). The commenter stated that the report explains that, '''large surplus lines carriers 'E&S companies work with wholesalers known as managing general agencies (MGAs) or managing general underwriters (MGUs). An MGA/MGU works on behalf of the insurer and organizes and manages its book of business. The MGA/MGU will employ the underwriters, develop premium-setting practices, issue policies on the insurer's behalf, and manage claims payments. They get a fee or share of premiums for these services. An MGU, as opposed to an MGA, also undertakes the underwriting. MGAs vary significantly in their size and scope. Some offer a wide range of E&S products; others focus on only a specific category of coverage or just one product. Some operate nationally; others work only in a given region or locality (Hull 2002).' '''

[11] *Id.* at 2.

[12] *Id.*

[13] *Id.*

[14] Office of Inspector Gen., U.S. Dep't of Hous. & Urban Dev., Audit Rep. No. 2021–KC–0002 (2021), *https://www.hudoig.gov/sites/default/files/2021-01/2021-KC-0002.pdf* (''Audit Rep. No. 2021–KC–0002'').

[15] *FHA Insured $940 Million in Loans for Properties in Flood Zones Without the Required Flood Insurance, HudOig.Gov.* Jan. 5, 2021, *https://www.hudoig.gov/reports-publications/report/fha-insured-940-million-loans-properties-flood-zones-without-required.*

[16] *See* Audit Rep. No. 2021–KC–0002, *supra* note 8.

lack technical expertise regarding flood insurance policies, to conclude that a policy meets the definition of ''private flood insurance'' without further review of the policy if the policy, or an endorsement to the policy, states: ''This policy meets the definition of private flood insurance contained in 24 CFR 203.16a(e) for FHA-insured mortgages.'' This proposed rule would also reduce the burden to all mortgagees, including those small entities, by aligning FHA's regulations with those issued by the Federal regulators.

For flood insurance companies, there is less data. However, existing analysis by Kousky et al. (2018) [17] on private insurers that are currently providing flood insurance shows that these private insurance companies are mostly surplus line carriers that operate globally. This finding implies that such carriers cannot be considered as small entities. Taking advantage of the business opportunities is more difficult for small firms because large firms are inherently favored by their ability to spread flood risk. However, as the private flood insurance market expands, it is expected to become less concentrated, to the benefit of small entities. Overall, HUD believes that this rule will not have a significant impact on a substantial number of small entities, and the impact of the rule on those small entities impacted will be beneficial rather than adverse. Therefore, HUD certifies that this rule is not expected to have a significant economic impact on small entities.

Environmental Impact

A Finding of No Significant Impact (FONSI) with respect to the environment was made at the proposed rule stage in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI remains applicable and is available for public inspection on *www.regulations.gov.*

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either (i) imposes substantial direct compliance costs on state and local governments and is not required by statute, or (ii) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This rule does not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This rule does not impose any Federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 201

Claims, Health facilities, Historic preservation, Home improvement, Loan programs-housing and community development, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 203

Hawaiian Natives, Home improvement, Indians-lands, Loan programs-housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

24 CFR Part 206

Aged, Condominiums, Loan programs-housing and community development, Mortgage insurance, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, HUD amends 24 CFR parts 201, 203, and 206 as follows:

PART 201—TITLE I PROPERTY IMPROVEMENT AND MANUFACTURED HOME LOANS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 12 U.S.C. 1703; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

■ 2. In § 201.28, revise paragraph (a) to read as follows:

§ 201.28 Flood and hazard insurance, and Coastal Barriers properties.

(a) *Flood insurance.* No property improvement loan or manufactured home loan shall be eligible for insurance under this part if the property securing repayment of the loan is located in a special flood hazard area identified by the Federal Emergency Management Agency (FEMA), unless the community in which the area is situated is participating in the National Flood Insurance Program, flood insurance under the National Flood Insurance Program (NFIP) is available with respect to such property improvements, and flood insurance on the property is obtained by the borrower in compliance with section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a). Such insurance shall be in the form of the standard policy issued under the National Flood Insurance Program (NFIP) or private flood insurance, as defined in 24 CFR 203.16a. Such insurance shall be obtained at any time during the term of the loan that the lender determines that the secured property is located in a special flood hazard area identified by FEMA and shall be maintained by the borrower for the remaining term of the loan, or until the lender determines that the property is no longer in a special flood hazard area, or until the property is repossessed or foreclosed upon by the lender. The amount of such insurance shall be at least equal to the unpaid balance of the Title I loan, and the lender shall be named as the loss payee for flood insurance benefits. A lender may determine that a private flood insurance policy meets the definition of private flood insurance, as defined in 24 CFR 203.16a, without further review of the policy, if the compliance aid statement provided in 24 CFR 203.16a(c) is included within the policy or as an endorsement to the policy.

* * * * *

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

■ 3. The authority citation for part 203 continues to read as follows:

Authority: 12 U.S.C. 1707, 1709, 1710, 1715b, 1715z–16, 1715u, and 1715z–21; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

■ 4. Revise § 203.16a to read as follows:

§ 203.16a Mortgagor and mortgagee requirement for maintaining flood insurance coverage.

(a) *In general.* (1) The requirements of this section apply if a mortgage is to cover property improvements that:

(i) Are located in an area designated by the Federal Emergency Management Agency (FEMA) as a floodplain area having special flood hazards;

(ii) Are otherwise determined by the Commissioner to be subject to flood hazard; or

(iii) Are not otherwise covered by the flood insurance standard for condominium projects established under § 203.43b(d)(6)(iii) or (i)(1).

[17] Kousky, C., H. Kunreuther, B. Lingle, and L. Shabman (2018). *The Emerging Private Residential Flood Insurance Market in the United States, Risk Management and Decision Processes Center, Wharton, University of Pennsylvania,* July.

(2) No mortgage may be insured that covers property improvements located in an area that has been identified by FEMA as an area having special flood hazards unless the community in which the area is situated is participating in the National Flood Insurance Program and flood insurance under the National Flood Insurance Program (NFIP) is available with respect to such property improvements. Such requirement for flood insurance shall be effective one year after the date of notification by FEMA to the chief executive officer of a flood prone community that such community has been identified as having special flood hazards.

(3) For purposes of this section, property improvement means a dwelling and related structures/equipment essential to the value of the property and subject to flood damage.

(b) *Flood insurance obligation.* The mortgagor and mortgagee shall be obligated, by a special condition to be included in the mortgage commitment, to obtain and maintain either NFIP flood insurance or private flood insurance coverage on the property improvements.

(c) *Insurance policy.* A mortgagee may accept a flood insurance policy in the form of the standard policy issued under the NFIP or a private flood insurance policy as defined in this section, and the mortgagee shall be named as the loss payee for flood insurance benefits. A mortgagee may determine that a private flood insurance policy meets the definition of private flood insurance in this section, without further review of the policy, if the following statement is included within the policy or as an endorsement to the policy: ''This policy meets the definition of private flood insurance contained in 24 CFR 203.16a(e) for FHA-insured mortgages.''

(d) *Duration and amount of coverage.* The flood insurance must be maintained during such time as the mortgage is insured in an amount at least equal to the lowest of the following:

(1) 100 percent replacement cost of the insurable value of the improvements, which consists of the development or project cost less estimated land cost; or

(2) The maximum amount of NFIP insurance available with respect to the particular type of property; or

(3) The outstanding principal balance of the loan.

(e) *Private flood insurance defined.* The term ''private flood insurance'' means an insurance policy that:

(1) Is issued by an insurance company that is:

(i) Licensed, admitted, or otherwise approved to engage in the business of insurance in the State or jurisdiction in which the insured building is located, by the insurance regulator of that State or jurisdiction; or

(ii) In the case of a policy of difference in conditions, multiple peril, all risk, or other blanket coverage insuring nonresidential commercial property, is recognized, or not disapproved, as a surplus lines insurer by the insurance regulator of the State or jurisdiction where the property to be insured is located;

(2) Provides flood insurance coverage that is at least as broad as the coverage provided under a standard flood insurance policy under the National Flood Insurance Program for the same type of property, including when considering deductibles, exclusions, and conditions offered by the insurer. To be at least as broad as the coverage provided under a standard flood insurance policy under the National Flood Insurance Program, the policy must, at a minimum:

(i) Define the term ''flood'' to include the events defined as a ''flood'' in a standard flood insurance policy under the National Flood Insurance Program;

(ii) Contain the coverage specified in a standard flood insurance policy under the National Flood Insurance Program, including that relating to building property coverage; personal property coverage, if purchased by the insured mortgagor(s); other coverages; and increased cost of compliance coverage;

(iii) Contain deductibles no higher than the specified maximum, and include similar non-applicability provisions, as under a standard flood insurance policy under the National Flood Insurance Program, for any total policy coverage amount up to the maximum available under the NFIP at the time the policy is provided to the lender;

(iv) Provide coverage for direct physical loss caused by a flood and may only exclude other causes of loss that are excluded in a standard flood insurance policy under the National Flood Insurance Program. Any exclusions other than those in a standard flood insurance policy under the National Flood Insurance Program may pertain only to coverage that is in addition to the amount and type of coverage that could be provided by a standard flood insurance policy under the National Flood Insurance Program or have the effect of providing broader coverage to the policyholder; and

(v) Not contain conditions that narrow the coverage provided in a standard flood insurance policy under the National Flood Insurance Program;

(3) Includes all of the following:

(i) A requirement for the insurer to give 45 days' written notice of cancellation or non-renewal of flood insurance coverage to:

(A) The insured;

(B) The mortgagee, if any; and

(C) Federal Housing Administration (FHA), in cases where the mortgagee has assigned the loan to FHA in exchange for claim payment;

(ii) Information about the availability of flood insurance coverage under the National Flood Insurance Program;

(iii) A mortgage interest clause similar to the clause contained in a standard flood insurance policy under the National Flood Insurance Program; and

(iv) A provision requiring an insured to file suit not later than 1 year after the date of a written denial of all or part of a claim under the policy; and

(4) Contains cancellation provisions that are as restrictive as the provisions contained in a standard flood insurance policy under the National Flood Insurance Program.

■ 5. In § 203.343, revise paragraph (b)(3) to read as follows:

§ 203.343 Partial release, addition or substitution of security.

* * * * *

(b) * * *

(3) The property to which the dwelling is removed is in an area known to be reasonably free from natural hazards or, if in a flood zone, the mortgagor will insure or reinsure under the National Flood Insurance Program or obtain equivalent private flood insurance coverage as defined in § 203.16a.

* * * * *

PART 206—HOME EQUITY CONVERSION MORTGAGE INSURANCE

■ 6. The authority citation for part 206 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715z–20; 42 U.S.C. 3535(d).

■ 7. In § 206.45, revise paragraph (c) to read as follows:

§ 206.45 Eligible properties.

* * * * *

(c) *Borrower and mortgagee requirement for maintaining flood insurance coverage*—(1) *In general.* (i) The requirements of this paragraph (c) apply if a mortgage is to cover property improvements that:

(A) Are located in an area designated by the Federal Emergency Management Agency (FEMA) as a floodplain area having special flood hazards;

(B) Are otherwise determined by the Commissioner to be subject to a flood hazard; or

(C) Are not otherwise covered by the flood insurance standard for condominium projects established under 24 CFR 203.43b(d)(6)(iii) or (i)(1).

(ii) No mortgage may be insured that covers property improvements located in an area that has been identified by FEMA as an area having special flood hazards, unless the community in which the area is situated is participating in the National Flood Insurance Program (NFIP) and flood insurance is obtained by the borrower. Such flood insurance shall be in the form of the standard policy issued under the NFIP or private flood insurance as defined in paragraph (c)(6) of this section. Such requirement for flood insurance shall be effective one year after the date of notification by FEMA to the chief executive officer of a flood prone community that such community has been identified as having special flood hazards.

(iii) For purposes of this section, property improvement means a dwelling and related structures/equipment essential to the value of the property and subject to flood damage.

(2) *Flood insurance obligation.* During such time as the mortgage is insured, the borrower and mortgagee shall be obligated, by a special condition to be included in the mortgage commitment, to obtain and to maintain flood insurance coverage under either the NFIP or equivalent private flood insurance coverage as defined in paragraph (c)(6) of this section on the property improvements. The mortgagee shall be named as the loss payee for flood insurance benefits. A mortgagee may determine that a private flood insurance policy meets the definition of private flood insurance in this section, without further review of the policy, if the compliance aid statement provided in 24 CFR 203.16a(c) is included within the policy or as an endorsement to the policy.

(3) *Duration and amount of coverage.* The flood insurance must be maintained during such time as the mortgage is insured in an amount at least equal to the lowest of the following:

(i) 100 percent replacement cost of the insurable value of the improvements, which consists of the development or project cost less estimated land cost; or

(ii) The maximum amount of the NFIP insurance available with respect to the particular type of the property; or

(iii) The outstanding principal balance of the loan.

(4) *Private flood insurance defined.* The term ''private flood insurance'' means an insurance policy that:

(i) Is issued by an insurance company that is:

(A) Licensed, admitted, or otherwise approved to engage in the business of insurance in the State or jurisdiction in which the insured building is located, by the insurance regulator of that State or jurisdiction; or

(B) In the case of a policy of difference in conditions, multiple peril, all risk, or other blanket coverage insuring nonresidential commercial property, is recognized, or not disapproved, as a surplus lines insurer by the insurance regulator of the State or jurisdiction where the property to be insured is located;

(ii) Provides flood insurance coverage that is at least as broad as the coverage provided under a standard flood insurance policy under the National Flood Insurance Program for the same type of property, including when considering deductibles, exclusions, and conditions offered by the insurer. To be at least as broad as the coverage provided under a standard flood insurance policy under the National Flood Insurance Program, the policy must, at a minimum:

(A) Define the term ''flood'' to include the events defined as a ''flood'' in a standard flood insurance policy under the National Flood Insurance Program;

(B) Contain the coverage specified in a standard flood insurance policy under the National Flood Insurance Program, including that relating to building property coverage; personal property coverage, if purchased by the insured mortgagor(s); other coverages; and increased cost of compliance coverage;

(C) Contain deductibles no higher than the specified maximum, and include similar non-applicability provisions, as under a standard flood insurance policy under the National Flood Insurance Program, for any total policy coverage amount up to the maximum available under the NFIP at the time the policy is provided to the lender;

(D) Provide coverage for direct physical loss caused by a flood and may only exclude other causes of loss that are excluded in a standard flood insurance policy under the National Flood Insurance Program. Any exclusions other than those in a standard flood insurance policy under the National Flood Insurance Program may pertain only to coverage that is in addition to the amount and type of coverage that could be provided by a standard flood insurance policy under the National Flood Insurance Program or have the effect of providing broader coverage to the policyholder; and

(E) Not contain conditions that narrow the coverage provided in a standard flood insurance policy under the National Flood Insurance Program;

(iii) Includes all of the following:

(A) A requirement for the insurer to give 45 days' written notice of cancellation or non-renewal of flood insurance coverage to:

(*1*) The insured;

(*2*) The mortgagee, if any; and

(*3*) Federal Housing Administration (FHA), in cases where the mortgagee has assigned the loan to FHA in exchange for claim payment;

(B) Information about the availability of flood insurance coverage under the National Flood Insurance Program;

(C) A mortgage interest clause similar to the clause contained in a standard flood insurance policy under the National Flood Insurance Program; and

(D) A provision requiring an insured to file suit not later than 1 year after the date of a written denial of all or part of a claim under the policy; and

(iv) Contains cancellation provisions that are as restrictive as the provisions contained in a standard flood insurance policy under the National Flood Insurance Program.

* * * * *

§ 206.134 [Amended]

■ 8. In § 206.134, amend paragraph (b)(3) by adding the phrase ''or obtain equivalent private flood insurance coverage, as defined in § 203.16a of this chapter'' after ''National Flood Insurance Program''.

Julia R. Gordon,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 2022–25258 Filed 11–18–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0938]

Special Local Regulations; Marine Events Within the Captain of the Port Charleston

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation to provide for the safety and security of certain

navigable waterways of Charleston Harbor during the Charleston Parade of Boats. Our regulation for marine events within the Captain of the Port Charleston identifies the regulated area for this event in the Charleston Harbor, SC. During the enforcement periods, no person or vessel may enter, transit through, anchor in, or remain within the designated area unless authorized by the Captain of the Port Charleston (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.704 will be enforced for the location identified in Item 10 of Table 1 to § 100.704 from 4 p.m. until 8 p.m. on December 10, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT. James Sullivan, Sector Charleston Waterways Management Division, U.S. Coast Guard; telephone (843) 740–3184, email *James.P.Sullivan2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the special local regulation in 33 CFR 100.704, Table 1 to § 100.704, Item 10, for the Charleston Parade of Boats from 4 p.m. until 8 p.m. on December 10, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Captain of the Port Charleston, § 100.704, specifies the location of the regulated area for the Charleston Parade of Boats which encompasses portions of the Charleston Harbor including Anchorage A, Shutes Folly, Bennis Reach, Horse Reach, Hog Island Reach, Town Creek Lower Reach, and Ashley River. During the enforcement periods, as reflected in § 100.100(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any official patrol vessel.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: November 15, 2022.

J.D. Cole,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2022–25283 Filed 11–18–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 801, 802, 808, 816, 835, and 852

RIN 2900–AQ23

VA Acquisition Regulation: Department of Veterans Affairs Acquisition Regulation System and Research and Development

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing a final rule amending the VA Acquisition Regulation (VAAR). This rulemaking revises VAAR coverage concerning Department of Veterans Affairs Acquisition Regulation System and Research and Development. It also revises affected parts concerning Definitions of Words and Terms, Required Sources of Supplies and Services, Types of Contracts and Solicitation Provisions and Contract Clauses.

DATES: Effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Glacia A. Holbert, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 810 Vermont Avenue NW, Washington, DC 20420, (202) 697–3614. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

VA published a proposed rule in the **Federal Register** at 87 FR 10158 on February 23, 2022, to amend the VAAR to implement and supplement the FAR. VA provided a 60-day comment period for the public to respond to the proposed rule and submit comments. The public comment period closed on April 25, 2022. VA received two comments from one respondent.

This rulemaking is issued under the authority of the Office of Federal Procurement Policy (OFPP) Act which provides the authority for an agency head to issue agency acquisition regulations that implement or supplement the FAR.

The VAAR has been revised to add new policy or regulatory requirements, to update existing policy, and to remove any redundant guidance where it may exist in affected parts, and to place guidance that is applicable only to VA's internal operating processes or procedures in the VAAM.

This rule adopts as a final rule the proposed rule published in the **Federal Register** on February 23, 2022, except for one technical non-substantive change to update terminology in accordance with FAR final rules as shown below.

Discussion and Analysis of Public Comments

The respondent alleged that the proposed rule could ''. . .unlawfully Amend U.S. Code to facilitate illegal land use at the WLA VA Soldiers Home.'' This issue has no relevance to the proposed rule. The respondent also expressed dismay that Department did not extend the ''Public a Comment Period on the WLA VA Soldiers Home's ''Master Plan'' and ''Community Plan.'' This comment did not have any application to AQ23 which deals with the Department of Veterans Affairs Acquisition Regulation System and Research and Development. VA appreciates the respondent's interest in the rule but the two comments do not pertain to the content of the regulation. Therefore, VA is taking no action to revise the rule based on these comments.

VA proposes to make the following changes to the VAAR in this phase of its revision and streamlining initiative. For procedural guidance cited below that is proposed to be deleted from the VAAR, each section cited for removal has been considered for inclusion in VA's internal agency operating procedures in accordance with FAR 1.301(a)(2). Similarly, delegations of authority that are removed from the VAAR will be included in the VAAM as internal agency guidance. The VAAM is being created in parallel with these revisions to the VAAR and is not subject to the rulemaking process as they are internal VA procedures and guidance. The VAAM will not be finalized until corresponding VAAR parts are finalized.

Technical Non-Substantive Changes to the Rule

This rule makes one non-substantive change to the rule to provide clarity, eliminate confusion, and to ensure compliance with the Federal Acquisition Regulation (FAR). Specifically, VA is revising the section covering the ratification of unauthorized commitments to clarify the delegation authority level for unauthorized commitments below $25,000.

VA is revising the final rule at 801.602–3 as reflected in the amendatory text as follows:

''801.602–3, Ratification of unauthorized commitments.

(a) This section applies to unauthorized commitments, including any commitment made by a contracting officer that exceeds that contracting

officer's contracting authority and unauthorized commitments made by a Government representative who lacked the authority to enter into that agreement on behalf of the Government.

(b) The approving authority and ratification official for unauthorized commitments is the HCA. This authority may be delegated to the chief of the contracting office or the equivalent for unauthorized commitments below $25,000.''

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this final rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

This rulemaking does not change VA's policy regarding small businesses and does not have a significant economic impact to individual businesses. The overall impact of the proposed rule would be of benefit to small businesses owned by Veterans or service-disabled Veterans as the VAAR is being updated to remove outdated guidance and to clarify and simplify the acquisition regulations VA's contractors must comply with. VA estimates no substantial cost impact to individual businesses will result from these rule updates. In total, this rulemaking does not change VA's policy regarding small businesses, does not have a substantial economic impact to individual businesses, and does not significantly increase or decrease costs small business were already required to bear when performing contracts.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal Governments or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects

48 CFR Part 801

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements.

48 CFR Parts 802, 808, and 816

Government procurement.

48 CFR Part 835

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 27, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 48 CFR chapter 8 as follows:

■ 1. Part 801 is revised to read as follows:

PART 801—DEPARTMENT OF VETERANS AFFAIRS ACQUISITION REGULATION SYSTEM

Sec.
801.000 Scope of part.

Subpart 801.1—Purpose, Authority, Issuance

801.101 Purpose.
801.103 Authority.
801.104 Applicability.
801.104–70 Exclusions.
801.106 OMB approval under the Paperwork Reduction Act.

Subpart 801.3—Agency Acquisition Regulations

801.301 Policy.
801.304 Agency control and compliance procedures.

Subpart 801.4—Deviations from the FAR

801.403 Individual deviations.
801.404 Class deviations.

Subpart 801.6—Career Development, Contracting Authority, and Responsibilities

801.601 General.
801.602–3 Ratification of unauthorized commitments.
801.604 Contracting Officer's Representative (COR).

Authority: 38 U.S.C. 8123; 38 U.S.C. 8153; 38 U.S.C. 8303; 40 U.S.C. 121(c); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

801.000 Scope of part.

This part includes general Department of Veterans Affairs (VA) Acquisition Regulation (VAAR) policies, including information regarding the maintenance and administration of the VAAR, acquisition policies and practices, and procedures for deviation from the VAAR and the Federal Acquisition Regulation (FAR).

Subpart 801.1—Purpose, Authority, Issuance

801.101 Purpose.

(a) VA established the VAAR to codify and publish uniform policies and procedures for VA's acquisition of supplies and services, including construction.

(b) The VAAR implements and supplements the FAR.

801.103 Authority.

The VA issues the VAAR under the authority of 41 U.S.C. 1707 and 48 CFR 1.301 through 1.304, and other authorities as cited.

801.104 Applicability.

The FAR and the VAAR apply to all FAR-based VA actions using appropriated funds unless otherwise

specified in this regulation. Supply Fund monies (38 U.S.C. 8121) and General Post Funds (38 U.S.C. 8302) are appropriated funds.

801.104–70 Exclusions.

(a) *Restricted gifts.* The FAR and VAAR do not apply to purchases and contracts that use General Post Funds if using the FAR and the VAAR would infringe upon a donor's right to specify the exact item to be purchased and/or the source of supply (38 U.S.C. 8303).

(b) *Procurement of prosthetic appliances.* The VA may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the VA may determine to be proper, without regard to any other provision of law (38 U.S.C. 8123).

(c) *Sharing of health-care resources.* (1) To secure health-care resources which otherwise might not be feasibly available, or to effectively utilize certain other health-care resources, the VA may, when the VA determines it to be in the best interest of the prevailing standards of the Department medical care program, make arrangements, by contract or other form of agreement for the mutual use, or exchange of use, of health-care resources between Department health-care facilities and any health-care provider, or other entity or individual.

(2) The VA may enter into a contract or other agreement under paragraph (c)(1) of this section if such resources are not, or would not be, used to their maximum effective capacity.

(3)(i) If the health-care resource required is a commercial service, the use of medical equipment or space, or research, and is to be acquired from an institution affiliated with the Department in accordance with 38 U.S.C. 7302, including medical practice groups and other entities associated with affiliated institutions, blood banks, organ banks, or research centers, the VA may make arrangements for acquisition of the resource without regard to any law or regulation (including any Executive order, circular, or other administrative policy) that would otherwise require the use of competitive procedures for acquiring the resource.

(ii) If the health-care resource required is a commercial service or the use of medical equipment or space, and is not to be acquired from an entity described in paragraph (c)(3)(i) of this section, any procurement of the resource may be conducted without regard to any law or regulation that would otherwise require the use of competitive procedures for procuring the resource, but only if the procurement is conducted in accordance with the simplified procedures prescribed in part 873. (38 U.S.C. 8153).

801.106 OMB approval under the Paperwork Reduction Act.

See VA Acquisition Manual (VAAM) M801.106 for a list of the information collection and recordkeeping requirements contained in this part that have been approved by the Office of Management and Budget.

Subpart 801.3—Agency Acquisition Regulations

801.301 Policy.

(a)(1) VA implementation and supplementation of the FAR is issued in the Veterans Affairs Acquisition Regulation (VAAR) under authorization and subject to the authority, direction, and control of the Secretary of Veterans Affairs. The VAAR contains—

(i) Requirements of law;

(ii) Agency policies;

(iii) Delegations of FAR authorities;

(iv) Deviations from FAR requirements; and

(v) Policies/procedures that have a significant effect beyond the internal operating procedures of VA or a significant cost or administrative impact on contractors or offerors.

(2) Relevant internal procedures, guidance, and information (PGI) that do not meet the criteria in paragraph (a)(1) of this section are issued in the Veterans Affairs Acquisition Manual (VAAM).

(b) [Reserved]

801.304 Agency control and compliance procedures.

The Principal Executive Director of VA's Office of Acquisition, Logistics and Construction is designated as the Department's Chief Acquisition Officer. The Executive Director for the Office of Acquisition and Logistics (OAL) is designated as the Department's Senior Procurement Executive (SPE). The SPE is responsible for amending the VAAR for compliance with FAR 1.304.

Subpart 801.4—Deviations From the FAR

801.403 Individual deviations.

The SPE may authorize individual deviations from the FAR and VAAR in accordance with FAR 1.403 when an individual deviation is in the best interest of the Government.

801.404 Class deviations.

The SPE may authorize class deviations from the FAR and VAAR when a class deviation is in the best interest of the Government.

Subpart 801.6—Career Development, Contracting Authority, and Responsibilities

801.601 General.

(a) The Senior Procurement Executive is granted the authority to appoint and terminate contracting officers. This authority is further delegated to the heads of the contracting activities (HCA) and others as appropriate. The SPE may also delegate authority to execute, award, and administer contracts, purchase orders, and other agreements to other VA officials, such as HCAs and contracting officers. All delegations of authority will be made in writing.

(b) HCAs may authorize the use of ordering officers to order supplies and services in accordance with the ordering limits identified in the contract or agreement or the specific ordering guide. Ordering officers shall be delegated in writing. The written delegation must be specific to the contract or agreement and articulate the limitations of the delegated authority. Ordering officers shall only place orders against the contract or agreement if it is awarded to a single awardee. Ordering officers may not negotiate contract terms and conditions, determine price reasonableness, or determine best value. If the contracting officer determines prior to award that ordering officers will be authorized to place orders against a contract or agreement, the contracting officer will furnish the contractor with the names of individuals delegated ordering officer authority by separate letter upon issuance of the contract.

801.602–3 Ratification of unauthorized commitments.

(a) This section applies to unauthorized commitments, including any commitment made by a contracting officer that exceeds that contracting officer's contracting authority and unauthorized commitments made by a Government representative who lacked the authority to enter into that agreement on behalf of the Government.

(b) The approving authority and ratification official for unauthorized commitments is the HCA. This authority may be delegated to the chief of the contracting office or the equivalent for unauthorized commitments below $25,000.

801.604 Contracting Officer's Representative (COR).

When the contracting officer intends to designate a Contracting Officer's Representative for a solicitation or contract, the contracting officer must

include the clause in 852. 201–70, Contracting Officer's Representative, in the solicitation and contract.

PART 802—DEFINITIONS OF WORDS AND TERMS

■ 2. The authority citation for part 802 continues to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301–1.304.

Subpart 802.1—Definitions

■ 3. Section 802.101 is amended by adding the definition ''Ordering officer'' in alphabetical order to read as follows:

802.101 Definitions.

* * * * *

Ordering officer means the VA official authorized to order supplies and services against a FAR-based contract or agreement in accordance with the ordering limits identified in the contract or agreement or the specific ordering guide in accordance with 801.601(b).

* * * * *

PART 808—REQUIRED SOURCES OF SUPPLIES AND SERVICES

■ 4. The authority citation for part 808 continues to read as follows:

Authority: 38 U.S.C. 8127–8128; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 808.4—Federal Supply Schedules

■ 5. Add section 808.470 to read as follows:

808.470 Ordering Officers.

In accordance with 801.601, when authorized, ordering officers may place orders for supplies and services against agreements or task or delivery orders established by a contracting officer against Federal Supply Schedules within the ordering limits identified in the contract or agreement or the specific ordering guide when funding is available. Ordering officers shall only place orders against the order or agreement if it is awarded to a single awardee. The contracting officer that awarded the Blanket Purchase Agreements (BPA) or order will provide the contractor a list of authorized ordering officers. Any modifications to the agreement or order must be performed by a contracting officer.

PART 816—TYPES OF CONTRACTS

■ 6. The authority citation for part 816 continues to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 816.5—Indefinite-Delivery Contracts

■ 7. Add section 816.570 to read as follows:

816.570 Ordering officers.

In accordance with 801.601, when authorized, ordering officers may place orders for supplies and services against established Indefinite-Delivery Contracts within the ordering limits identified in the contract or the specific ordering guide when funding is available. Ordering officers shall only place orders against the contract if it is awarded to a single awardee. When a contracting officer appoints an ordering officer in writing after award, the contracting officer will furnish the contractor with an updated list of individual ordering officers authorized to place orders against the contract. Ordering officers may not negotiate contract terms and conditions, determine price reasonableness, or determine best value.

■ 8. Part 835 is added to subchapter F to read as follows:

PART 835—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.

835.001–70 Veterans Affairs (VA) definitions.
835.003–70 VA policy.
835.003–71 Research misconduct.
835.003–72 Protection of human subjects.
835.003–73 Animal welfare.
835.003–74 Facilities.
835.003–75 Acknowledgement of support and disclaimer.
835.010 Scientific and technical reports.

Authority: 38 U.S.C. 7303; 40 U.S.C. 121(c); 41 U.S.C. 1702 and 48 CFR 1.301 through 1.304.

835.001–70 Veterans Affairs (VA) definitions.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Research impropriety refers to noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of the Office of Research Oversight (ORO) (*e.g.,* waste, fraud, abuse, or fiscal mismanagement).

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

VA facility means a component of the VA national health care system, such as a VA Medical Center, VA Health Care System, or VA Medical and Regional Office Center.

835.003–70 VA policy.

(a) Pursuant to 38 U.S.C. 7303, VA is authorized to carry out a program of medical research in connection with the provisions of medical care and treatment to Veterans.

(b) The Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office that advises the Under Secretary for Health on all compliance matters related to—

(1) Human subject protections;
(2) Laboratory animal welfare;
(3) Research safety;
(4) Research laboratory security;
(5) Research information security;
(6) Research misconduct; and
(7) Other research improprieties.

835.003–71 Research misconduct.

The contracting officer shall insert the clause at 852.235–70, Research Misconduct, in all research and development (R&D) solicitations and contracts.

835.003–72 Protection of human subjects.

The contracting officer shall insert the clause at 852.235–71, Protection of Human Subjects, in all research and development (R&D) solicitations and contracts.

835.003–73 Animal welfare.

The contracting officer shall insert the clause at 852.235–72, Animal Welfare, in all research and development (R&D) solicitations and contracts.

835.003–74 Facilities.

If the contracting officer determines that the facilities to be assigned to perform effort on a research and development (R&D) contract are critical to the success of the R&D effort, the contracting officer shall insert the clause at 852.235–73, Facilities, in the solicitation and contract.

835.003–75 Acknowledgement of support and disclaimer.

The contracting officer shall insert the clause at 852.235–74, Acknowledgement of Support and Disclaimer, in all research and development (R&D) solicitations and contracts.

835.010 Scientific and technical reports.

The contracting officer shall insert the clause at 852.235–75, Scientific and Technical Reports, in all research and development (R&D) solicitations and contracts.

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 9. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 8127–8128, and 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3), 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

■ 10. Section 852.235–70 is added to read as follows:

852.235–70 Research Misconduct.

As prescribed at 835.003–71, insert the following clause:

Research Misconduct (DEC 2022)

(a) The Contractor is responsible for maintaining the integrity of research performed pursuant to this contract award including the prevention, detection and remediation of research misconduct as defined in 835.001–70.

(b) The Contractor shall notify the Contracting Officer within 7 business days of any research misconduct allegations received by the facility concerning this contract award.

(c) The Contractor shall conduct an initial inquiry into any allegation of research misconduct. If the Contractor determines that there is sufficient evidence to proceed to an investigation, the Contractor shall notify the Contracting Officer and, unless otherwise instructed shall—

(1) Conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an identification of appropriate remedies, or a recommendation that no further action is warranted;

(2) When the investigation results in a research misconduct finding, ensure the matter is adjudicated by a responsible official who was not involved in the inquiry or investigation and is organizationally separated from the element which conducted the investigation. The adjudication shall include a review of the investigation record and a recommendation of appropriate corrective actions and sanctions; and

(3) When an investigation is complete, the Contractor shall forward to the Contracting Officer a copy of the evidentiary record, the investigative report, any recommendations made to the Contractor's adjudicating official, the adjudicating official's recommendation and notification of any proposed corrective action, and the subject's written response, if any. The Contracting Officer will review the documentation to determine whether the proposed corrective action can proceed.

(d) The VA may elect to act in lieu of the Contractor in conducting an inquiry or investigation into an allegation of research misconduct if the Contracting Officer finds that—

(1) The research organization is not prepared to handle the allegation in a manner consistent with this clause and it is believed it cannot reasonably conduct the inquiry;

(2) VA involvement is necessary to ensure the public health, safety, and security, or to prevent harm to the public interest; or

(3) The allegation involves possible criminal misconduct.

(e) The Contractor shall provide safeguards for information received and protect informants, witnesses and respondents of allegations as follows:

(1) The Contractor shall provide safeguards to ensure that individuals may bring allegations of research misconduct made in good faith to the attention of the Contractor without suffering retribution. Safeguards include: protection against retaliation; fair and objective procedures for examining and resolving allegations; and diligence in protecting positions and reputations.

(2) The Contractor shall also assure the respondent that their rights are protected and that the mere filing of an allegation of research misconduct will not result in an adverse action. Safeguards include timely written notice regarding substantive allegations against them, a description of the allegations and reasonable access to any evidence submitted to support each allegation. Respondents must be given the opportunity to prepare a response to an allegation and notice of any findings of research misconduct.

(f) *Objectivity and expertise.* The Contractor shall select individual(s) to inquire, investigate, and adjudicate allegations of research misconduct who have appropriate expertise and have no unresolved conflict of interest. The individual(s) who conducts the adjudication must not be the same individual(s) who conducted the inquiry or investigation and must be separate organizationally from the element that conducted the inquiry or investigation.

(End of clause)

■ 11. Section 852.235–71 is added to read as follows:

852.235–71 Protection of Human Subjects.

As prescribed at 835.003–72, insert the following clause:

Protection of Human Subjects (DEC 2022)

(a) Research involving human subjects is not permitted under this award unless expressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(b) The Federal Policy for the Protection of Human Subjects (the ''Common Rule''), adopted by VA (see 38 CFR part 16), requires Contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a ''human subject'' as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term ''research'' means a systematic investigation, including research development and/or testing and evaluation, designed to develop or contribute to generalized knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR part 27. These categories may be found at 15 CFR 27.101.

(c) Should research involving human subjects be included in the proposal, prior to issuance of an award, the Contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that the Contractor has established a relationship with an appropriate Institutional Review Board (''cognizant IRB''). An appropriate IRB is one that is located within the United States and within the community in which the research will be conducted;

(2) Documentation to verify that the cognizant IRB possesses a valid registration with the United States Department of Health and Human Services' Office for Human Research Protections (''OHRP'');

(3) Documentation to verify that the Contractor has a valid Federal-wide Assurance (FWA) issued by OHRP.

(d) Prior to starting any research involving human subjects, the Contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval. This documentation may include:

(1) Copies of the research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule (Note: this option is not available for activities that fall under 45 CFR part 46, subpart C).

(e) Additionally, if the Contractor modifies a research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the Contractor shall submit a copy of all modified material along with documentation of approval for said modification by the cognizant IRB to the Contracting Officer for institutional review and approval. The Contractor shall not implement any IRB approved modification without written approval by the Contracting Officer.

(f) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(g) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agency or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(h) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements, the Contracting Officer may immediately suspend the research and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete the corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract and the Contractor's name may be removed from the list of those Contractors with approved Department of Health and Human Services Human Subject Assurances.

(End of clause)

■ 12. Section 852.235–72 is added to read as follows:

852.235–72 Animal Welfare.

As prescribed in 835.003–73, insert the following clause:

Animal Welfare (DEC 2022)

(a) The Contractor shall—

(1) Use the Veterans Affairs (VA), Office of Research Oversight (ORO) Laboratory Animal Welfare Checklist;

(2) Comply with the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations at *https://www.aphis.usda.gov/animal_welfare,* and the Animal Welfare Information Center's (AWIC) information for improved animal care and use in research, testing, and teaching provided at *https://www.nal.usda.gov/awic;*

(3) Develop and provide to the Contracting Officer a written plan of providing adequate veterinary care to laboratory animals, including—

(i) The frequency of visits; and

(ii) Provisions for after-hours, weekend and holiday veterinary coverage.

(b) The Contracting Officer may immediately suspend the work by issuance of a stop work order and suspend further payments under this contract for failure to comply with the requirements of this clause.

(c) The suspension will stay in effect until the Contractor complies with the requirements. Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract.

(d) The Contractor shall include the substance of this clause, in all subcontracts involving research and development, testing, evaluation or training that use live vertebrate animals.

(End of clause)

■ 13. Section 852.235–73 is added to read as follows:

852.235–73 Facilities.

As prescribed at 835.003–74, insert the following clause:

Facilities (DEC 2022)

(a) The facilities specified in the contract are considered essential to the work being performed under this contract. Therefore, prior to removing, replacing, or diverting any of the listed or specified facilities, the Contractor shall—

(1) Notify the Contracting Officer in writing; and

(2) Submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the potential impact on this contract.

(b) The Contractor shall make no removal, replacement or diversion of facilities without the Contracting Officer's written consent.

(End of clause)

■ 14. Section 852.235–74 is added to read as follows:

852.235–74 Acknowledgement of Support and Disclaimer.

As prescribed at 835.003–75, insert the following clause:

Acknowledgement of Support and Disclaimer (DEC 2022)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the (name of contracting agency) under this VA contract.

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer:

Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the VA.

(End of clause)

■ 15. Section 852.235–75 is added to read as follows:

852.235–75 Scientific and Technical Reports.

As prescribed at 835.010, insert the following clause:

Scientific and Technical Reports (DEC 2022)

The Contractor shall submit an electronic copy of the approved scientific technical reports, not a summary, delivered under this contract

to the National Technical Information Service (NTIS) as delineated at FAR 35.010.

(End of clause)

852.270–1 [Redesignated]

■ 16. Redesignate Section 852.270–1 as section 852.201–70 and revise newly redesignated section 852.201–70 to read as follows:

852.201–70 Contracting Officer's Representative.

As prescribed in 801.604, insert the following provision:

Contracting Officer's Representative (DEC 2022)

The Contracting Officer reserves the right to designate representatives to act for him/her in furnishing technical guidance and advice or generally monitor the work to be performed under this contract. Such designation will be in writing and will define the scope and limitation of the designee's authority. A copy of the designation letter shall be furnished to the Contractor.

(End of provision)

[FR Doc. 2022–23961 Filed 11–18–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 221115–0240]

RTID 0648–XC516

Atlantic Surfclam and Ocean Quahog Fisheries; 2023 Fishing Quotas for Atlantic Surfclams and Ocean Quahogs; and Suspension of Atlantic Surfclam Minimum Size Limit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces that the quotas for the Atlantic surfclam and ocean quahog fisheries for 2023 will remain status quo. NMFS also suspends the minimum size limit for Atlantic surfclams for the 2023 fishing year. Regulations for these fisheries require NMFS to notify the public of the allowable harvest levels for Atlantic surfclams and ocean quahogs from the Exclusive Economic Zone even if the previous year's quota specifications remain unchanged. The 2023 quotas were previously announced as projected values. This action confirms the final quotas are unchanged from those projections. This action would not result in harm to these fisheries.

DATES: Effective January 1, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978–281–9341.

SUPPLEMENTARY INFORMATION: The Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP) requires that NMFS issue notice in the **Federal Register** of the upcoming year's quota, even if the quota remains unchanged from the previous year. At its June 2022 meeting, the Mid-Atlantic Fishery Management Council recommended no change to the quota specifications for Atlantic surfclams and ocean quahogs for the 2023 fishing year. We are announcing 2023 quota levels of 3.4 million bushels (bu) (181 million L) for Atlantic surfclams, 5.36 million bu (288 million L) for ocean quahogs, and 100,000 Maine bu (3.52 million L) for Maine ocean quahogs. These quotas were published as projected 2023 limits in the **Federal Register** on May 13, 2021 (86 FR 26186). This rule establishes these quotas as unchanged from 2021 and final.

The regulations at 50 CFR 648.75(b)(3) allow the Regional Administrator to annually suspend the minimum size limit for Atlantic surfclams unless discard, catch, and biological sampling data indicate that 30 percent or more of the Atlantic surfclams have a shell length less than 4.75 inches (in) (121 millimeters (mm)) and the overall reduced size is not attributable to harvest from beds where growth of the individual clams has been reduced because of density-dependent factors. The default minimum size limit is intended to prevent the fishery from harvesting too many small clams that it could harm the overall population. The size limit is unnecessary if small clams are not a significant portion of overall catch. At its June 2022 meeting, the Council reviewed recent developments in the fishery and recommended the Regional Administrator once again suspend the minimum size limit for Atlantic surfclams for the 2023 fishing year. Commercial surfclam data for 2022 indicated that 27.6 percent of the overall commercial landings were composed of surfclams that were less than the 4.75-in (121-mm) default minimum size.

Based on the information available, the Regional Administrator concurs with the Council's recommendation and is suspending the minimum size limit for Atlantic surfclams for the upcoming fishing year (January 1 through December 31, 2023).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator for Fisheries, NOAA, has determined that this rule is consistent with the Atlantic Surfclam and Ocean Quahog FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This action does not introduce any new reporting, recordkeeping, or other compliance requirements. This rule does not duplicate, overlap, or conflict with other Federal rules.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be unnecessary and contrary to the public interest. This rule is routine and formulaic. The public was given the opportunity to comment on the proposed rule for the 2021–2026 specifications (86 FR 9901, February 17, 2021), including the projected 2023 specifications, which remain unchanged. Delaying this action would prolong public uncertainty about the final quotas for the 2023 fishing year, and could delay issuance of 2023 ITQ cage tags to quota shareholders. The public and industry participants expect this action because we previously alerted the public that we would conduct this review in interim years of the multi-year specifications and announce the final quotas before or as close as possible to the January 1 start of the fishing year. This rule could not be published earlier because of the time necessary to collect data and conduct the analysis to support suspending the minimum size limit for Atlantic surfclams.

This rule is exempt from the requirements of Executive Order 12866.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable. Accordingly, no Regulatory Flexibility Analysis is required and none has been prepared.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–25295 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 223
Monday, November 21, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA–2022–F–2725]

Cargill, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Cargill, Inc., proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide (CAS Reg. No. 7722–84–1) as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide.

DATES: The food additive petition was filed on August 30, 2022. Either electronic or written comments on the petitioner's environmental assessment must be submitted by December 21, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–F–2725 for ''Cargill, Inc.; Filing of Food Additive Petition.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Karen Hall, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9195.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 2A4833), submitted by Cargill, Inc., 15407 McGinty Rd., Wayzata, MN 55391. The petition proposes to amend the food additive regulations in § 173.356 (21 CFR 173.356) *Hydrogen peroxide,* to provide for the safe use of hydrogen peroxide (CAS Reg. No. 7722–84–1) as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide.

We are reviewing the potential environmental impact of this petition. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), we are placing the

environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Staff (see **DATES** and **ADDRESSES**) for public review and comment.

We will also place on public display, at the Dockets Management Staff and at *https://www.regulations.gov,* any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on our review, we find that an environmental impact statement is not required, and this petition results in a regulation, we will publish the notice of availability of our finding of no significant impact and the evidence supporting that finding with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25310 Filed 11–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

[Application No. D–11799]

RIN 1210–ZA23

Prohibited Transaction Exemption (PTE) 2002–51 To Permit Certain Transactions Identified in the Voluntary Fiduciary Correction Program

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Proposed amendment to prohibited transaction exemption.

SUMMARY: This document gives notice of a proposed amendment to Prohibited Transaction Exemption 2002–51, an exemption for certain transactions identified in the Department's Voluntary Fiduciary Correction Program (VFC Program or VFCP). The VFC Program allows persons who may have engaged in a breach of fiduciary duty under the Employee Retirement Income Security Act (ERISA) to correct the breach and avoid certain Department of Labor-initiated civil actions and assessment of civil penalties. PTE 2002–51 (the VFCP Class Exemption) is a related class exemption that provides an exemption from excise taxes imposed by the Internal Revenue Code of 1986, as amended, for certain eligible transactions corrected pursuant to the VFC Program. This amendment to the VFCP Class Exemption is being proposed in connection with the Department's amendment and restatement of the VFC Program, published elsewhere in today's issue of the **Federal Register** (2022 Program Notice). If granted, the amendment to the VFCP Class Exemption would affect plans, participants and beneficiaries of such plans, and certain other persons engaging in such transactions.

DATES: Written comments on the proposed amendment must be received by the Department by January 20, 2023.

ADDRESSES: All written comments and requests for a hearing concerning the proposed amendment to the class exemption should be sent to the Office of Exemption Determinations through the Federal eRulemaking Portal and identified by Application No. D–11799:

Federal eRulemaking Portal: http://www.regulations.gov at Docket ID number: EBSA–2022–0024. Follow the instructions for submitting comments.

See **SUPPLEMENTARY INFORMATION** below for additional information regarding comments.

FOR FURTHER INFORMATION CONTACT: Susan Wilker, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone number (202) 693–8540 (this is not a toll-free number).

Customer Service Information: Individuals interested in obtaining information from the Department concerning ERISA and employee benefit plans may call the Employee Benefits Security Administration's Toll-Free Hotline, at 1–866–444–EBSA (3272) or visit the Department's website (*www.dol.gov/ebsa*).

SUPPLEMENTARY INFORMATION:

Comment Instructions

All comments and requests for a hearing must be received by the end of the comment period. Requests for a hearing must state the issues to be addressed and include a general description of the evidence to be presented at the hearing. Persons are encouraged to submit all comments electronically and not to submit paper copies. The comments and hearing requests may be available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue NW, Washington, DC 20210. Comments and hearing requests will also be available online at *http://www.regulations.gov,* at Docket ID number: EBSA–2022–0024 and *http://www.dol.gov/ebsa,* at no charge.

Warning: All comments received will be included in the public record without change and will be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential or other information whose disclosure is restricted by statute. If you submit a comment, EBSA recommends that you include your name and other contact information, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as Social Security number or unlisted phone number), or confidential business information that you do not want publicly disclosed. However, if EBSA cannot read your comment due to technical difficulties and cannot contact you for clarification, EBSA might not be able to consider your comment. Additionally, the *http://www.regulations.gov* website is an ''anonymous access'' system, which means EBSA will not know your identity or contact information unless you provide it.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or

the principles set forth in the Executive Order. Pursuant to the terms of the Executive Order, OMB has determined that this action is ''significant'' within the meaning of Section 3(f)(4) of the Executive Order. Accordingly, the Department has undertaken an assessment of the costs and benefits of the proposed amendment, and OMB has reviewed this regulatory action.[1]

Paperwork Reduction Act

The amendments to the VFC Program include a revision to its information collection provisions. Accordingly, the revisions have been submitted to OMB for review and approval under the Paperwork Reduction Act (PRA). Because this proposed amendment to the VFCP Class Exemption would be used when finalized in connection with the VFC Program, and for ease of public review, the burden of the Information Collection Request (ICR) in the VFC Program is combined with the burden of the information collection provisions of the exemption for purposes of accounting for burden under the PRA. These burden calculations can be viewed in the PRA analysis included in the 2022 Program Notice, Amendment and Restatement of Voluntary Fiduciary Correction Program, published elsewhere in today's **Federal Register**.

Persons are not required to respond to the information collection unless it displays a currently valid OMB control number 1210–0118, which is scheduled to expire on May 31, 2025. Currently, EBSA is soliciting comments concerning the proposed changes to this ICR. A copy of the ICR may be obtained by contacting the PRA addressee shown in the 2022 Program Notice.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA)[2] imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act, or any other law, and are likely to have a significant economic impact on a substantial number of small entities.[3] Unless the head of an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to prepare and make available for public comment an initial regulatory flexibility analysis of the proposed rule.[4]

The Department certifies that these proposed amendments to PTE 2002–51 will not have a significant economic impact on a substantial number of small entities. See 2022 Program Notice for the factual basis for the certification.

Background

History of the VFC Program and VFCP Class Exemption

The Department of Labor's Employee Benefits Security Administration (EBSA) originally adopted the VFC Program in 2002, and later revised it in 2005 and 2006.[5] EBSA designed the VFC Program to encourage employers and plan fiduciaries to voluntarily comply with the Employee Retirement Income Security Act (ERISA) and allow those potentially liable for certain specified fiduciary breaches under ERISA to voluntarily apply for relief from enforcement actions and certain penalties, provided they meet the VFC Program's criteria and follow the procedures outlined in the VFC Program. Many workers have benefited from the VFC Program due to the restoration of plan assets and the payment of promised benefits.

The VFC Program describes how to apply for relief and lists the specific transactions covered and acceptable methods for correcting fiduciary breaches under the Program. The most frequently corrected transaction under the Program is the correction of delinquent participant contributions. The Program provides a model application form, a checklist, and an online calculator for determining amounts to be restored to plans. Eligible applicants that satisfy the terms and conditions of the existing VFC Program receive a no-action letter from EBSA and avoid the assessment of civil monetary penalties. The VFC Program has been, and will continue to be, administered in EBSA's Regional Offices.

The Department granted the VFCP Class Exemption in connection with the VFC Program. Some of the breaches that may be corrected under the VFC Program are also prohibited transactions subject to excise tax under Internal Revenue Code (Code) section 4975. Reorganization Plan No. 4 of 1978 transferred the authority of the Secretary of Treasury to issue exemptions from the prohibited transaction provisions of Code section 4975 to the Secretary of Labor.[6] Therefore, the exemption provides excise tax relief to parties that correct certain specified breaches under the VFC Program.

The VFCP Class Exemption currently covers the following transactions:

- The failure to transmit participant contributions to a pension plan within the time frames described in the Department's regulation, and/or failure to transmit participant loan repayments to a pension plan within a reasonable time after withholding or receipt by the employer.[7]
- The making of a loan at a fair market interest rate to a disqualified person.
- The purchase or sale of an asset (including real property) between a plan and a disqualified person at fair market value.
- The sale of real property to a plan by the employer and the leaseback of the property to the employer, at fair market value and fair market rental value, respectively.
- The purchase of an asset (including real property) by a plan where the asset has later been determined to be illiquid, or in which the asset was acquired from an unrelated third party, and/or the subsequent sale of such asset in a prohibited transaction pursuant to Code section 4975(c)(1).
- The use of plan assets to pay expenses, including commissions or fees, to a service provider for services provided in connection with the establishment, design or termination of the plan, provided that the payment of these settlor expenses was not expressly prohibited by the plan.

The VFCP Class Exemption is subject to several general conditions. First, the breach must be appropriately corrected and the party applying must satisfy all the conditions of the VFC Program and receive a no-action letter from EBSA. Further, the applicant may not have taken advantage of the relief provided by the VFC Program and the exemption for a similar type of transaction(s) during three years before the current VFCP application.[8] The applicant must provide notice to interested persons of the transaction for which relief is sought within 60 days of the VFC Program submission. However, notice is not required if the excise tax that would otherwise be imposed under the Code is less than or equal to $100 and that

[1] *See* 2022 Program Notice, Section D, ''Regulatory Impact Analysis.''

[2] 5 U.S.C. 601 *et seq.* (1980).

[3] 5 U.S.C. 551 *et seq.* (1946).

[4] 5 U.S.C. 604 (1980).

[5] 67 FR 15062 (March 28, 2002); 70 FR. 17516 (April 6, 2005); 71 FR. 20262 (April 19, 2006).

[6] 5 U.S.C. App. 252 (2020).

[7] *See* 29 CFR 2510.3–102.

[8] There is an exception to the three-year rule for certain service providers that are broker-dealers, banks, insurance companies and their affiliates and that did not use their discretion to cause the prohibited transaction and did not have actual knowledge or reason to know that the underlying transaction was a non-exempt prohibited transaction.

amount is paid to the plan and allocated to participants and beneficiaries.

In addition to these general conditions, the exemption includes certain transaction-specific conditions. For example, as relevant to this proposal, participant contributions and loan repayments that are not timely transmitted (referred to collectively as delinquent participant contributions) must be transmitted to the pension plan no more than 180 calendar days from the date they either were received by the employer or otherwise would have been payable to the participant in cash.

2022 Amendments to VFC Program

The 2022 Program Notice contains an amended and restated VFC Program including the establishment of a self-correction feature for certain delinquent participant contributions and loan repayments to pension plans (the SC Component). The VFC Program is used most frequently to correct delinquent participant contributions; therefore, the Department has concluded that an appropriately designed self-correction feature will: (1) positively respond to public feedback concerning the time and expense currently required to file VFC Program applications for transactions that involve small dollar amounts; (2) offer plan officials and other responsible fiduciaries a streamlined correction process thereby encouraging more voluntary corrections; and (3) enable EBSA to better allocate resources currently dedicated to processing VFC Program applications for these transactions.

If granted, this amendment to the VFCP Class Exemption would provide excise tax relief for transactions that are corrected pursuant to the SC Component. The proposed amendment also would clarify existing transactions eligible for correction under the Program, expand the scope of other transactions currently eligible for correction, and simplify certain administrative or procedural requirements for participation in, and correction of, transactions under the VFC Program. Code section 4975, which governs the Department's authority to issue exemptions from the prohibited transaction provisions in the Code, requires the Department to provide notice to interested persons and opportunity for public comment before issuing an exemption or amendment thereto.[9] Thus the amendments to the VFCP Class Exemption proposed in this notice will not be effective until the Department grants a final amendment to the exemption.

Description of the Proposed Amendments to the VFCP Class Exemption

Self-Correction Feature for Delinquent Participant Contributions and Loan Repayments to Pension Plans

The 2022 Program Notice establishes the SC Component for certain delinquent contributions to pension plans. The SC Component allows ''self-correctors'' to make a plan whole and receive relief under the VFC Program without submitting an application to EBSA and receiving a no-action letter. Instead, self-correctors provide a notice (the SCC notice) to EBSA through an electronic tool on EBSA's website and receive an email acknowledgement from EBSA of a properly completed and submitted SCC notice. Relief under the SC Component for delinquent participant contributions is limited to corrections where the amount of lost earnings is $1,000.00 or less.[10] In the 2022 Program Notice, the Department solicits comments on specific aspects of the SC Component. To the extent commenters suggest changes to the SC Component, the Department requests comments on whether corresponding changes to the exemption are necessary.

The Department is proposing to amend Section I.A. of the exemption to clarify that excise tax relief is available for transactions that are corrected under the SC Component. These transactions would be required to comply with the applicable exemption conditions, including the requirement that delinquent contributions may not have been transmitted to the plan more than 180 calendar days from the date they were either received by the employer or otherwise would have been payable to the participant in cash.

The proposal also includes an amendment to Section III.B of the exemption, which provides that the exemption will apply only if the applicant receives an EBSA no-action letter pursuant to the VFC Program. Since self-correctors will receive an email acknowledgement instead of a no-action letter from EBSA, this condition would be amended to add a specific reference to the email acknowledgement of a properly completed and submitted SCC notice.

Frequency of Use

The exemption is generally unavailable to VFC Program applicants that have, within the previous three years, taken advantage of the relief provided by the VFC Program and the exemption for a similar type of transaction. The exemption provides a narrow exception from the three-year limitation for certain service providers (broker-dealers, banks, insurance companies and their affiliates) who may have reasonably relied on a plan fiduciary's mistaken belief that an administrative or statutory exemption was available.

The Department is proposing to eliminate the three-year limitation. The three-year provision was initially included in the exemption to prevent parties from becoming lax in complying with fiduciary and other ERISA duties because of the availability of the exemption. Based on the Department's experience with the VFC Program and the exemption, the Department concluded that the risk of such behavior is low. Notwithstanding the three-year limit on use of the exemption., applicants may correct covered transactions under the VFC Program itself multiple times within three years, but the Department has not seen indications that they are doing so in significant numbers. More importantly, the application filing process and reporting requirements under the VFC Program and the SC Component provide the Department with notice of repeat usage. This, together with the ''under investigation'' ineligibility condition, provides the Department with tools to protect participants and beneficiaries from inappropriate use of the exemption. Thus, in the Department's view, the VFC Program (including the SC Component) and the other conditions of this exemption should provide sufficient safeguards to ensure that the exemption is in the interests of plans, their participants and beneficiaries and protective of the rights of participants and beneficiaries as required by Code section 4975(c)(2).

The Department requests comments regarding whether removal of the three-year limitation would encourage greater use of the VFC Program without loss of meaningful protections for participants and beneficiaries or whether the three-year provision or some other frequency limitation should be retained for some or all covered transactions because it provides protection for participants and beneficiaries that cannot be achieved by the application, reporting, and of other conditions in the exemption and VFC Program.

[9] As noted above, under Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 252 (2020), the authority of the Secretary of Treasury to issue exemptions pursuant to Code section 4975 was transferred to the Secretary of Labor.

[10] The $1,000 limit is calculated without regard to any amount that is contributed to the plan under the exception to the notice provision.

Sale and Leaseback of Real Property to an Employer

Section I.D. of the VFCP Class Exemption applies to the sale of real property to a plan by the sponsoring employer and the leaseback of such property to the same employer if it is corrected as required under the VFC Program. The amendment would expand the covered transactions in Section I.D. to include affiliates of plan sponsors, which reflects a change made in the 2022 Program Notice. Accordingly, the amended exemption would be available for a sale of real property by an affiliate of the employer sponsoring the plan, to the plan, and a leaseback of such property to the affiliate of the sponsoring employer.

In the proposed amendment, the term ''affiliate'' of a person would be defined as follows—

(1) any person directly, or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person; (2) any officer, director, partner, employee, or member of the family (as defined in Code section 4975(e)(6)) of the person; or (3) any corporation or partnership of which such person is an officer, director, partner or employee.

The proposal also would define the term ''control'' as the power to exercise a controlling influence over the management of a person other than an individual.[11]

Proposed Deletion of Section II.E.

The proposed amendment would delete Section II.E. of the exemption. The condition relates to all the covered transactions under Section I and requires that ''the transaction was not part of an agreement, arrangement or understanding designed to benefit a disqualified person.'' The Department believes that this condition is unnecessary in light of the other, more specific conditions of the exemption, and the fact that the transaction must have been corrected in accordance with the applicable requirements of the VFC Program for the exemption to apply.

Notice to Interested Persons

The proposed amendment to the VFCP Class Exemption would make several changes to Section IV of the exemption, which governs notice to interested persons. Under existing Section IV, VFC Program applicants seeking relief under the exemption must provide written notice to interested persons of the transactions for which relief is sought pursuant to the VFC Program and the exemption. A copy of the notice must be provided to the appropriate EBSA Regional Office.

There is an existing exception to the notice requirement for delinquent participant contributions and/or loan repayments described in Section I.A. of the exemption if the amount of the excise tax that would otherwise be paid under Code section 4975 is less than or equal to $100. Under the exception in Section IV.C., applicants may pay to the plan an amount equal to the excise tax otherwise due, instead of providing the written notice to interested persons. VFC Program applicants using the exception must provide a copy of a completed IRS Form 5330 or written documentation containing the information required by IRS Form 5330 and proof of payment with the submission of their VFC Program applications to the appropriate EBSA Regional Office.

The proposed amendment would provide a special rule for self-correctors with respect to providing notice to interested persons. In light of the streamlined procedure for self-correction and the small amounts of excise taxes that would be imposed on transactions corrected under the SC Component, the Department is proposing in Section IV.D. to make the exception to the notice provision mandatory for self-correctors. For purposes of this proposed condition, the amount of the excise tax that would otherwise be imposed by Code section 4975 would be paid to the plan and allocated to the individual accounts of participants and beneficiaries in the same manner as provided under the plan with respect to plan earnings. The Department also is proposing that self-correctors using the exemption would not be subject to the requirement to provide a copy of the completed IRS Form 5330 along with proof of payment to the appropriate EBSA Regional Office. Instead, such self-correctors would be required to retain a completed Form 5330 or other written documentation of the determination of the otherwise applicable excise taxes and proof of payment of the amounts paid to the plan and provide a copy of such documentation to be kept by the plan administrator.

The Department has not proposed any dollar limitation for amounts contributed to the plan pursuant to Section IV.D., because the amounts should be small due to the 2022 Program Notice's $1,000 limitation on lost earnings. However, the Department requests comment on whether there should be a dollar limit associated with this condition in case the $1,000 dollar threshold to participate in the SC Component is later raised or eliminated. In that event, should self-correctors be required to follow the general rule set forth in Section IV.C., under which notice must be provided to interested persons unless the amount of the excise tax that would otherwise be paid is less than or equal to $100?

Section IV.B. of the exemption, relating to the manner of providing the notice to interested persons, also would be amended to prohibit that notice from being provided through posting alone. The Department no longer believes that posting the notification is reasonably calculated to ensure that interested persons actually receive the notice.

The Department has reviewed several notices to interested persons submitted to the applicable Regional Offices and found that some of them do not meet the applicable requirements of Section IV. To facilitate compliance with Section IV, the Department has prepared a model notice to interested persons as an appendix to this proposal. Because the purpose of the model notice is to provide compliance assistance, VFC Program applicants are not required to use the model notice.

Other Proposed Amendments

The Department is also proposing certain ministerial changes to PTE 2002–51 to improve readability. For example, the Department is proposing to replace references ''to sections of the Code'' to instead refer to ''Code section.''

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under Code section 4975(c)(2) does not relieve a fiduciary or other disqualified person with respect to a plan from certain other provisions of ERISA and the Code, including any prohibited transaction provisions to which the exemption does not apply, the requirement that all assets of an employee benefit plan be held in trust by one or more trustees, and the general fiduciary responsibility provisions of ERISA which require, among other things, that a fiduciary discharge their duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion; nor does it affect the requirement of Code section 401(a) that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) The proposed amendment to PTE 2002–51, if granted, would not extend to

[11] Both terms are defined in a proposed new Section V.

transactions prohibited under Code section 4975(c)(1)(F).

(3) Before the proposed amendment is granted under Code section 4975(c)(2), the Department must find that the amendment is administratively feasible, in the interests of plans and their participants and beneficiaries, and protective of the rights of participants and beneficiaries of such plans.

(4) The proposed amendment to the exemption, if granted, would be supplemental to, and not in derogation of other provisions of ERISA and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(5) If granted, the amendment to the exemption would be applicable to a transaction only if the conditions specified in the class exemption are satisfied.

Proposed Amendment to PTE 2002–51

Under Code section 4975(c)(2) and in accordance with the procedures set forth in 29 CFR 2570, subpart B (76 FR 66637, October 27, 2011), the Department proposes to amend and restate PTE 2002–51 as set forth below.

Section I. Eligible Transactions

The sanctions resulting from the application of Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall not apply to the following eligible transactions described in Section 7 of the Voluntary Fiduciary Correction (VFC) Program, as amended, provided that the applicable conditions set forth in Sections II, III, and IV are met:

A. Failure to forward participant contributions and/or loan repayments to a pension plan for investment within the time frames determined with reference to the principles of the Department's regulation at 29 CFR 2510.3–102 so that the employer retains such contributions or loan repayments for a longer period of time. (*See* VFC Program, Section 7.1(a) and Section 7.1(b) (relating to the Self-Correction (SC) Component of the VFC Program).)

B. Loan at a fair market interest rate to a disqualified person with respect to a plan. (*See* VFC Program, Section 7.2(a).)

C. Purchase or sale of an asset (including real property) between a plan and a disqualified person at fair market value. (*See* VFC Program, Sections 7.4(a) and 7.4(b).)

D. Sale of real property to a plan by the employer or an affiliate of such an employer and the leaseback of the property to the employer or the affiliate, at fair market value and fair market rental value, respectively. (*See* VFC Program, Section 7.4(c).)

E. Purchase of an asset (including real property) by a plan, where the asset has later been determined to be illiquid as described under the VFC Program in a transaction which was a prohibited transaction pursuant to Code section 4975(c)(1), or in which the asset was acquired from an unrelated third party, and/or the subsequent sale of such asset in a transaction prohibited pursuant to Code section 4975(c)(1). (*See* VFC Program, Section 7.4(f).)

F. Use of plan assets to pay expenses, including commissions or fees, to a service provider (*e.g.,* attorney, accountant, recordkeeper, actuary, financial advisor, or insurance agent) for services provided in connection with the establishment, design or termination of the plan (settlor expenses), which relate to the activities of the plan sponsor in its capacity as settlor, provided that the payment of the settlor expense was not expressly prohibited by a plan provision relating to the payment of expenses by the plan. (*See* VFC Program, Section 7.6(b).)

Section II. Conditions

A. With respect to a transaction involving participant contributions or loan repayments to pension plans described in Section I.A., the contributions or repayments were transmitted to the pension plan not more than 180 calendar days from the date the amounts were received by the employer (in the case of amounts that a participant or beneficiary pays to an employer) or the date the amounts otherwise would have been payable to the participant in cash (in the case of amounts withheld by an employer from a participant's wages).

B. With respect to the transactions described in Sections I.B., I.C., I.D., or I.E., the plan assets involved in the transaction, or series of related transactions, did not, in the aggregate, exceed 10 percent of the fair market value of all the assets of the plan at the time of the transaction.

C. The fair market value of any plan asset involved in a transaction described in Sections I.C., I.D., or I.E., was determined in accordance with Section 5 of the VFC Program.

D. The terms of a transaction described in Sections I.B., I.C., I.D., I.E., or I.F., were at least as favorable to the plan as the terms generally available in arm's-length transactions between unrelated parties.

E. With respect to a transaction involving a sale of an illiquid asset under the VFC Program described in Section I.E., the plan paid no brokerage fees, or commissions in connection with the sale of the asset.

F. With respect to any transaction described in Section I.F., the amount of plan assets involved in the transaction or series of related transactions did not, in the aggregate, exceed the lesser of $10,000 or five (5) percent of the fair market value of all the assets of the plan at the time of the transaction.

Section III. Compliance With the VFC Program

A. The applicant or self-corrector, as applicable, has met all applicable requirements of the VFC Program.

B. EBSA has issued a no-action letter to the applicant pursuant to the VFC Program with respect to a transaction described in Section I, other than for transactions corrected pursuant to the SC Component of the VFC Program. For transactions corrected pursuant to the SC Component of the VFC Program, the terms of this section will be satisfied if EBSA has acknowledged receipt of the SCC notice in accordance with Section 6.2 of the VFC Program.

Section IV. Notice to Interested Persons and Special Rules for Self-Correctors

A. Written notice of the transaction(s) for which the applicant is seeking relief pursuant to the VFC Program, and this exemption, and the method of correcting the transaction, was provided to interested persons within 60 calendar days following the date of the submission of an application under the VFC Program. A copy of the notice was provided to the appropriate Regional Office of the United States Department of Labor, Employee Benefits Security Administration, within the same 60-day period, and the applicant indicated the date upon which notice was distributed to interested persons. Plan assets were not used to pay for the notice. The notice included an objective description of the transaction and the steps taken to correct it, written in a manner reasonably calculated to be understood by the average Plan participant or beneficiary. The notice provided for a period of 30 calendar days, beginning on the date the notice was distributed, for interested persons to provide comments to the appropriate Regional Office, and it included the address and telephone number of such Regional Office. The Model Notice to Interested Persons contained in the Appendix may be used to satisfy the written notice

requirement contained in this Section IV.

B. The notice to interested persons described in Section IV.A. was given in a manner that was reasonably calculated, taking into consideration the circumstances of the plan, to result in the receipt of such notice by interested persons, including but not limited to regular mail, or electronic mail, or any combination thereof. The notice informed interested persons of the applicant's participation in the VFC Program and intention of availing itself of relief under the exemption.

C. Notwithstanding the foregoing and solely with respect to applicants seeking relief with respect to the VFC Program other than through the SC Component, Section IV.A. and IV.B. shall not apply to a transaction described in Section I.A., provided that: (1) the applicant under the VFC Program has met all of the other applicable Program requirements; (2) the amount of the excise tax that otherwise would be imposed by Code section 4975 with respect to any transaction(s) described in Section I.A would be less than or equal to $100; (3) the amount of the excise tax that otherwise would be imposed by Code section 4975 was paid to the plan and allocated to the individual accounts of participants and beneficiaries in the same manner as provided under the plan with respect to plan earnings; and (4) the applicant under the VFC Program provides a copy of a completed IRS Form 5330 or written documentation containing the information required by IRS Form 5330 and proof of payment with the submission of the application to the appropriate EBSA Regional Office. For the sole purpose of determining whether the excise tax due under Code section 4975 on the ''amount involved'' with respect to the prohibited transaction involving the failure to timely transmit participant contributions and loan repayments is less than or equal to $100, an applicant may calculate the excise tax due based upon the Lost Earnings amount computed using the online calculator provided under the Program.

D. Notwithstanding the foregoing and solely with respect to self-correctors seeking relief with respect to transactions corrected pursuant to the SC Component of the VFC Program, Section IV.A. and B. shall not apply, and additionally the self-corrector must: (1) pay to the plan the amount of the excise tax that otherwise would be imposed by Code section 4975 and allocate such amount to the individual accounts of participants and beneficiaries in the same manner as provided under the plan with respect to plan earnings, and (2) retain a copy of a completed IRS Form 5330 or written documentation regarding the determination of the otherwise applicable excise tax and proof of payment of the amounts paid to the plan pursuant to the VFC Program and this exemption and (3) provide to the plan administrator a copy of such documentation. Self-correctors must calculate the excise tax otherwise due based upon the Lost Earnings amount computed using the online calculator provided under the Program.

Section V. Definitions

A. For purposes of this exemption the term ''affiliate'' of a person means—

(1) any person directly, or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) any officer, director, partner, employee, member of the family (as defined in Code section 4975(e)(6)) of the person; or

(3) any corporation or partnership of which such person is an officer, director, partner or employee.

B. For purposes of this Section V, the term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

Signed at Washington, DC, this 7th day of November, 2022.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Appendix—Model Notice to Interested Persons

Dear [Participant or Beneficiary],

The purpose of this letter is to notify you that the [Insert Name of Applicant] is participating in the U.S. Department of Labor's Voluntary Fiduciary Correction (VFC) Program with respect to the [Insert Name of Plan]. The VFC Program is a voluntary enforcement program that encourages the correction of possible breaches of Title I of the Employee Retirement Income Security Act (ERISA).

ERISA is the federal law that covers most employee benefit plans in the private sector. The U.S. Department of Labor's Employee Benefits Security Administration (EBSA) enforces many parts of ERISA. If the terms and conditions of the VFC Program are met by [Insert Name of Applicant], EBSA will not initiate a civil investigation under Title I of ERISA with respect to the transaction and voluntary correction described below.

The VFC Program is accompanied by a ''class exemption'' from certain excise taxes imposed under the Internal Revenue Code on parties participating in ''prohibited transactions'' as defined in ERISA and the Code. The purpose of the prohibited transaction rules is to prevent dealings with persons or entities that may be in a position to exercise improper influence over employee benefit plan assets including [Name of the Plan]. If the terms of the class exemption are met, [Insert Name of Applicant] will qualify for relief from the excise taxes that would otherwise apply.

One of the requirements for excise tax relief is for [Insert Name of Applicant] to provide you with this notice so you have an opportunity to provide comments to EBSA about the prohibited transaction and the steps taken to correct the prohibited transaction, both of which are described below. To the extent that you are interested in providing your written comments to EBSA, you may mail them to [Insert the Name of the Appropriate EBSA Regional Office from the VFC Program Notice, Appendix C]. The written comments should be made to the attention of the ''VFC Program Coordinator.'' The address and telephone number for this office are [Insert from VFC Program Notice, Appendix C]. You have 30 calendar days, beginning on the date this notice was distributed, to provide written comments. Individuals submitting written comments on this matter are advised not to disclose sensitive personal data such as social security numbers.

[Insert An Objective Description of the Transaction and the Steps Taken to Correct the Transaction]

Please feel free to contact me if you have any questions at [Insert Telephone Number of a Person Employed by the Applicant Who Is Knowledgeable About this Matter].

Sincerely,
[Insert Name and Title of Person Employed by the Applicant]

[FR Doc. 2022–24702 Filed 11–18–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0265; FRL–9781–01–R4]

Air Plan Approval; North Carolina; Charlotte-Gastonia-Rock Hill Area Limited Maintenance Plan for the 1997 8-Hour Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of North Carolina, through the North Carolina Division of Air Quality (NCDAQ), via a letter dated December 9, 2021. The SIP revision includes the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the North Carolina portion (hereinafter referred to as the Metrolina

Area) of the Charlotte-Gastonia-Rock Hill NC-SC 1997 8-hour ozone maintenance area (hereinafter referred to as the ''Charlotte NC-SC 1997 8-hour NAAQS Area''). The Charlotte NC-SC 1997 8-hour NAAQS Area is comprised of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan, and Union Counties and a portion of Iredell County (*i.e.,* Coddle Creek and Davidson Townships) in North Carolina; and the Rock Hill Metropolitan Planning Organization boundary in York County, South Carolina. EPA is proposing to approve the Metrolina Area LMP because it provides for the maintenance of the 1997 8-hour ozone NAAQS within the Metrolina Area through the end of the second 10-year portion of the maintenance period in 2034. The effect of this action would be to make certain commitments related to maintenance of the 1997 8-hour ozone NAAQS in the Metrolina Area federally enforceable as part of the North Carolina SIP.

DATES: Comments must be received on or before December 21, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0265 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Jane Spann, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9029. Ms. Spann can also be reached via electronic mail at *spann.jane@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. Summary of EPA's Proposed Action

In accordance with the Clean Air Act (CAA or Act), EPA is proposing to approve the Metrolina Area LMP for the 1997 8-hour ozone NAAQS that was submitted by NCDAQ as a revision to the North Carolina SIP on December 9, 2021. In 2004, the Charlotte NC-SC 1997 8-hour NAAQS Area, which includes the Metrolina Area, was designated as nonattainment for the 1997 8-hour ozone NAAQS. Subsequently, in 2013, after a clean data determination and EPA's approval of a maintenance plan, the Metrolina Area was redesignated to attainment for the 1997 8-hour ozone NAAQS. *See* 76 FR 70656 (November 15, 2011) *and* 78 FR 72036 (December 2, 2013

The Metrolina Area LMP is designed to maintain the 1997 8-hour ozone NAAQS within the Metrolina Area through the end of the second 10-year portion of the maintenance period beyond redesignation. EPA is proposing to approve the plan because it meets all applicable requirements under CAA sections 110 and 175A.

As a general matter, the Metrolina Area LMP relies on the same control measures and contingency provisions to maintain the 1997 8-hour ozone NAAQS during the second 10-year portion of the maintenance period as the maintenance plan submitted by NCDAQ for the first 10-year period.

II. Background

Ground-level ozone is formed when oxides of nitrogen (NO_X) and volatile organic compounds (VOC) react in the presence of sunlight. These two pollutants, referred to as ozone precursors, are emitted by many types of pollution sources, including on- and off-road motor vehicles and engines, power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints. Scientific evidence indicates that adverse public health effects occur following exposure to ozone, particularly in children and in adults with lung disease. Breathing air containing ozone can reduce lung function and inflame airways, which can increase respiratory symptoms and aggravate asthma and other lung diseases.

Ozone exposure also has been associated with increased susceptibility to respiratory infections, medication use, doctor visits, and emergency department visits and hospital admissions for individuals with lung disease. Children are at increased risk from exposure to ozone because their lungs are still developing and they are more likely to be active outdoors, which increases their exposure.[1]

In 1979, under section 109 of the CAA, EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), or 120 parts per billion (ppb), averaged over a 1-hour period. *See* 44 FR 8202 (February 8, 1979). On July 18, 1997, EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. *See* 62 FR 38856 (July 18, 1997).[2] EPA set the 8-hour ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set. EPA determined that the 8-hour NAAQS would be more protective of human health, especially for children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 15, 2004, EPA designated the Charlotte NC-SC 1997 8-hour NAAQS Area, which consists of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan and Union Counties and a portion of Iredell County (*i.e.,* Coddle Creek and Davidson Townships) in North Carolina; and the Rock Hill Metropolitan Planning Organization boundary in York County,

[1] *See* ''Fact Sheet, Proposal to Revise the National Ambient Air Quality Standards for Ozone,'' January 6, 2010, *available at https://www.epa.gov/sites/default/files/2020-12/documents/decision_to_retain_ozone_standards_fact_sheet_final2.pdf, and* 27 FR 2938 (January 19, 2010).

[2] In March 2008, EPA completed another review of the primary and secondary ozone NAAQS and tightened them further by lowering the level for both to 0.075 ppm. *See* 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone NAAQS and tightened them by lowering the level for both to 0.070 ppm. *See* 80 FR 65292 (October 26, 2015).

South Carolina, as nonattainment for the 1997 8-hour ozone NAAQS. The designation became effective on June 15, 2004. *See* 69 FR 23858 (April 30, 2004).

Similarly, on May 21, 2012, EPA designated areas as unclassifiable/attainment or nonattainment for the 2008 8-hour ozone NAAQS. The Charlotte-Gastonia-Rock Hill NC-SC Area [3] (hereinafter referred to as the Charlotte NC-SC 2008 NAAQS Area) was designated as nonattainment for the 2008 8-hour ozone NAAQS and classified as a marginal nonattainment area. This designation became effective on July 20, 2012. *See* 77 FR 30088.

In addition, on November 16, 2017, areas were designated for the 2015 8-hour ozone NAAQS. The entire states of North Carolina and South Carolina were designated attainment/unclassifiable for the 2015 8-hour ozone NAAQS, with an effective date of January 16, 2018. *See* 82 FR 54232.

A state may submit a request that EPA redesignate a nonattainment area that is attaining a NAAQS to attainment, and, if the area has met other required criteria described in section 107(d)(3)(E) of the CAA, EPA may approve the redesignation request.[4] One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the NAAQS for the period extending ten years after redesignation, and it must contain such additional measures as necessary to ensure maintenance and such contingency provisions as necessary to assure that violations of the NAAQS will be promptly corrected. Eight years after the effective date of redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the NAAQS for an additional ten years pursuant to CAA section 175A(b) (*i.e.,* ensuring maintenance for 20 years after redesignation).

EPA has published long-standing guidance for states on developing maintenance plans, beginning with a 1992 memo referred to as the Calcagni memo.[5] The Calcagni memo provides that states may generally demonstrate maintenance in one of two ways: by either performing air quality modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS, or by showing that projected future emissions of a pollutant and its precursors will not exceed the level of emissions generated during a year when the area was attaining the NAAQS (*i.e.,* attainment year inventory). *See* Calcagni memo at page 9. EPA clarified in three subsequent guidance memos that certain areas can meet the CAA section 175A requirement to provide for maintenance by showing that the area is unlikely to violate the NAAQS in the future, using information such as the area's design value [6] being well below the standard and the area having a historically stable design value.[7] EPA refers to a maintenance plan containing this streamlined demonstration as an LMP.

EPA has interpreted CAA section 175A as permitting the LMP option because section 175A of the Act does not define how areas may demonstrate maintenance, and in EPA's experience implementing the various NAAQS, areas that qualify for LMPs and have approved LMPs have rarely, if ever, experienced subsequent violations of the NAAQS. As noted in the LMP guidance memoranda, states seeking an LMP must still submit the other maintenance plan elements outlined in the Calcagni memo, including: an attainment emissions inventory, provisions for the continued operation of the ambient air quality monitoring network, verification of continued attainment, and a contingency plan in the event of a future violation of the NAAQS. Moreover, a state seeking an LMP must still submit its section 175A maintenance plan as a revision to its SIP, with all attendant notice and comment procedures. While the LMP guidance memoranda were originally written with respect to certain NAAQS,[8] EPA has extended the LMP interpretation of section 175A to other NAAQS and pollutants not specifically covered by the previous guidance memos.[9]

In this case, EPA is proposing to approve the Metrolina Area LMP because the State has made a showing, consistent with EPA's prior LMP guidance, that the Charlotte NC-SC 1997 8-hour NAAQS Area's ozone concentrations are well below the 1997 8-hour ozone NAAQS and have been historically stable, and that it has met the other maintenance plan requirements. NCDAQ submitted this LMP for the Metrolina Area to fulfill the second maintenance plan requirement in the Act. EPA's evaluation of the Metrolina Area LMP is presented below.

In November of 2011 and in March of 2013, NCDAQ submitted to EPA a request to redesignate the Metrolina Area of the Charlotte NC-SC 1997 8-hour NAAQS Area to attainment for the 1997 8-hour ozone NAAQS. This submittal included a plan to provide for maintenance of the 1997 8-hour ozone NAAQS in the Metrolina Area through 2024 as a revision to the North Carolina SIP. EPA approved North Carolina's Metrolina Area maintenance plan and the State's request to redesignate the North Carolina portion of the Charlotte NC-SC 1997 NAAQS Area to attainment for the 1997 8-hour ozone NAAQS effective January 2, 2014.[10]

Under CAA section 175A(b), states must submit a revision to the first maintenance plan eight years after redesignation to provide for maintenance of the NAAQS for ten additional years following the end of the first 10-year period. EPA's final implementation rule for the 2008 8-hour ozone NAAQS revoked the 1997 8-hour ozone NAAQS and stated that one consequence of revocation was that areas that had been redesignated to attainment (*i.e.,* maintenance areas) for the 1997 NAAQS no longer needed to submit second 10-year maintenance

[3] The Charlotte-Gastonia-Rock Hill NC-SC Area for the 2008 8-hour ozone NAAQS consists of portions of Cabarrus, Gaston, Iredell, Lincoln, Rowan and Union Counties and the entirety of Mecklenburg County in North Carolina, and a portion of York County, South Carolina, which excludes the Catawba Area.

[4] Section 107(d)(3)(E) of the CAA sets out the requirements for redesignating a nonattainment area to attainment. They include attainment of the NAAQS, full approval of the applicable SIP pursuant to CAA section 110(k), determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

[5] John Calcagni, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards (OAQPS), ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' September 4, 1992 (Calcagni memo, *available at https://www.epa.gov/ground-level-ozone-pollution/procedures-processing-requests-redesignate-areas-attainment*).

[6] The ozone design value for a monitoring site is the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations. The design value for an ozone area is the highest design value of any monitoring site in the area.

[7] *See* ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas'' from Sally L. Shaver, OAQPS, dated November 16, 1994; ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph Paisie, OAQPS, dated October 6, 1995; and ''Limited Maintenance Plan Option for Moderate PM_{10} Nonattainment Areas'' from Lydia Wegman, OAQPS, dated August 9, 2001. Copies of these guidance memoranda can be found in the docket for this proposed rulemaking.

[8] The prior memos addressed: unclassifiable areas under the 1-hour ozone NAAQS, nonattainment areas for the PM_{10} (particulate matter with an aerodynamic diameter less than 10 microns) NAAQS, and nonattainment areas for the carbon monoxide (CO) NAAQS.

[9] *See, e.g.,* 79 FR 41900 (July 18, 2014) (Approval of the second ten-year LMP for the Grant County 1971 SO_2 maintenance area).

[10] *See* 78 FR 72036 (December 2, 2013).

plans under CAA section 175A(b). *See* 80 FR 12264, 12315 (March 6, 2015).

In *South Coast Air Quality Management District* v. *EPA,* the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated the EPA's interpretation that, because of the revocation of the 1997 8-hour ozone NAAQS, second maintenance plans were not required for ''orphan maintenance areas,'' *i.e.,* areas that had been redesignated to attainment for the 1997 8-hour ozone NAAQS and were designated attainment for the 2008 ozone NAAQS. *South Coast,* 882 F.3d 1138 (D.C. Cir. 2018). Thus, states with these ''orphan maintenance areas'' under the 1997 8-hour ozone NAAQS must submit maintenance plans for the second maintenance period. Accordingly, on December 9, 2021, North Carolina submitted a second 10-year maintenance plan covering the Metrolina Area that provides for attainment of the 1997 8-hour ozone NAAQS through 2034.

In recognition of the continuing record of air quality monitoring data showing ambient 8-hour ozone concentrations in the Charlotte NC-SC 1997 8-hour NAAQS Area well below the 1997 8-hour ozone NAAQS, NCDAQ chose the LMP option for the development of its second 1997 8-hour ozone NAAQS maintenance plan covering the Metrolina Area.

III. North Carolina's SIP Submittal

As mentioned above, on December 9, 2021, NCDAQ submitted the Metrolina Area LMP as a revision to the North Carolina SIP. The submittal includes the LMP, air quality data, emissions inventory information, and appendices. Appendices to the plan include average 2017 summer day anthropogenic emissions by county and sector and documentation of notice, hearing, and public participation prior to adoption of the plan by NCDAQ on December 9, 2021. The Metrolina Area LMP does not include any additional emission reduction measures but relies on the same emission reduction strategy as the first 10-year maintenance plan that provides for the maintenance of the 1997 8-hour ozone NAAQS through 2024. Specifically, the measures upon which the second 10-year LMP for the Metrolina Area relies include the foundation control program, which consists of federal and state control measures that ensure continued maintenance of the NAAQS, as well as supporting programs such as the Air Awareness Program, Advance Program, Grant Program, Volkswagen Settlement, and EPA Consent Decree with Duke Energy Corporation. It also relies on continued implementation of federal measures (*e.g.,* Tier 2 and 3 Motor Vehicle Emission and Fuel Standards,[11] Utility New Source Performance Standards (NSPS),[12] NO_X SIP Call,[13] and interstate transport rules such as the Cross-State Air Pollution Rule (CSAPR)[14] and CSAPR Update).[15]

IV. EPA's Evaluation of North Carolina's SIP Submittal

EPA has reviewed the Metrolina Area's LMP, which is designed to maintain the 1997 8-hour ozone NAAQS within the Metrolina Area through the end of the 20-year period beyond redesignation, as required under CAA Section 175A(b). The following is a summary of EPA's interpretation of the section 175A requirements[16] and EPA's evaluation of how each requirement is met.

A. Attainment Emissions Inventory

For maintenance plans, a state should develop a comprehensive, accurate inventory of actual emissions for an attainment year to identify the level of emissions which is sufficient to maintain the NAAQS. A state should develop this inventory consistent with EPA's most recent guidance on emissions inventory development. For ozone, the inventory should be based on typical summer day emissions of VOCs and NO_X, as these pollutants are precursors to ozone formation. The Metrolina LMP includes an ozone attainment emissions inventory for the Metrolina Area that reflects typical summer day emissions in 2017. Table 1 presents a summary of the inventory for 2017 contained in this LMP.

TABLE 1—AVERAGE SUMMER DAY 2017 ANTHROPOGENIC NO_X AND VOC EMISSIONS BY SECTOR FOR THE METROLINA AREA

[Tons/summer day]

Sector	NO_X	VOC
Fire	0.028	0.269
Nonpoint	0.267	2.266
Nonroad	0.436	0.451
Onroad	2.184	1.376
Point	0.072	0.912
Total	2.987	5.274

The Attainment Emissions Inventory section of the Metrolina Area's LMP describes the methods, models, and assumptions used to develop the attainment inventory. As described in the Emissions Inventory section (Section 3.1) of the LMP, NCDAQ generally relied on the 2017 National Emissions Inventory (NEI).[17] The Metrolina Area's maintenance inventory is comprised of anthropogenic sources. Naturally occurring, or biogenic, emissions are not included in the inventory, as these emissions are outside the State's purview. Because much of the EPA's 2017 NEI is compiled at the county level, but the Metrolina Area includes only a subset of the townships in relevant counties, the NCDAQ developed methodologies to estimate the proportion of county emissions occurring in the maintenance area. When available, these methodologies utilize locational information; otherwise, they assume population as a surrogate indicator of emissions activity.

Based on our review of the methods, models, and assumptions used by NCDAQ to develop the inventory, as well as our review of the 2017 summer emissions data, EPA proposes to find that the Metrolina Area's LMP includes

[11] *See* 79 FR 23414 (April 28, 2014).

[12] *See* 77 FR 9304 (February 16, 2012).

[13] *See* 63 FR 57355 (October 27, 1998).

[14] *See* 76 FR 48208 (August 8, 2011).

[15] *See* 81 FR 74504 (October 26, 2016).

[16] *See* Calcagni memo at pages 7–13.

[17] U.S. EPA, 2017 Emissions Modeling Data downloaded from *ftp://newftp.epa.gov/air/emismod/2017/reports,* accessed August 2021.

a comprehensive, reasonably accurate inventory of actual ozone precursor emissions in attainment year 2017 and proposes to conclude that this is acceptable for the purposes of a subsequent maintenance plan under CAA section 175A(b).

B. Maintenance Demonstration

The maintenance demonstration requirement is considered satisfied in an LMP if the state can provide sufficient weight of evidence indicating that air quality in the area is well below the level of the NAAQS, that past air quality trends have been shown to be stable, and that the probability of the area experiencing a violation over the second 10-year maintenance period is low.[18] These criteria are evaluated below with regard to the Charlotte NC-SC 1997 8-hour NAAQS Area as a whole.

1. Evaluation of Ozone Concentration Levels

To attain the 1997 8-hour ozone NAAQS, the three-year average of the fourth-highest daily maximum 8-hour average ozone concentrations (*i.e.,* the design value) at each monitor within an area must not exceed 0.08 ppm. Based on the rounding convention described in 40 CFR part 50, Appendix I, the NAAQS is attained if the design value is 0.084 ppm or below. At the time of submission, EPA evaluated quality assured and certified 2018–2020 monitoring data [19] and determined that the design value for the Charlotte NC-SC 1997 8-hour NAAQS Area was 0.067 ppm, or 80 percent of the level of the 1997 8-hour ozone NAAQS (measured at the Garinger High School Monitor (AQS ID: 37–119–0041) and the University Meadows monitor (AQS ID: 37–119–0046) in Mecklenburg County, NC). Consistent with prior guidance, EPA believes that if the most recent air quality design value for the area is at a level that is well below the NAAQS (*e.g.,* below 85 percent of the NAAQS, or in this case below 0.071 ppm), then EPA considers the state to have met the section 175A requirement for a demonstration that the area will maintain the NAAQS for the requisite period. Such a demonstration assumes continued applicability of prevention of significant deterioration requirements and any control measures already in the SIP and that Federal measures will remain in place through the end of the second 10-year maintenance period, absent a showing consistent with section 110(l) that such measures are not necessary to assure maintenance.

Tables 2a and 2b present the 2003–2021 design values for each monitor in the Charlotte NC-SC 1997 8-hour NAAQS Area. As shown in these tables, all sites have been below the level of the 1997 8-hour ozone NAAQS since the area was redesignated to attainment, and the most recent design value is below the level of 85 percent of the NAAQS, consistent with prior LMP guidance. The 2019–2021 design value is 0.066 ppm or 79 percent of the level of the 1997 8-hour ozone NAAQS (measured at the Garinger High School Monitor (AQS ID: 37–119–0041) and the University Meadows monitor (AQS ID: 37–119–0046) in Mecklenburg County, NC).

TABLE 2a—1997 8-HOUR OZONE NAAQS 2003–2011 DESIGN VALUES (ppm) AT MONITORING SITES IN THE CHARLOTTE NC-SC 1997 NAAQS AREA

AQS site ID	Site name	County name	2001–2003 DV	2002–2004 DV	2003–2005 DV	2004–2006 DV	2005–2007 DV	2006–2008 DV	2007–2009 DV	2008–2010 DV	2009–2011 DV
37–109–0004	Crouse	Lincoln	0.092	0.086	0.081	0.079	0.083	0.082	0.076	0.072	0.071
37–119–0041	Garinger	Mecklenburg	0.096	0.091	0.086	0.088	0.090	0.089	0.082	0.078	0.079
37–119–0046	University Meadows	Mecklenburg	.....	.....	.....	.....	.....	.....	.....	.....	.....
37–119–1005	Arrowood	Mecklenburg	0.084	0.081	0.078	0.080	0.083	0.079	0.076	0.073	0.076
37–119–1009	County Line	Cabarrus	0.098	0.092	0.087	0.088	0.093	0.094	0.086	0.082	0.078
37–159–0021	Rockwell CSS	Rowan	0.100	0.094	0.088	0.083	0.089	0.088	0.083	0.077	0.075
37–159–0022	Enochville	Rowan	0.099	0.091	0.085	0.085	0.090	0.088	0.083	0.077	0.076
37–179–0003	Monroe	Union	0.088	0.085	0.079	0.078	0.081	([e])	0.076	0.072	0.070
45–091–8801	Catawba Longhouse	Catawba Indian Nation	.....	.....	.....	.....	.....	.....	.....	.....	.....

TABLE 2b—1997 8-HOUR OZONE NAAQS 2012–2021 DESIGN VALUES (ppm) AT MONITORING SITES IN THE CHARLOTTE NC-SC 1997 NAAQS AREA

AQS site ID	Site name	County name	2010–2012 DV	2011–2013 DV	2012–2014 DV	2013–2015 DV	2014–2016 DV	2015–2017 DV	2016–2018 DV	2017–2019 DV	2018–2020 DV	2019–2021 DV
37–109–0004.	Crouse	Lincoln (NC)	0.075	0.072	0.068	0.065	0.067	0.067	0.065	0.064	0.060	0.061
37–119–0041.	Garinger	Mecklenburg (NC)	0.083	0.078	0.070	0.068	0.069	0.069	0.068	0.070	0.067	0.066
37–119–0046.	University Meadows	Mecklenburg (NC)	.....	.....	.....	.....	[a] 0.070	[a] 0.070	0.070	0.069	0.067	0.066
37–119–1005.	Arrowood	Mecklenburg (NC)	0.077	0.072	[b] 0.066	.....	.....	.....	.....	.....	.....	.....
37–119–1009.	County Line	Cabarrus (NC)	0.083	0.078	0.073	[c] 0.067	.....	.....	.....	.....	.....	.....
37–159–0021.	Rockwell CSS	Rowan (NC)	0.078	0.073	0.068	0.064	0.065	0.064	0.062	0.062	0.061	0.062
37–159–0022.	Enochville	Rowan (NC)	0.077	[d] 0.072	.....	.....	.....	.....	.....	.....	.....	.....
37–179–0003.	Monroe	Union (NC)	0.073	0.070	0.068	0.067	.....	.....	([e])	([e])	0.063	0.062

[18] *See* Footnote 7.

[19] *See https://www.epa.gov/air-trends/air-quality-design-values#report* (follow the ''Ozone Design Values 2020 (xlsx)'' hyperlink, then open ''Table4. County Status'' in the spreadsheet and scroll down to North Carolina).

TABLE 2b—1997 8-HOUR OZONE NAAQS 2012–2021 DESIGN VALUES (ppm) AT MONITORING SITES IN THE CHARLOTTE NC-SC 1997 NAAQS AREA—Continued

AQS site ID	Site name	County name	2010–2012 DV	2011–2013 DV	2012–2014 DV	2013–2015 DV	2014–2016 DV	2015–2017 DV	2016–2018 DV	2017–2019 DV	2018–2020 DV	2019–2021 DV
45–091–8801.	Catawba Longhouse	Catawba Indian Nation	.....	.....	.....	.....	.....	.....	0.063	0.064	0.062	0.062

[a] Monitor started in 2016 to replace 37–119–1009; EPA approved combining data for the two sites to calculate a design value; value reported is a combined design value.
[b] Monitor was shut down at the end of the 2014 ozone season.
[c] Monitor was shut down at the end of the 2015 ozone season and replaced by 37–119–0046 in 2016. EPA approved combining data from the two monitors to calculate design values.
[d] Monitor was shut down at the end of the 2013 ozone season.
[e] Monitor did not meet the 3-year completeness requirement of 90 percent.

Therefore, the Metrolina Area is eligible for the LMP option, and EPA proposes to find that the long record of monitored ozone concentrations that attain the NAAQS, together with the continuation of existing VOC and NO_X emissions control programs, adequately provide for the maintenance of the 1997 8-hour ozone NAAQS in the Metrolina Area through the second 10-year maintenance period and beyond.

Additional supporting information that the Metrolina Area is expected to continue to maintain the NAAQS can be found in projections of future year design values that EPA recently completed for the Revised Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS that EPA finalized on April 30, 2021.[20] Those projections, made for the year 2023, show that the maximum design value for the Charlotte NC-SC 1997 Ozone Area is expected to be 60.3 parts per billion (ppb). EPA is not proposing to make any finding in this action regarding interstate transport obligations for any state.

2. Stability of Ozone Levels

As discussed above, the Charlotte NC-SC 1997 8-hour NAAQS Area has maintained air quality below the 1997 8-hour ozone NAAQS over the past twelve design values. Additionally, the design value data shown in Tables 2a and 2b illustrate that ozone levels have been relatively stable over the 2001–2021 timeframe, with an overall downward trend. For example, data in Tables 2a and 2b indicate that the largest year over year change in design values at any one monitor during these seventeen years was 0.008 ppm, which occurred between the 2003 and 2004 design values and between the 2013 and the 2014 design values, representing approximately an 8 percent and 10 percent decrease at monitors 37–159–0022 (Enochville) and 37–119–0041 (Garinger), respectively. Furthermore, the overall trend in design values for the Charlotte NC-SC 1997 8-hour NAAQS Area between the 2003–2021 design values, shows a decrease of 38 percent at the highest monitor, Rockwell CSS monitor 37–159–002. This downward trend in ozone levels, coupled with the relatively small year over year variation in ozone design values, makes it reasonable to conclude that the Charlotte NC-SC 1997 8-hour NAAQS Area will not exceed the 1997 8-hour ozone NAAQS during the second 10-year maintenance period.

C. Monitoring Network and Verification of Continued Attainment

EPA periodically reviews the ozone monitoring networks operated and maintained by the states in accordance with 40 CFR part 58. The network plans are submitted annually to EPA, and network assessments are submitted every five years. NCDAQ operates a network plan with multiple monitors within the boundary of the Charlotte NC-SC 1997 8-hour NAAQS Area.[21] The annual network plan developed by NCDAQ follows a public notification and review process. EPA has reviewed and approved the North Carolina 2021 Ambient Air Monitoring Network Plan (''2021 Annual Network Plan'').[22] Mecklenburg County Air Quality and NCDAQ also submitted 2020 Ambient Air Monitoring Network Assessments as required by 40 CFR 58.10(d).

To verify the attainment status of the Metrolina Area over the maintenance period, the maintenance plan should contain provisions for continued operation of an appropriate, EPA-approved monitoring network in accordance with 40 CFR part 58. As noted above, North Carolina's 2020 Annual Network Plan, which covers the monitors within the Charlotte NC-SC 1997 8-hour NAAQS Area, has been approved by EPA in accordance with 40 part 58. In the LMP, North Carolina commits to continue to monitoring ozone in the Metrolina Area. North Carolina states that any monitoring changes will only be made if they are consistent with 40 CFR part 58 and that any monitor shutdowns or relocations will only be made with EPA's approval.

D. Contingency Plan

Section 175A(d) of the Act requires that a maintenance plan include contingency provisions. The purpose of such contingency provisions is to prevent future violations of the NAAQS or to promptly remedy any NAAQS violations that might occur during the maintenance period. The state should identify specific triggers which will be used to determine when the contingency measures need to be implemented.

The LMP has three triggers. The primary trigger will be a violating design value of the 1997 8-hour ozone NAAQS within the Charlotte NC-SC 1997 8-hour NAAQS Area. The trigger date will be 60 days from the date on which an ozone monitor in the Area records a fourth highest value that, when averaged with the two previous ozone seasons' fourth highest values, results in a three year average equal to

[20] On April 30, 2021, EPA published the final Revised Cross-State Air Pollution Rule (CSAPR) Update (RCU) using updated modeling that focused on analytic years 2023 and 2028 and an ''interpolation'' analysis of these modeling results to generate air quality and contribution values for the 2021 analytic year. *See* 86 FR 23054. *https://www.govinfo.gov/content/pkg/FR-2021-04-30/pdf/2021-05705.pdf.* This modeling included projected ozone design values for ozone monitors in the Charlotte SC-NC maintenance area. See the spreadsheet titled ''Data File with Ozone Design Values and Ozone Contributions (xlsx)'' at *https://www.epa.gov/csapr/revised-cross-state-air-pollution-rule-update.*

[21] South Carolina maintains one monitor in York County. Although that monitor is near the maintenance boundary, it is not used to determine compliance of the Charlotte NC-SC 1997 8-hour NAAQS Area with the 1997 8-hour ozone NAAQS because it is not located within the maintenance area. The Catawba Longhouse monitor referenced in Tables 2a and 2b is a monitor maintained by the Catawba Indian Nation (CIN), and the CIN land was included in the Charlotte NC-SC 1997 8-hour NAAQS Area boundary.

[22] *See* October 27, 2021, letter and approval from Caroline Freeman, Director, Air and Radiation Division, EPA Region 4 to Mike Abraczinskas, Director, Division of Air Quality, North Carolina Department of Environmental Quality, available in the docket for this proposed action.

or greater than 85 ppb. If this trigger or the secondary trigger is activated, the LMP requires North Carolina to conduct analyses to determine the emission control measures that will be necessary for attaining or maintaining the 1997 8-hour ozone NAAQS. The plan outlines the steps that North Carolina must conduct to determine control measures, including verification and analysis of data related to the exceedance, and possible causes. North Carolina will adopt and implement as expeditiously as practicable, but no later than 24 months after the trigger event, at least one control measure that is determined to be most appropriate for reducing NOx emissions.[23]

The secondary trigger will apply if the state finds monitored ozone levels indicating that an actual ozone NAAQS violation may be imminent, *i.e.,* when there are two consecutive ozone seasons in which the fourth highest values are 85 ppb or greater at a single monitor within the maintenance area. The tertiary trigger will be a first alert as to a potential future violation and will be activated when a monitor in the Area has a fourth highest value of 85 ppb or greater, starting the first year after the maintenance plan has been approved. Like the primary trigger, the trigger date for the secondary and tertiary triggers will be 60 days from the date on which an ozone monitor in the Area records the pertinent fourth highest value. Tertiary trigger activation will result in the analyses described in the LMP to understand why a fourth high exceedance has occurred and in the development of an outreach plan identifying any additional voluntary measures that can be implemented.

EPA proposes to find that the contingency provisions in North Carolina's second maintenance plan for the 1997 8-hour Ozone NAAQS meet the requirements of the CAA section 175A(d).

E. Conclusion

EPA proposes to find that the Metrolina Area LMP for the 1997 8-hour ozone NAAQS includes an approvable update of various elements of the initial EPA-approved maintenance plan for the 1997 8-hour ozone NAAQS. EPA also proposes to find that the Metrolina Area qualifies for the LMP option and adequately demonstrates maintenance of the 1997 8-hour ozone NAAQS through the documentation of monitoring data showing maximum 1997 8-hour ozone levels well below the NAAQS and historically stable design values. EPA believes the Metrolina Area LMP, which retains existing control measures in the SIP, is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Metrolina Area over the second maintenance period (*i.e.,* through 2034) and thereby satisfies the requirements for such a plan under CAA section 175A(b). EPA is therefore proposing to approve North Carolina's December 9, 2021, submission of the Metrolina Area LMP as a revision to the North Carolina SIP.

V. Transportation Conformity and General Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS. *See* CAA 176(c)(1)(A) and (B). EPA's transportation conformity rule at 40 CFR part 93 subpart A requires that transportation plans, programs, and projects conform to SIPs, and that it establishes the criteria and procedures for determining whether they conform. The conformity rule generally requires a demonstration that emissions from the Regional Transportation Plan (RTP) and the Transportation Improvement Program (TIP) are consistent with the motor vehicle emissions budget (MVEB) contained in the control strategy SIP revision or maintenance plan. *See* 40 CFR 93.101, 93.118, and 93.124. A MVEB is defined as ''the portion of the total allowable emissions defined in the submitted or approved control strategy implementation plan revision or maintenance plan for a certain date for the purpose of meeting reasonable further progress milestones or demonstrating attainment or maintenance of the NAAQS, for any criteria pollutant or its precursors, allocated to highway and transit vehicle use and emissions.'' *See* 40 CFR 93.101.

Under the conformity rule, LMP areas may demonstrate conformity without a regional emissions analysis. *See* 40 CFR 93.109(e). On August 13, 2013, EPA made a finding that the MVEBs for the first 10 years of the 1997 8-hour ozone maintenance plan for the North Carolina portion of the Charlotte NC-SC 1997 8-hour NAAQS Area were adequate for transportation conformity purposes. In a **Federal Register** notice dated August 13, 2013, EPA notified the public of that finding. *See* 78 FR 49265. This adequacy determination became effective on August 28, 2013.

After approval of this LMP or an adequacy finding for this LMP, there is no requirement to meet the ''budget test'' for motor vehicle emissions pursuant to the transportation conformity rule for the Metrolina Area. All actions that would require a transportation conformity determination for the Metrolina Area under EPA's transportation conformity rule provisions are considered to have already satisfied the regional emissions analysis and ''budget test'' requirements in 40 CFR 93.118 as a result of EPA's adequacy finding for this LMP. *See* 69 FR 40004 (July 1, 2004).

However, because LMP areas are still maintenance areas, certain aspects of transportation conformity determinations still will be required for transportation plans, programs, and projects. Specifically, for such determinations, RTPs, TIPs, and transportation projects still will have to demonstrate that they are fiscally constrained (40 CFR 93.108) and meet the criteria for consultation (40 CFR 93.105) and Transportation Control Measure implementation in the conformity rule provisions (40 CFR 93.113) as well as meet the hot-spot requirements for projects (40 CFR 93.116).[24] Additionally, conformity determinations for RTPs and TIPs must be determined no less frequently than every four years, and conformity of plan and TIP amendments and transportation projects is demonstrated in accordance with the timing requirements specified in 40 CFR 93.104. In addition, in order for projects to be approved they must come from a currently conforming RTP and TIP. *See* 40 CFR 93.114 and 40 CFR 93.115. The Charlotte NC-SC 2008 NAAQS Area must continue to meet all applicable requirements of the general conformity regulations.

VI. Proposed Action

Under sections 110(k) and 175A of the CAA and for the reasons set forth above, EPA is proposing to approve the Metrolina Area LMP for the 1997 8-hour ozone NAAQS, submitted by NCDAQ on December 9, 2021, as a revision to the North Carolina SIP. EPA is proposing to approve the Metrolina Area LMP because it includes an acceptable update of various elements of the 1997 8-hour ozone NAAQS Maintenance Plan approved by EPA for the first 10-year period (including emissions inventory, assurance of adequate monitoring and verification of

[23] *See* Contingency Plan section of the LMP for further information regarding the contingency plan, including measures that North Carolina will consider for adoption if the trigger is activated. The LMP is available in the docket for this proposed action.

[24] A conformity determination that meets other applicable criteria in Table 1 of paragraph (b) of this section (93.109(e)) is still required, including the hot-spot requirements for projects in CO, PM_{10}, and fine particulate matter ($PM_{2.5}$) areas.

continued attainment, and contingency provisions), and retains the relevant provisions of the SIP.

EPA also finds that the Metrolina Area qualifies for the LMP option and that, therefore, the Metrolina Area's LMP adequately demonstrates maintenance of the 1997 8-hour ozone NAAQS through documentation of monitoring data showing maximum 1997 8-hour ozone levels well below the NAAQS and continuation of existing control measures. EPA believes that the Metrolina Area's 1997 8-Hour Ozone LMP is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Metrolina Area over the second 10-year maintenance period, through 2034, and thereby satisfies the requirements for such a plan under CAA section 175A(b).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental Protection, Air Pollution Control, Incorporation by reference, Intergovernmental Relations, Nitrogen Oxides, Ozone, Reporting and Recordkeeping Requirements, Volatile Organic Compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 10, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–25078 Filed 11–18–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 22–1167; MB Docket No. 22–373; RM–11933; FR ID 113831]

Radio Broadcasting Services; South Padre Island, Texas

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a Petition for Rule Making filed by Eduardo Gallegos, proposing to amend the FM Table of Allotments, by substituting Channel 288A for vacant Channel 237A at South Padre Island, Texas to accommodate the hybrid modification application of Station KRIX(FM) that proposes the substitution of Channel 237A for Channel 288A at Port Isabel, Texas and modification of Station KRIX(FM)'s license to specify operation on Channel 237A at Port Isabel, Texas. A staff engineering analysis indicates that Channel 288A can be allotted to South Padre Island, Texas, consistent with the minimum distance separation requirements of the Commission's rules (Rules), with a site restriction of 11 km (7 miles) south of the community. The reference coordinates are 26–01–30 NL and 97–09–15 WL.

DATES: Comments must be filed on or before January 3, 2023, and reply comments on or before January 18, 2023.

ADDRESSES: Secretary, Federal Communications Commission, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the counsel to petitioner as follows: Dan J. Alpert, Esq., The Law Office of Dan J. Alpert, 2120 21st Rd. N, Arlington, VA 22201.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2054.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Federal Communications Commission's (Commission) Notice of Proposed Rule Making, MB Docket No. 22–373, adopted November 9, 2022, and released November 9, 2022. The full text of this Commission decision is available online at *https://apps.fcc.gov/ecfs.* The full text of this document can also be downloaded in Word or Portable Document Format (PDF) at *https://www.fcc.gov/edocs.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

On December 8, 2021, the Audio Division cancelled the license of station DKZSP, Fac. ID No. 56473, Channel 237A, South Padre Island, TX. *See FCC Broadcast Actions,* Report No. 50134, released December 13, 2021. Channel 237A at South Padre Island, Texas, is, therefore, considered a vacant allotment resulting from the license cancellation of FM station DKZSP. Vacant Channel 237A at South Padre Island, Texas, is not currently listed in the FM Table of Allotments.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter

is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336 and 339.

■ 2. In § 73.202(b), amend the Table of FM Allotments under Texas by adding an entry for ''South Padre Island'' to read as follows:

§ 73.202 Table of Allotments.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)

[U.S. States]	Channel No.
* * * * *	
Texas	
* * * * *	
South Padre Island	288A
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[FR Doc. 2022–25262 Filed 11–18–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 221110–0238]

RIN 0648–BL59

International Fisheries; Pacific Tuna Fisheries; 2022–2024 In-Season Action Announcement Procedures for Commercial Pacific Bluefin Tuna in the Eastern Pacific Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing regulations under the Tuna Conventions Act of 1950, as amended (TCA), to revise in-season action announcement procedures for the commercial fisheries for Pacific bluefin tuna. This proposed rule would amend procedures to add notification of in-season action by direct emails to the affected public. In-season actions would be effective upon the earlier of either receipt of the notification by email or publication of the notice in the **Federal Register**. In-season actions would also be posted on the NMFS website. This proposed rule would also add a provision to the in-season action procedures to allow any Pacific bluefin tuna already on board a fishing vessel on the effective date of a notification of in-season action to be retained on board and landed or transshipped within 24 hours of the effective date of the in-season action.

DATES: Comments on the proposed rule and supporting documents must be submitted in writing by December 6, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2022–0106, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2022–0106'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Celia Barroso, NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2022–0106'' in the comments.

Instructions: Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the draft Regulatory Impact Review (RIR) and other supporting documents are available via the Federal e-Rulemaking Portal: *https://www.regulations.gov,* docket NOAA–NMFS–2022–0106 or contact the Highly Migratory Species Branch Chief, Lyle Enriquez, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or *WCR.HMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Celia Barroso, NMFS, 562–432–1850, *Celia.Barroso@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background on the IATTC

The United States is a member of the Inter-American Tropical Tuna Commission (IATTC), which was established under the Convention for the Establishment of an IATTC signed in 1949 (1949 Convention). The 1949 Convention provides an international agreement to ensure the effective international conservation and management of highly migratory species of fish in the IATTC Convention Area. In 2003, the IATTC updated the 1949 Convention through the adoption of the Convention for the Strengthening of the IATTC Established by the 1949 Convention between the United States of America and the Republic of Costa Rica (Antigua Convention).[1] The IATTC Convention Area, as amended by the Antigua Convention, includes the waters of the eastern Pacific Ocean (EPO) bounded by the coast of the Americas, the 50° N and 50° S parallels, and the 150° W meridian.

[1] *See https://www.iattc.org/PDFFiles/IATTC-Instruments/_English/IATTC_Antigua_Convention%20Jun%202003.pdf.*

The IATTC consists of 21 member nations and 5 cooperating non-member nations. The IATTC facilitates scientific research into, as well as the conservation and management of, tuna and tuna-like species in the Convention Area. The IATTC maintains a scientific research and fishery monitoring program, and regularly assesses the status of tuna, shark, and billfish stocks in the EPO to determine appropriate catch limits and other measures to promote sustainable fisheries and prevent overexploitation.

International Obligations of the United States Under the Antigua Convention

As a Party to the Antigua Convention and a member of the IATTC, the United States is legally bound to implement decisions of the IATTC. The TCA, 16 U.S.C. 951 *et seq.,* directs the Secretary of Commerce, in consultation with the Secretary of State and, with respect to enforcement measures, the U.S. Coast Guard, to promulgate such regulations as may be necessary to carry out the United States' obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. The authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS.

Recent Pacific Bluefin Tuna Rulemaking

NMFS recently published a final rule that implemented IATTC Resolution C–21–05 (Measures for the Conservation and Management of Pacific Bluefin Tuna in the Eastern Pacific Ocean) on commercial catch limits for Pacific bluefin tuna (87 FR 47939, August 5, 2022). That final rule established biennial and annual catch limits for 2022–2024 and trip limits on individual fishing vessels that adjust as catch thresholds are met throughout each year. That final rule also established procedures for announcing in-season actions to reduce the trip limit and close the fishery, as necessary (*see* 50 CFR 300.25(g)(7)). The procedures for announcing in-season actions initially proposed in that rulemaking could not be implemented because one component relied on a U.S. Coast Guard (USCG) Broadcast Notice to Mariners (BNM), and the USCG determined that announcements of in-season actions for the Pacific bluefin tuna fishery was outside of the scope of their allowed BNMs. Consequently, that final rule implemented the other components of the in-season action announcement procedures contained in the proposed rule (*i.e.,* announcing in-season actions via a posting on the NMFS website followed by publication in the **Federal Register** as soon as practicable), but the rule removed notification by BNM.

NMFS is soliciting public comment on a revised set of procedures for announcing in-season actions that are more consistent with the intent behind the original proposed rule implementing the IATTC resolution. The intent behind the revised procedures is to allow for quicker in-season action in part because the Pacific bluefin tuna fishery may catch a lot of the catch limit in a short period of time when Pacific bluefin tuna are available in U.S. waters. Quicker in-season action will assist NMFS in remaining within the U.S. catch limits agreed to in the IATTC. As discussed further in the next section, this rule proposes amending the procedures for announcing in-season actions to add notification by direct emails to the affected public. In-season actions would be effective from the earlier of either receipt of notification by email or publication in the **Federal Register**.

NMFS is also soliciting comment on proposed regulations on prohibitions applicable to U.S. commercial fishing vessels in the event of an in-season action to reduce the trip limit. While the new trip limits would be in effect at the time and date announced, there may be instances in which vessels already had Pacific bluefin tuna in excess of the reduced trip limit on board at the time the in-season action was announced. As a result, NMFS is proposing to allow 24 hours for vessels that already had Pacific bluefin tuna on board in excess of the trip limit to land their catch.

Proposed Regulations for In-Season Action Announcements for Commercial Pacific Bluefin Tuna for 2022–2024

As indicated in the previous section, NMFS is proposing to revise the existing procedures at 50 CFR 300.25(g)(7) for announcing in-season actions to reduce trip limits or close the fishery by adding notification by direct email to the affected public. In-season actions would still be published in the **Federal Register** and would also appear on the NMFS website at *https://www.fisheries.noaa.gov/west-coast/sustainable-fisheries/pacific-bluefin-tuna-commercial-harvest-status.* In-season actions would be effective upon the time and date that would appear in the earlier of either receipt by notification in a direct email or publication in the **Federal Register**. In accordance with the August 5, 2022, final rule, in the event the trip limit was reduced early or the fishery was closed due to an overestimation of catch, NMFS could reverse immediately the prior in-season action using the same procedures outlined above.

This proposed rule would also revise 50 CFR 300.25(g)(6) to clarify that, upon the effective date of a notice of in-season action to change a trip limit, targeting, retaining on board, transshipping or landing Pacific bluefin tuna in excess of the trip limit in the Convention Area will be prohibited. To avoid regulatory discards, that prohibition would include an exception to allow any Pacific bluefin tuna already on board a fishing vessel on the effective date of the in-season action to be retained on board and landed or transshipped within 24 hours after the effective date announced in the in-season action, to the extent authorized by applicable laws and regulations.

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Tuna Conventions Act and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Economic Analysis

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Under the Regulatory Flexibility Act (RFA), the SBA defines a ''small business'' (or ''small entity'') as one with annual revenue that meets or is below an established size standard. On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for RFA compliance purposes only (80 FR 81194). The $11 million standard became effective on July 1, 2016, and is to be used in place of the U.S. SBA current standards of $20.5 million, $5.5 million, and $7.5 million for the finfish (NAICS 114111), shellfish (NAICS 114112), and other marine fishing (NAICS 114119) sectors of the U.S. commercial fishing industry in all NMFS rules subject to the RFA after July 1, 2016. *Id.* at 81194.

The entities the proposed action would directly affect are all U.S. commercial fishing vessels that may target (*e.g.,* coastal pelagic purse seine vessels) or incidentally catch (*e.g.,* drift gillnet vessels) Pacific bluefin tuna in

the Convention Area. In 2020, there were 137 participants in the commercial fishery, whether targeting Pacific bluefin tuna or catching Pacific bluefin tuna incidentally. Not all vessels that have participated in this fishery decide to do so every year. For example, the coastal purse seine fleet participation in the Pacific bluefin tuna fishery has ranged from five to nine during 2016–2020. These vessels are characterized in greater detail below. U.S. commercial catch of Pacific bluefin tuna from the IATTC Convention Area is primarily made in waters off of California by the coastal pelagic small purse seine fleet, which targets Pacific bluefin tuna opportunistically, and other fleets (*e.g.,* California large-mesh drift gillnet, surface hook-and-line, west coast longline, and Hawaii's pelagic fisheries) that catch Pacific bluefin tuna in small quantities, such as incidentally.

U.S. Coastal Purse Seine Fleet

Since 2006, the average annual revenue per vessel from all finfish fishing activities for the U.S. purse seine fleet that have landed Pacific bluefin tuna has been less than $11 million, whether considering an individual vessel or per vessel average. From 2016–2020, purse seine vessels that caught tuna had an average ex-vessel revenue of about $1,044,000 per vessel per year (based on all species landed). Annually, from 2016 to 2020, the number of small coastal pelagic purse seine vessels that landed Pacific bluefin tuna to the U.S. West Coast ranged from five to nine. Table 1 below summarizes the number of coastal purse seine vessels landing Pacific bluefin tuna in each year 2016–2020, along with total annual landings and revenues.

TABLE 1—NUMBER OF SMALL COASTAL PURSE SEINE VESSELS LANDING PACIFIC BLUEFIN TUNA TO THE U.S. WEST COAST, ALONG WITH ANNUAL LANDINGS AND REVENUES FROM PACIFIC BLUEFIN TUNA, 2016–2020 [2]

Year	Number of vessels	Landings (mt)	Ex-vessel revenue
2016	5	315.72	$351,767
2017	8	466.43	516,135
2018	8	11.53	11,378
2019	9	226.11	258,937
2020	6	116.19	126,054

The revenue derived from tuna is 11.3 percent of the overall revenue for coastal pelagic purse seine vessels that landed tuna (annually from 2016–2020), with the majority of revenue in recent years from Pacific sardine, market squid, and to a lesser extent yellowfin tuna. In particular, on average (annually 2016–2020) yellowfin tuna made up 65 percent of all tuna landings by this fleet. Revenues and costs, and corresponding profitability, of coastal purse seine vessels are not expected to be significantly altered as a result of this proposed rule.

Other U.S. Fleets That Catch Pacific Bluefin Tuna

Since 2006, the average annual revenue per vessel from all finfish fishing activities for the U.S. fleet with landings of Pacific bluefin tuna in small quantities, such as from incidental catch or hook-and-line, has been less than $11 million. These vessels include drift gillnet, surface hook-and-line, and longline gear-types. The revenues of these vessels are also not expected to be significantly altered by the proposed rule. From 2016 to 2020, between 7 and 14 drift gillnet vessels, 40 to 116 surface hook-and-line vessels, and 1 longline vessel landed Pacific bluefin tuna. During these years, vessels with gears other than purse seine landed an annual average of 55.2 mt of Pacific bluefin tuna, worth approximately $487,300. If the fishery is closed before the end of the calendar year, regulatory discards by these fleets are likely. Such a scenario would result in a greater impact to the fleet that catches Pacific bluefin tuna in small quantities, as opposed to the coastal purse seine fleet, which would simply cease targeting of Pacific bluefin tuna. Implementation of this proposed amended in-season action procedures would more closely align with the intent of the management scheme in the proposed (87 FR 12409, March 4, 2022) initial rulemaking that was finalized on August 5, 2022. That is, to provide NMFS with quicker in-season action to avoid exceeding catch limits, allow for more operational flexibility to the fleet to harvest the full catch limit while aiming to avoid regulatory discards in the event of a fishery closure.

Pursuant to the RFA and NMFS' December 29, 2015, final rule (80 FR 81194), this certification was developed using NMFS' revised size standards. NMFS considers all entities subject to this proposed action, which based on recent participation ranges from 88 to 137 because participation fluctuates substantially from year-to-year, to be small entities as defined by both the former, lower size standards and the revised size standards. Based on profitability analysis above, the proposed action, if adopted, will not have significant adverse economic impacts on these small business entities. As a result, an initial regulatory flexibility analysis is not required and was not prepared for this proposed rule.

Paperwork Reduction Act

This proposed rule contains no collection of information requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: November 14, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 2. In § 300.25, revise paragraphs (g)(6) and (7) to read as follows:

§ 300.25 Fisheries management.

* * * * *

(g) * * *

(6) *In-season actions for trip limits and closure of the fishery.* If NMFS determines that action to change a trip limit needs to be taken under paragraphs (g)(3) through (5) of this

[2] Landings and ex-vessel revenue are for all small coastal purse seine vessels that landed Pacific bluefin tuna in the year. Source: Pacific Fisheries Information Network

section, the revised trip limit will be effective upon the date provided in a notification of in-season action in accordance with paragraph (g)(7) of this section. Upon the effective date of an in-season action to change trip limits under paragraphs (g)(3) through (5) of this section, targeting, retaining on board, transshipping or landing Pacific bluefin tuna in the Convention Area in violation of the in-season action shall be prohibited, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date of the notification of in-season action may be retained on board and landed or transshipped within 24 hours after the effective date of the notification, to the extent authorized by applicable laws and regulations. After NMFS determines that the annual catch limits under paragraphs (g)(3) through (5) of this section are expected to be reached, NMFS will close the fishery effective upon the date provided in the notification in accordance with paragraph (g)(7) of this section. Upon the effective date in the notification, targeting, retaining on board, transshipping or landing Pacific bluefin tuna in the Convention Area shall be prohibited through the end of the calendar year, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date of the notification may be retained on board and landed or transshipped within 14 days after the effective date published in the fishing closure notification, to the extent authorized by applicable laws and regulations.

(7) *Announcement and effective dates of in-season actions.* If in-season actions under paragraphs (g)(2) through (6) of this section are needed, NMFS will post a notification on the NMFS web page (*https://www.fisheries.noaa.gov/west-coast/sustainable-fisheries/pacific-bluefin-tuna-commercial-harvest-status*) announcing the in-season action, including effective dates. NMFS will also send emails with notification of the in-season action to affected vessel owners. This action will also be published in the **Federal Register** as soon as practicable. The in-season action will be effective upon the earlier of either (1) receipt by email of such notification, or (2) publication in the **Federal Register**.

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[FR Doc. 2022–25251 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 87, No. 223

Monday, November 21, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 21, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Horse Protection Regulations.

OMB Control Number: 0579–0056.

Summary of Collection: The Horse Protection Act (HPA) of 1970 (Pub. L. 91–540), as amended July 13, 1976 (Pub. L. 94–360), was enacted to prevent showing, exhibiting, selling, or auctioning of ''sore'' horses, and certain transportation of sore horses in connection therewith, at horse shows, horse exhibitions, horse sales, and horse auctions. ''Soring'' is a process whereby chemical or mechanical agents, or a combination thereof, are applied to the limbs of a horse in order to exaggerate its gait. A ''sore'' horse is one that has been subjected to prohibited practices and, as a result, suffers, or can reasonably be expected to suffer, physical pain or distress, inflammation, or lameness when walking, trotting or otherwise moving. A horse that is ''sore'' is prohibited from entering or participating in HPA-regulated events because exhibitors, owners, and trainers of such horse may obtain unfair advantage over individuals exhibiting horses that are not ''sore.''

Need and Use of the Information: APHIS uses the following information collection activities to enforce the Horse Protection Act:

Access to and Inspection of Event Management Records;

Request for Certification of DQP Program and Detailed Outline of Such a Program, Including Standards of Conduct and Procedures for Enforcing Such Standards;

List of DQPs and Notification to USDA of Changes to the List and Any Warnings or Revocations Issued to Any DQP;

HIO Report of Violations and Recordkeeping;

Certified DQP Program Written Warning to DQP of Unsatisfactory Performance;

Certified DQP Program Cancellation of DQP License After Warning;

Request by DQP to USDA to Appeal License Cancellation;

Appeal of Revocation and DQP Access to Records (previously titled Appeal of Revocation);

Written Notification to USDA and Certified DQP Programs by Event Management of Unsatisfactory DQP Performance;

Records of Events Containing Tennessee Walking Horses or Racking Horses Maintained by Management;

Providing Contact Information for Recordkeeper;

Inspection of Horse Industry Organization Records;

Management Report to USDA of Any Regulated Horse Event Involving Tennessee Walking Horses or Racking Horses;

Management Report to USDA of Any Regulated Horse Event Not Involving Tennessee Walking Horses or Racking Horses;

Required Information in Rulebooks and Rulebook Submission;

Appeals and Reports; and

Certified DQP Program Quarterly Reports on Disciplinary Action and Recordkeeping (previously titled Certified DQP Program Quarterly Reports on Disciplinary Actions);

If the information were collected less frequently or not collected, APHIS would not be able to accurately assess compliance with the HPA.

Description of Respondents: Business or not-for-profit; individuals and households.

Number of Respondents: 442.

Frequency of Responses: Recordkeeping; reporting.

Total Burden Hours: 2,650.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–25255 Filed 11–18–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket ID: NRCS–2022–0015]

Request for Public Input About Implementation of the Inflation Reduction Act Funding

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Request for information.

SUMMARY: The Natural Resources Conservation Service (NRCS) requests public input for NRCS to use to inform how NRCS will implement funds received under the Inflation Reduction

Act (IRA) to fund the deployment of climate-smart practices on US farms, ranches, and forestlands through four Farm Bill conservation programs. NRCS is also requesting input on funding to quantify carbon sequestration and carbon dioxide, methane, and nitrous oxide emissions at the field scale. NRCS is specifically interested in public input and recommendations that NRCS can use to improve, expand, and/or build on scientifically-designed quantification systems to monitor and quantify improvements in soil carbon, reductions in nitrogen losses, and the reduction, capture, avoidance, or sequestration of carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production. In implementing the IRA, NRCS is interested in supporting program implementation and improving program delivery by effectively leveraging partners to increase outreach and expand access to underserved producers. This effort will help NRCS identify and prioritize process improvements for the delivery of funding made available under IRA and the overall administration of the NRCS conservation programs. NRCS will look to identify immediate changes that can be implemented for funding available for fiscal year (FY) 2023 and will continue to identify and adopt additional changes in future years.

DATES: We will consider comments that we receive by December 21, 2022. Comments received after that date will be considered to the extent possible.

ADDRESSES: We invite you to send comments in response to this notice. You may send comments through the method below:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for Docket ID: NRCS–2022–0015. Follow the online instructions for submitting comments.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2022, President Biden signed IRA, (Pub. L. 117–169) into law. IRA builds on the Biden-Harris Administration's historic investments in rural America and furthers the commitment to rural communities demonstrated in the American Rescue Plan Act of 2021 (Pub. L. 117–2) and the Infrastructure Investment and Jobs Act also known as ''Bipartisan Infrastructure Law'' (Pub. L. 117–58). IRA is a once-in-a-generation opportunity to build critical infrastructure, to protect communities from wildfire and extreme heat and to drive climate-smart agriculture and renewable energy initiatives nationwide.

Agriculture, in particular, is at the forefront of the United States' effort to address climate change. From incentivizing the adoption of climate-smart agriculture, to supporting healthy forests and conservation, to clean energy tax credits, to biofuels, infrastructure and beyond, IRA provides the United State Department of Agriculture (USDA) with significant additional resources to lead this historic charge.

IRA provides unprecedented funding levels targeted to improve soil carbon, reduce nitrogen losses, or reduce, capture, avoid, or sequester carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production for several NRCS programs. The increased funding levels begin in FY 2023, and rapidly build over 4 years, resulting in the following total additional funds by program and NRCS administrative costs:

- Environmental Quality Incentives Program—$8.45 billion;
- Conservation Stewardship Program—$3.25 billion;
- Regional Conservation Partnership Program—$4.95 billion;
- Agricultural Conservation Easement Program—$1.4 billion;
- Conservation Technical Assistance—$1 billion;
- Greenhous Gas (GHG) Monitoring—$300 million; and
- Administrative costs—$100 million.

These funds provide NRCS with an unprecedented opportunity to implement practices and quantify greenhouse gas emission reductions. NRCS is soliciting public input and recommendations to determine how NRCS can maximize, target, monitor, and quantify improvements to soil carbon, reductions in nitrogen losses, and the reduction, capture, avoidance, or sequestration of carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production. To minimize complexity and ensure equity across NRCS program implementation, NRCS also requests recommendations on how to streamline and improve program delivery while also expanding access for underserved producers. NRCS will use the input provided in response to this request to implement IRA funding over the next several years.

List of Questions for Commenters

The list of questions below is non-exhaustive, but meant to assist members of the public in formulating comments on some of the most important issues that NRCS is considering as they implement the program. This list of questions is not intended to restrict the feedback that members of the public may provide:

(1) What systems of quantification should NRCS use to measure the carbon sequestration and carbon dioxide, methane, and nitrous oxide emissions outcomes associated with activities funded through IRA?

- How should NRCS design a scientifically-based framework for field-based quantification and analysis that can integrate into USDA's Greenhouse Gas Inventory and Assessment Program?
- What methods should NRCS use to quantify carbon sequestration and carbon dioxide, methane, and nitrous oxide emissions?
- What sources of information should NRCS consider in developing protocols or what preexisting, standardized protocols should be used to support field-based data collection and analysis?
- What types of field-based data should be collected and analyzed to assess carbon sequestration and reduction in carbon dioxide, methane, and nitrous oxide emissions outcomes associated with agricultural and conservation activities?
- How should USDA monitor and track carbon sequestration and greenhouse gas emissions trends and the effects of NRCS supported activities?
- How or should the framework developed by NRCS to provide field-based quantification integrate with satellite data to provide a comprehensive picture of GHG emissions and removals from agricultural activities and conservation practice implementation?

(2) How can NRCS engage the private sector and private philanthropy to leverage the IRA investments, including for systems of quantification?

(3) How should NRCS target IRA funding to maximize improvements to soil carbon, reductions in nitrogen losses, and the reduction, capture, avoidance, or sequestration of carbon dioxide, methane, or nitrous oxide emissions, associated with agricultural production?

(4) How should NRCS streamline and improve program delivery to increase efficiencies and expand access to IRA funded programs and projects for producers, particularly underserved producers?

(5) How can NRCS expand capacity among partners to assist in providing outreach and technical assistance to support the implementation of IRA funding?

Maximizing the Value of Public Feedback

NRCS plans to use the answers provided by the public to inform the approach to determining the best delivery of the IRA funds and the overall administration of NRCS conservation programs. NRCS encourages public comment on these questions and requests any other information or data commenters believe are relevant to this document. The type of feedback that is most useful to NRCS will be comments that identify specific data, policies, procedures or processes, and include actionable information and data, or viable alternatives that meet IRA and other programmatic goals and requirements. To be most useful to NRCS, comments need to do more than simply state that the commenter feels strongly that NRCS should change processes. Instead, to be most helpful, comments should state in plain language what change NRCS should consider or how a suggested change will meet specific goals and requirements, or otherwise improve existing processes.

We highlight a few of those points here, noting that comments that will be most useful to NRCS are those that are guided by the following principles. Commenters should consider these principles as they respond to the questions in this document:

- Specify, to the extent possible, the NRCS program, regulation, or policy at issue and provide the Code of Federal Regulation (CFR) and NRCS Manual citation, where available or applicable. See *https://directives.sc.egov.usda.gov* for NRCS current policy manuals and handbooks.
- Explain, in the most specific and concise language, why an NRCS regulation, policy, form, or program process should be modified, streamlined, expanded, or removed, as well as specific suggestions about how NRCS can better achieve IRA objectives and reduce unnecessary burdens on producers and partners.
- Provide data to support how specific recommendations would increase benefits achievable by the IRA funding. Commenters may also address how NRCS can best quantify or otherwise obtain and consider accurate, objective information and data about outcomes achieved through IRA funding.

You may contact us by sending an email to: *NRCS.IRA.Input@usda.gov* if you have questions or concerns. Please specify the docket ID Docket ID: NRCS–2022–0015 in the subject line.

Review of Public Feedback

NRCS will use the public comments to improve our program delivery with the funds made available by IRA and to consider NRCS conservation program improvements more broadly.

This document is issued solely for information and program-planning purposes. Public comments provided in response to this document will not bind NRCS to any further actions, including publication of any formal response or agreement to initiate a recommended change. NRCS will consider the feedback and make changes or process improvements at our sole discretion.

Finally, comments submitted in response to this document will not be considered as petitions for rulemaking submitted as specified in the Administrative Procedure Act (5 U.S.C. 553(e)).

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-aprogram-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov*.

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Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2022–25292 Filed 11–17–22; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the South Carolina Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the South Carolina Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a business meeting on Thursday, December 1, 2022, at 12:30 p.m. (ET). The purpose of the meeting is to discuss the post-report stage of the Committee's project on Civil Asset Forfeiture in South Carolina.

DATES: The meeting will take place on Thursday, December 1, 2022, at 12:30 p.m. (ET).

Meeting Link (Audio/Visual): https://tinyurl.com/2s64wdex.

Telephone (Audio Only): Dial 1–833–568–8864 USA Toll Free; Meeting ID: 160 518 4384.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, DFO, at *ero@usccr.gov* or 1–202–529–8246.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and

providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *ero@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at 1–202–376–7533.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, South Carolina Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Discussion: Post-Report Activities
III. Other Business
IV. Public Comment
V. Next Steps
VI. Adjournment

Dated: November 16, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–25290 Filed 11–18–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; National Survey of Children's Health Longitudinal Cohort (NSCH–LC)

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed new information collection, of the National Survey of Children's Health Longitudinal Cohort, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 20, 2023.

ADDRESSES: Interested persons are invited to submit written comments by email to *ADDP.NSCH.List@census.gov.* Please reference National Survey of Children's Health Longitudinal Cohort in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2022–0019, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Carolyn Pickering, Survey Director, by way of phone (301–763–3873) or email (*Carolyn.M.Pickering@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

Sponsored by the U.S. Department of Health and Human Services' Health Resources Services Administration's Maternal and Child Health Bureau (HRSA MCHB), the National Survey of Children's Health Longitudinal Cohort (NSCH–LC) will produce unique data on the physical and emotional health of 3- to 23-year-olds in the United States with a focus on the COVID–19 pandemic. The NSCH–LC will collect information related to the health and well-being of children, young adults, and their families, including access to and use of health care, family interactions, parental health, school, and after-school experiences.

The goal of the NSCH–LC is to provide HRSA MCHB, other government agencies, and other data users with the necessary data to assess the effects of the COVID–19 pandemic on U.S. children, young adults, and their families, to illuminate key risk and protective factors for this cohort, and to identify gaps in health care and education during this period.

The data collection strategy for the NSCH–LC is informed by the data collection strategies of other similar surveys, such as the annual National Survey of Children's Health (NSCH). The data collection strategy for the NSCH–LC will consist of the following components:

- *Sampling Frame*—The base sample will consist of 60,000 households that responded to the annual NSCH in 2018 and 2019.
- *Incentive Distribution*—The NSCH–LC will provide a $5 pre-paid unconditional cash incentive to 100% of the total sampled addresses.
- *Mailing Materials Strategy*—Households will be assigned to a mailing strategy based on respondent behavior in the NSCH 2018/2019. All sampled addresses will receive an initial web invitation letter to complete the NSCH–LC followed by a pressure-sealed reminder postcard one week later. All non-responding households may receive up to one additional pressure-sealed reminder postcard and up to three additional nonresponse follow-up mailings. Households will receive a paper questionnaire based on their prior response preference on the NSCH 2018/2019. Households with a preference to respond with the paper instrument may receive an English questionnaire as early as the first follow-up mailing. Households with a preference to respond with the web instrument may receive an English questionnaire as early as the second follow-up mailing. For households that preferred to respond in Spanish, those households will receive a Spanish paper questionnaire in the initial mailing and with each nonresponse follow-up mailing. The NSCH–LC mailed correspondence will be addressed to the ''Parent or Previous Caregiver of [child's/person's name]'' or to the ''Parent or Previous Caregiver''. For those households that complete the survey, they may receive a ''thank you'' letter after the data has been publicly released thanking them for their response and sharing information about where to find the published datasets.
- *Questionnaire Content*—The content for the NSCH–LC has undergone

two rounds of cognitive testing [1] and asks households to report retrospectively on different topics during the COVID–19 pandemic at the time of response when the NSCH–LC will be fielded in late Summer 2023. Additional content will be from the annual NSCH covering topics such as physical and emotional health, health insurance coverage, health care access, community, childcare, and school engagement, development, learning, and school readiness, and family resources. The overlap of content with the annual NSCH was done to provide a comparison of content collected in NSCH 2018/2019 to the NSCH–LC in 2023. Some of the content from the NSCH 2018/2019 was updated to a gender-neutral text to match current standards. This cognitive testing request was submitted under the generic clearance package and approved by OMB. Based on the results of cognitive testing, a final set of proposed new and modified content will be included in the full OMB ICR for the NSCH–LC.

• *Data Collection*—The NSCH–LC is a one-phase data collection. Households will be assigned one of the three age-based topical questionnaires. To support the full age range of 3–23 years old for the NSCH–LC sampled children and young adults, the questionnaire age splits will be as followed: LC1/S–LC1 is 3- to 5-years-old, the LC2_3/S–LC2_3 is 6- to 17-years-old, and the LC4/S–LC4 is 18- to 23-years-old.

• *Nonresponse Follow-up*—If there is evidence during the NSCH–LC data collection that the household has moved, that household case may be sent for interviewer follow-up. Interviewer nonresponse follow-up is fully dependent on funding being available. These interviewers will not administer the survey, but they will encourage response through the web instrument, paper instrument, or TQA phone support.

• *Data Mode Collection*—There will be two modes of data collection for the NSCH–LC. Households will be able to answer by a self-administered internet/web instrument (English only) or they will be able to answer by paper questionnaire (available in both English and Spanish). Additionally, they may call into the TQA line to complete the survey over the phone with an operator. TQA operators will be using the same web instrument used by respondents. All non-responding households will receive a paper questionnaire by the second nonresponse follow-up mailing.

• *Branding*—Mailing materials will be sent using U.S. Census Bureau letterhead and envelopes. Mailing materials will be reviewed during cognitive testing and based on the annual NSCH mailing materials.

• *Respondent Help/Support Operations*—The NSCH–LC will have a TQA line available for those who experience technical problems, have questions about the NSCH–LC, would like to complete the survey with an operator, or would like to request a paper questionnaire. In addition, email questionnaire assistance will be available for these households should they prefer that method of contact.

II. Method of Collection

The NSCH–LC will consist of both a web-push and a mixed mode data collection design. Every mailing the household receives will include a web invitation to complete the English web instrument. However, depending on the mode of completion and language preference in NSCH 2018/2019, the NSCH–LC invitation mail package may also include a paper questionnaire (either English or Spanish). The Spanish language response preference group will also receive instructions for calling into the TQA line to complete the survey in Spanish over the phone. Households that prefer to complete the survey using a paper questionnaire may call TQA to request a questionnaire be mailed to them in their next scheduled mailing.

III. Data

OMB Control Number: 0607–XXXX.

Form Number(s): NSCH–LC1 (English topical questionnaire for 3- to 5-year-old children), NSCH–LC2_3 (English topical questionnaire for 6- to 17-year-old children), NSCH–LC4 (English topical questionnaire for 18- to 23-year-old persons), NSCH–S–LC1 (Spanish topical questionnaire for 3- to 5-year-old children), NSCH–S–LC2_3 (Spanish topical questionnaire for 6- to 17-year-old children), NSCH–S–LC4 (Spanish topical questionnaire for 18- to 23-year-old persons).

Type of Review: Regular submission, New Information Collection Request.

Affected Public: Parents, researchers, policymakers, and family advocates.

Estimated Number of Respondents: 45,000.

Estimated Time per Response: Response time for households with eligible children will be approximately 40 minutes.

Estimated Total Annual Burden Hours: 30,000.

Estimated Total Annual Cost to Public: $0 (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 8(b); 42 U.S.C. 701; and 42 U.S.C. 241.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–25319 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–07–P

[1] Generic Clearance Information Collection Request: *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-0607-002&icID=251581.*

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Annual Integrated Economic Survey

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed new survey, the Annual Integrated Economic Survey (AIES), prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 20, 2023.

ADDRESSES: Interested persons are invited to submit written comments by email to *Thomas.J.Smith@census.gov.* Please reference Annual Integrated Economic Survey (AIES) in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2022–0024, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Blynda Metcalf, U.S. Census Bureau, Associate Directorate for Economic Programs (ADEP) by phone (301) 763–4781, or by email at *Blynda.K.Metcalf@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to conduct the AIES on an annual basis, beginning for survey year 2023 (collected in calendar year 2024) and a Dress Rehearsal for the AIES for survey year 2022 (collected in calendar year 2023). The AIES is a new survey designed to integrate and replace seven existing annual business surveys into one survey. The AIES will provide the only comprehensive national and subnational data on business revenues, expenses, and assets on an annual basis. The AIES is designed to combine Census Bureau collections to reduce respondent burden, increase data quality, and allow the Census Bureau to operate more efficiently to reduce costs. The existing collections integrated into the AIES are the Annual Retail Trade Survey (ARTS), Annual Wholesale Trade Survey (AWTS), Service Annual Survey (SAS), Annual Survey of Manufactures (ASM), Annual Capital Expenditures Survey (ACES), Manufacturer's Unfilled Orders Survey (M3UFO), and the Report of Organization. The ARTS has been conducted annually since 1951 to collect sales, expenses, and other items for the retail sector of the economy. The AWTS has been conducted annually since 1978 to collect data on sales, inventories, operational expenses, and purchases for wholesale trade. The SAS has been conducted annually since 1982 to collect revenues and other measures for most traditional service industries. The ASM has been conducted annually since 1948 to collect revenues, expenses, capital expenditures, fuels and electric energy used, and inventories in the manufacturing sector. The ACES has been conducted annually since 1996 to collect capital spending for new and used structures and equipment in agriculture, construction, mining, manufacturing, retail, wholesale, and service sectors. The M3UFO began collecting manufacturing revenue and unfilled orders data in 2010. The Report of Organization has been collecting information on organization and structure of firms to maintain the Business Register on an annual basis since 1973.

Estimates currently published in ARTS, AWTS, SAS, ASM, and ACES will be produced as part of the AIES and expanded to include subnational data across the economy. Previously, the ASM (manufacturing) was the only annual survey being integrated into AIES that produced subnational data. AIES will produce subnational data for manufacturing, retail, wholesale, and service sectors if quality standards are met. The AIES information previously collected on the Report of Organization will continue to be used to update the Business Register, and the AIES data previously collected on the M3UFO will continue to be used for the Manufacturers' Shipments, Inventories, and Orders (M3) Survey benchmarking purposes. Data users will be able to access the AIES estimates through the use of visualizations and *data.census.gov.* Private businesses, organizations, industry analysts, educators and students, and economic researchers have used the data and estimates provided by these seven existing collections for analyzing and conducting impact evaluations on past and current economic performance, short-term economic forecasts, productivity, long-term economic growth, market analysis, tax policy, capacity utilization, business fixed capital stocks and capital formation, domestic and international competitiveness trade policy, product development, market research, and financial analysis. Trade and professional organizations have used the estimates to analyze industry trends and benchmark their own statistical programs, develop forecasts, and evaluate regulatory requirements. Government program officials and agencies have used the data for research, economic policy making, and forecasting. Based on the use of the data of the existing collections, estimates produced from the AIES will serve as a benchmark for Census Bureau indicator programs, such as the Advance Monthly Sales for Retail and Food Services (MARTS), the Monthly Retail Trade Survey (MRTS), Manufacturers' Shipments Inventories & Orders (M3), Monthly Wholesale Trade Survey (MWTS), and the Quarterly Services Survey (QSS). Like the previous collections, the AIES will provide updates to the Longitudinal Research Database (LRD), and Census Bureau staff and academic researchers with special sworn status will continue to use the LRD for micro data analysis. The Census Bureau will also continue to use information collected in the AIES to update and maintain the centralized, multipurpose Business Register that provides sampling populations and enumeration lists for the Census Bureau's economic surveys and censuses. The Bureau of Economic Analysis (BEA) will continue to use the estimates to derive industry output for the input-output accounts and for the gross domestic product (GDP). We expect that the Bureau of Labor

Statistics (BLS) will continue to use the data as input to its Producer Price Index (PPI) and in developing productivity measurements; the Federal Reserve Board (FRB) will continue to use the data to prepare the Index of Industrial Production, to improve estimates of investment indicators for monetary policy, and in monitoring retail credit lending; the Centers for Medicare and Medicaid Services (CMS) will continue to use the data to estimate expenditures for the National Health Accounts and for monitoring and evaluating healthcare industries; and the Department of the Treasury will continue use the data to analyze depreciation and to research economic trends.

The AIES covers domestic, nonfarm employer businesses with operations during the survey year. Non-employer businesses are not within the scope of this new AIES. The Census Bureau will submit a separate request for approval to collect data from non-employer businesses, if it is determined that a collection is needed to produce those estimates.

The AIES will collect the following information from employer businesses in sample:

—Business characteristics, including employment, operating status, organizational change, ownership information, and co-op status
—Business classification, including business activity, type of operation, and tax status
—Revenue, including sales, shipments, and receipts, revenue by class of customer, taxes, contributions, gifts, and grants, products, and e-commerce activity
—Operating expenses, including purchased services, payroll, benefits, rental payments, utilities, interest, resales, equipment, materials and supplies, research and development, and other detailed operating expenses
—Assets, including capital expenditures, inventories, and depreciable assets
—Robotic equipment

Additional topics of collections in the AIES include sources of revenue for providers (*e.g.,* hospitals and other businesses in the health industry) of select services such as inpatient days, outpatient visits to hospitals, patient visits for other selected health industries, revenue from telemedicine services, and expenses for electronic health records. Product data will be collected from businesses operating in manufacturing and services industries. Merchandise lines data will be collected from businesses operating in select retail industries will collect merchandise lines data. Detailed inventories will be collected for trucks, truck tractors, and trailers.

The AIES may include new questions each year based on relevant business topics. Potential topics for such new questions could include technological advances, management and business practices, exporting practices, and globalization. Any new questions will be submitted to OMB for review using the appropriate clearance vehicle.

In 2020 and 2021, research was conducted on the potential impacts of a coordinated collection of SAS, ARTS, and AWTS. This coordinated collection research was designed to investigate the impact of implementing the existing contact strategy that encompassed multiple survey requests. Following this coordinated collection research effort, approximately 19 interviews were conducted with nonrespondents, and 35 interviews were conducted with respondents. In 2021, AIES data accessibility and recordkeeping studies were conducted with about 60 companies. In 2022, a pilot AIES survey was administered to 78 companies, including 2,863 establishments, to test the respondent experience; the pilot AIES survey focused on the layout and design of the collection instrument and harmonized content. From the pilot survey, 10 interviews were conducted with respondents, and 15 Response Analysis Surveys (RAS) were completed by respondents. Cognitive testing encompassing survey structure, instrument design, and respondent reporting process was conducted with about 40 companies in 2022. Usability testing on the electronic collection instrument will be conducted with up to 30 companies at the end of 2022 and will continue into 2023. A Phase II pilot will be conducted in February 2023 with approximately 562 companies. Phase II will follow the same model as the first pilot with debriefing interviews and a response analysis survey planned. In the Spring of 2023, we also plan to conduct Large Firm Response Research with up to 35 of the largest firms in the AIES sample. All the afore-mentioned work has been, or will be, conducted under the Census Bureau's Generic clearance for Field Tests and Evaluations (OMB# 0607–0971) or the Generic Clearance for Questionnaire Pretesting Research (OMB# 0607–0725).

In June of 2023, the Census Bureau plans to conduct a Dress Rehearsal for the AIES with up to 10,000 companies. The Dress Rehearsal will be large-scale test of the forms and procedures planned for the AIES. The burden estimate is 3 hours and 47 minutes per respondent. The Dress rehearsal will allow us to examine patterns of non-response and to determine what additional support respondents will need. Paradata gathered from respondents' interactions with the online collection instrument during the Dress Rehearsal will help refine our burden estimate. We will also compare the quality of responses received to historic data collected in the 7 surveys the AIES will replace. Up to 30 debriefing interviews with respondents will also be conducted.

The total annual reporting burden for the Dress Rehearsal will be 37,786 hours (10,000 × 3 hours and 47 minutes). Debriefing interviews will take approximately 1 hour each and will add 30 hours to this total.

To minimize the burden imposed on respondents already in sample for the seven annual surveys the AIES will replace, we will use the AIES responses from companies that participate in the Dress Rehearsal to satisfy their reporting requirement for the annual surveys for which they are in sample for the 2022 survey year. Given that the AIES Dress Rehearsal will be conducted during the same calendar year as we will be conducting the 2022 Economic Census, we may use AIES Dress Rehearsal to supplement Economic Census responses, pursuant to 13 U.S.C. 193.

After conclusion of the Dress Rehearsal, and based on refinements made to forms and procedures, the Census Bureau will begin conducting the full-scale AIES in 2024. The AIES will select a stratified sequential random sample of 380,199 companies from a frame of approximately 5.4 million companies constructed from the Business Register, which is the Census Bureau's master business list. The AIES will impose an estimated 1,436,619 hours of annual reporting burden (380,199 × 3 hours and 47 minutes). If the current sample size or burden estimate changes, based on our analysis of paradata information gathered during the Dress Rehearsal, the Census Bureau will submit a request to adjust the burden using the appropriate clearance vehicle. Businesses which reported business activity on Internal Revenue Service tax forms 941, ''Employer's Quarterly Federal Tax Return''; 944, ''Employer's Annual Federal Tax Return''; 1065 ''U.S. Return of Partnership Income''; or any one of the 1120 corporate tax forms will be eligible for selection.

The AIES will replace the ARTS, AWTS, SAS, ASM, ACES, M3UFO, and the Report of Organization in survey year 2023, at which time the Census

Bureau will discontinue these collections.

II. Method of Collection

The AIES Dress Rehearsal conducted for survey year 2022 and the AIES conducted for survey year 2023 and beyond will be collected using Centurion, the Census Bureau's secure online survey collection tool. Respondents will receive an email and/or letter notifying them of their requirement to respond and how to access the survey. Responses will be due approximately 30 days from receipt. Select businesses will receive a due date reminder via a letter or email prior to the due date. Additionally, email follow-ups and up to three mail follow-ups to nonrespondents will be conducted at approximately one-month intervals. Selected nonrespondents will receive a priority class mailing for the third follow-up if needed. Selected nonrespondents will also receive follow-up telephone calls.

III. Data

OMB Control Number: 0607–XXXX.

Type of Review: Regular submission, new collection.

Affected Public: Businesses, or other for profit or non-profit institutions or organizations.

Estimated Number of Respondents: Dress Rehearsal—10,000 companies; AIES—380,199 companies.

Estimated Time Per Response: 3 hours and 47 minutes per company.

Estimated Total Annual Burden Hours: Dress Rehearsal—37,816; AIES—1,436,619.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. Sections 131, 182, and 193.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–25312 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Automated Export System Program

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed revision to the Automated Export System Program prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 20, 2023.

ADDRESSES: Interested persons are invited to submit written comments by email to *Thomas.J.Smith@census.gov*. Please reference Automated Export System Program in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2022–0023, to the Federal e-Rulemaking Portal: *https://www.regulations.gov*. All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Kiesha Downs, Chief, Trade Regulations Branch, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–6700, (301) 763–7079, or by email *kiesha.downs@census.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Title 13, United States Code (U.S.C.), Chapter 9, Section 301 authorizes the U.S. Census Bureau (Census Bureau) to collect, compile and publish trade data. Title 15, Code of Federal Regulations (CFR), Part 30, known as the Foreign Trade Regulations (FTR), contains the regulatory provisions for preparing and filing Electronic Export Information (EEI) in the Automated Export System (AES). The Census Bureau uses the AES or successor system as the instrument for collecting export trade data from parties exporting commodities from the United States. In addition to the collection of data, the Census Bureau compiles these export data from the AES. These data, along with import data function as the basis for the official U.S. trade statistics. The Census Bureau publishes import and export statistics that are used to determine the balance of international trade and are designated for use as a principal economic indicator. The Census Bureau releases these statistics monthly according to the U.S. International Trade in Goods and Services Press Release Schedule.

These data are used in the development of U.S. government economic and foreign trade policies, including export control purposes under Title 50, U.S.C. The Bureau of Industry and Security, U.S. Customs and Border

Protection (CBP), and other enforcement agencies use these data to detect and prevent the export of certain items by unauthorized parties to unauthorized destinations or end users. The published export data enables U.S. businesses to develop practical marketing strategies as well as provide a means to assess the impact of exports on the domestic economy.

Recently, the Census Bureau published a Notice of Proposed Rulemaking (NPRM) on December 15, 2021. The NPRM proposed to add a conditional data element, country of origin, in the AES. In addition to the new reporting requirement, the Census Bureau is making remedial changes to the FTR to improve clarity of the reporting requirements and to correct errors. It is critical for the Census Bureau to ensure that any revisions made to the FTR will allow for the continued collection and compilation of complete, accurate and timely trade statistics. This proposed rule would require an exporter to report the country of origin only when foreign origin goods are exported.

II. Method of Collection

Automated Export System

Except as noted in Title 15 CFR, Part 30, Section 30.2(a)(1)(iv), EEI is required for all export shipments of goods valued over $2,500 per Schedule B or Harmonized Tariff Schedule of the United States commodity classification number from the United States, including Foreign Trade Zones located therein, Puerto Rico, and the U.S. Virgin Islands to foreign countries; for exports between the United States and Puerto Rico; and for exports to the U.S. Virgin Islands from the United States or Puerto Rico. The AES program is unique among Census Bureau statistical collections since it is not sent to respondents to solicit responses, as is the case with surveys. Filing EEI via the AES is a mandatory process under the statutory authority of Title 13 U.S.C., Chapter 9, Section 301. The statutory requirement is implemented by Title 15, CFR, Part 30, also referred to as the FTR. The export trade community can access the AES via a free internet-based system, called AES*Direct,* or they can use software that connects directly with the Automated Commercial Environment (ACE). In most instances, the United States Principal Party in Interest or authorized agent must file EEI via the AES and annotate the commercial loading documents with the proof of filing citation prior to the export of a shipment. For scenarios where the EEI filing is not required, the proper exemption or exclusion legend must be noted on the commercial loading documents per Section 30.7 of the FTR.

For exports to Canada, a Memorandum of Understanding (MOU) signed by CBP, Canada Border Services Agency, Statistics Canada, and the Census Bureau enables the United States to substitute Canadian import statistics for U.S. export statistics. Similarly, in accordance with the MOU, Canada substitutes U.S. import statistics for Canadian exports to the United States. This exchange of data eliminates the requirement for the export trade community to file the EEI with the U.S. Government for the majority of export shipments to Canada, thus resulting in the elimination of over eight million EEI records filed in the AES annually. EEI must be filed through the AES for export shipments to Canada that require mandatory EEI filing under Title 15 CFR, Part 30, Section 30.2(a)(1)(iv). In addition, export shipments from the United States through Canada destined to a country other than Canada require EEI filing in the AES.

The AES enables the U.S. Government to significantly improve the quality, timeliness, and coverage of export statistics. Since July 1995, the Census Bureau and the CBP have utilized the AES to improve the reporting of export trade information, customer service, increase compliance with and enforcement of export laws, and to provide paperless reports of export information. The AES also enables the U.S. Government to increase its ability to prevent the export of certain items by unauthorized parties to unauthorized destinations and end users through electronic filing.

In addition to the AES, CBP continues to explore the ability to receive advance export manifest data, which may improve the accuracy of transportation data elements in the EEI filing and reduce updates to shipment information. CBP has extended and renewed its tests of the ACE Export Manifest for air, rail, and ocean cargo. These tests assess the electronic export manifest message specifications from the pilot participants to the ACE. These pilots are focused on CBP receiving electronic data and returning specific status messages back to the pilot participants. Since August 2021, the Census Bureau has been evaluating the collection of data from the electronic export rail manifest for goods moving from Port Huron, MI and departing on one rail carrier. The evaluation has proven that transportation data provided by the carrier is more accurate than transportation data estimated by the U.S. Principal Party in Interest and authorized agent. The Census Bureau's evaluation of the data quality from the electronic export rail manifest included the data elements: method of transportation, date of export, port of export, carrier identification and carrier name and foreign port of unlading.

Steel Mill Statistics

Since 1999, the Department of Commerce (DOC) has been approved to release data on imports of steel mill products in advance of the regular monthly trade statistics release. The International Trade Administration relies heavily on the preliminary import statistics of steel mill products provided by the Census Bureau in an effort to monitor steel imports so that industry can identify trends and potential shifts in trade patterns so that appropriate action can be taken. With the revision to the AES Program in 2019, the Census Bureau eliminated the need for a separate annual approval from OMB for the early release of preliminary steel mill import statistics since it is included in this clearance.

The FTR, subpart F addresses the general requirements for filing import entries with CBP in the ACE in accordance with 19 CFR, which is the source of the import data on steel mill products.

III. Data

OMB Control Number: 0607–0152.

Form Number(s): Automated Export System.

Type of Review: Regular submission, Request for a Revision of a Currently Approved Collection.

Affected Public: Exporters, Forwarding agents, Export Carriers.

Estimated Number of Respondents: 277,489.

Estimated Time Per Response: 3 minutes per AES submission.

Estimated Total Annual Burden Hours: 851,261.

Estimated Total Annual Cost to Public: $18,727,742.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 United States Code, Chapter 9, Section 301.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality,

utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–25316 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–51–2022]

Foreign-Trade Zone 39—Dallas/Fort Worth, Texas, Application for Reorganization and Expansion Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Dallas/Fort Worth international Airport Board, grantee of Foreign-Trade Zone 39, requesting authority to reorganize the zone to expand its service area and to include a new usage-driven site under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on November 15, 2022.

FTZ 39 was approved by the FTZ Board on August 17, 1978 (Board Order 133, 43 FR 37478, August 23, 1978), reorganized under the ASF on January 15, 2010 (Board Order 1660, 75 FR 4355, January 27, 2010), and expanded the ASF service area on May 16, 2014 (Board Order 1939, 79 FR 30079, May 27, 2014). The zone currently has a service area that includes Dallas, Tarrant, Kaufman, Collin, Grayson, Denton and Hunt Counties, Texas.

The applicant is now requesting authority to expand the service area of the zone to include Hill County, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Dallas/Fort Worth Customs and Border Protection Port of Entry.

The applicant is also requesting to expand its zone to include an additional usage-driven site: Proposed Site 34 (127 acres)—Frontier Support Logistics facilities located at 201, 350, 401 and 788 Industrial Loop Boulevard in Hillsboro, Hill County.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 20, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 6, 2023.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.* For further information, contact Camille Evans at *Camille.Evans@trade.gov.*

Dated: November 15, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–25268 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–52–2022]

Foreign-Trade Zone 64—Jacksonville, Florida, Application for Reorganization (Expansion of Service Area) Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Jacksonville Port Authority, grantee of Foreign-Trade Zone 64, requesting authority to reorganize the zone to expand its service area under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on November 15, 2022.

FTZ 64 was approved by the FTZ Board on December 29, 1980 (Board Order 170, 46 FR 1330, January 6, 1981) and reorganized under the ASF on May 6, 2011 (Board Order 1759, 76 FR 28418, May 17, 2011). The ASF service area was expanded on July 5, 2012 (Board Order 1840, 77 FR 41374, July 13, 2012) and on March 15, 2019 (Board Order 2080, 84 FR 10298, March 20, 2019). The zone currently has a service area that includes Baker, Bradford, Clay, Columbia, Duval, Flagler, Nassau, Putnam and St. Johns Counties, Florida.

The applicant is now requesting authority to expand the service area of the zone to include a portion of Alachua County, Florida, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Jacksonville, Florida U.S. Customs and Border Protection Port of Entry.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be

addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 20, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 6, 2023.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.* For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov.*

Dated: November 15, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–25269 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Rossiya Airlines, Pilotov St 18–4, St. Petersburg, Russia, 196210

Order Renewing Temporary Denial of Export Privileges

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on May 20, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On May 20, 2022, I signed an order denying the export privileges of Rossiya Airlines (''Rossiya'') for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2]

On October 24, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on May 20, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to Rossiya in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (Section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* Section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (Section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on May 20, 2022, was based on evidence that Rossiya engaged in conduct prohibited by the Regulations by operating multiple aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022, from destinations including but not limited to, Hurghada, Egypt; Sharm el-Sheikh, Egypt; Dubai, United Arab Emirates; and Sharjah, United Arab Emirates, without the required BIS authorization.[5] Further evidence submitted by BIS indicated that Rossiya was continuing to operate aircraft subject to the EAR domestically

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. App. § 2401 *et seq.* (''EAA''), (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, Section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on May 25, 2022 (87 FR 31856).

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

[5] Publicly available flight tracking information shows that on March 8, 2022, serial number (SN) 27650 flew from Hurghada, Egypt to Moscow, Russia. On March 6, 2022, SN 41212 flew from Sharm el-Sheikh, Egypt to St. Petersburg, Russia and SN 44435 flew from Dubai, United Arab Emirates to St. Petersburg, Russia. In addition, on March 7, 2022, SN 41202 flew from Sharjah, United Arab Emirates to Moscow, Russia.

on flights within Russia, potentially in violation of Section 736.2(b)(10) of the Regulations.

In its October 24, 2022, request for renewal of the TDO, BIS has submitted evidence that Rossiya continues to operate in violation of the May 20, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b. Specifically, BIS's evidence and related investigation indicated that after the issuance of the TDO, Rossiya continued to fly aircraft into Russia in violation of the EAR including flights from Antalya and Istanbul, Turkey. Furthermore, Rossiya has continued to operate aircraft subject to the EAR, which were flown into Russia on or after March 2, 2022, on flights within Russia, including, but not limited to, between such cities as Anadyr, Russia; Kaliningrad, Russia; Khaborovsk, Russia; Magadan, Russia; and Moscow, Russia, in violation of Section 736.2(b)(10) of the Regulations. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73292	28531	777–312 (B773)	Moscow, RU/Anadyr, RU	November 10, 2022.
RA–73292	28531	777–312 (B773)	Anadyr, RU/Moscow, RU	November 7, 2022.
RA–73292	28531	777–312 (B773)	Khaborovsk, RU/Moscow, RU	November 5, 2022.
RA–73292	28531	777–312 (B773)	Moscow, RU/Khaborovsk, RU	November 4, 2022.
RA–73292	28531	777–312 (B773)	Moscow, RU/Anadyr, RU	October 30, 2022.
RA–73279	28515	777–312 (B773)	Magadan, RU/Moscow, RU	October 17, 2022.
RA–73279	28515	777–312 (B773)	Moscow, RU/Magadan, RU	October 17, 2022.
RA–73279	28515	777–312 (B773)	Magadan, RU/Moscow, RU	October 18, 2022.
RA–73279	28515	777–312 (B773)	Moscow, RU/Magadan, RU	October 23, 2022.
RA–73279	28515	777–312 (B773)	Khaborovsk, RU/Moscow, RU	October 31, 2022.
RA–73218	35278	737–8Q8 (B738)	Antalya, TR/Moscow, RU	November 12, 2022.
RA–73218	35278	737–8Q8 (B738)	Istanbul, TR/Moscow, RU	November 11, 2022.
RA–73218	35278	737–8Q8 (B738)	Kaliningrad, RU/Moscow, RU	September 29, 2022.
RA–73218	35278	737–8Q8 (B738)	Moscow, RU/Kaliningrad, RU	September 28, 2022.
RA–73218	35278	737–8Q8 (B738)	Kaliningrad, RU/Moscow, RU	September 28, 2022.
RA–73191	33622	737–8AS (B738)	Antalya, TR/Moscow, RU	November 1, 2022.
RA–73191	33622	737–8AS (B738)	Istanbul, TR/St. Petersburg, RU	November 2, 2022.
RA–73191	33622	737–8AS (B738)	Moscow, RU/Krasnoyarsk, RU	November 4, 2022.
RA–73191	33622	737–8AS (B738)	Krasnoyarsk, RU/Irkutsk, RU	November 5, 2022.
RA–73193	33602	737–8AS (B738)	Antalya, TR/Moscow, RU	November 3, 2022.
RA–73193	33602	737–8AS (B738)	Istanbul, TR/Moscow, RU	November 4, 2022.
RA–73193	33602	737–8AS (B738)	Antalya, TR/Moscow, RU	November 5, 2022.
RA–73193	33602	737–8AS (B738)	Antalya, TR/Moscow, RU	November 8, 2022.
RA–73193	33602	737–8AS (B738)	Istanbul, TR/St. Petersburg, RU	November 9, 2022.

III. Findings

Under the applicable standard set forth in Section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Rossiya has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with Rossiya, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, Rossiya Airlines, Pilotov St 18–4, St. Petersburg, Russia, 196210, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Rossiya any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Rossiya of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Rossiya acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Rossiya of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

D. Obtain from Rossiya in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Rossiya, or service any item, of whatever origin, that is owned, possessed or controlled by Rossiya if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Rossiya by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of Sections 766.24(e) of the EAR, Rossiya may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Rossiya as provided in Section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Rossiya, and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2022–25265 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–913, C–821–834]

Oil Country Tubular Goods From the Republic of Korea and the Russian Federation: Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing countervailing duty orders on oil country tubular goods (OCTG) from the Republic of Korea (Korea) and the Russian Federation (Russia).

DATES: Applicable November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Melissa Porpotage (Korea) and Theodore Pearson (Russia), AD/CVD Operations, Offices I and II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1413 and (202) 482–2631, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with section 705(d) of the Tariff Act of 1930, as amended (the Act), on September 29, 2022, Commerce published its affirmative final determinations in the countervailing duty investigations of OCTG from Korea and Russia.[1] On November 14, 2022, the ITC notified Commerce of its affirmative final determinations that an industry in the United States is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act, by reason of subsidized imports of subject merchandise from Korea and Russia.[2]

Scope of the Orders

The products covered by these orders are OCTG from Korea and Russia. For a complete description of the scope of the orders, *see* the appendix to this notice.

Countervailing Duty Orders

As noted above, on November 14, 2022, in accordance with section 705(d) of the Act, the ITC notified Commerce of its final determinations in these investigations, in which it found that an industry in the United States is materially injured by reason of subsidized imports of OCTG from Korea and Russia.[3] Therefore, in accordance with section 705(c)(2) of the Act, Commerce is issuing these countervailing duty orders. Because the ITC determined that imports of OCTG from Korea and Russia are materially injuring a U.S. industry, unliquidated entries of such merchandise from Korea and Russia, entered or withdrawn from warehouse for consumption, are subject to the assessment of countervailing duties.

[1] *See Oil Country Tubular Goods from the Republic of Korea: Final Affirmative Countervailing Duty Determination,* 87 FR 59056 (September 29, 2022) (*Korea Final Determination*); *see also Oil Country Tubular Goods from the Russian Federation: Final Affirmative Countervailing Duty Determination and Final Negative Critical Circumstances Determination,* 87 FR 59057 (September 29, 2022).

[2] *See* ITC Letter, ''Chairman Transmittal of Determinations to Commerce,'' dated November 14, 2022.

[3] *Id.*

In accordance with section 706(a) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, countervailing duties for all relevant entries of OCTG from Korea and Russia. Regarding Korea, because Commerce made a preliminary negative countervailing duty determination,[4] Commerce did not direct CBP to suspend liquidation or to require a cash deposit of estimated countervailing duties for entries of OCTG from Korea on or after March 14, 2022, the date of publication of the *Korea Preliminary Determination.* However, because Commerce made a final affirmative countervailing duty determination, Commerce directed CBP to begin suspension of liquidation of OCTG from Korea entered, or withdrawn from warehouse, for consumption on or after September 29, 2022, the date of publication of the *Korea Final Determination*.[5] Regarding Russia, with the exception of entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final affirmative injury determinations, as further described below, countervailing duties will be assessed on unliquidated entries of OCTG from Russia entered, or withdrawn from warehouse, for consumption on or after March 14, 2022, the date of publication of the *Russia Preliminary Determination*.[6]

Suspension of Liquidation

In accordance with section 706 of the Act, Commerce will instruct CBP to continue to suspend liquidation of all relevant entries of OCTG from Korea. For Russia, Commerce will instruct CBP to reinstitute the suspension of liquidation of OCTG from Russia, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. These instructions suspending liquidation will remain in effect until further notice.

Commerce also intends, pursuant to section 706(a)(1) of the Act, to instruct CBP to assess countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates below. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, CBP must require, at the same time as importers would deposit estimated normal customs duties on this merchandise, a cash deposit equal to the rates listed in the table below. The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

Because the countervailable subsidy rate is *de minimis* for subject merchandise produced and exported by Hyundai Steel Corporation, entries of shipments of subject merchandise from this producer/exporter combination are excluded from the countervailing duty order on subject merchandise from Korea.

Producer/exporter	Subsidy rate (percent *ad valorem*)
Korea:	
Hyundai Steel Company[7]	0.25
SeAH Steel Corporation[8]	1.33
All Others	1.33
Russia:	
Volzhsky Pipe Plant, Joint Stock Company; Sinarsky Pipe Plant, Joint Stock Company; Seversky Pipe Plant, Joint Stock Company; Taganrog Metallurgical Plant, Joint Stock Company; Orsky Machine Building Plant, Joint Stock Company; and PAO TMK[9]	1.30
JSC Vyksa Steel Works[10]	1.59
All Others	1.43

(*de minimis*)

Provisional Measures

Section 703(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. For Russia, in the underlying investigation, Commerce published the *Russia Preliminary Determination,* which was affirmative, on March 14, 2022. Therefore, the four-month period beginning on the date of the publication of the *Russia Preliminary Determination* ended on July 11, 2022.

In accordance with section 703(d) of the Act, we instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, unliquidated entries of OCTG from Russia entered, or withdrawn from warehouse, for consumption after July 11, 2022, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[11] On September 27, 2021, Commerce also published the

[4] *See Oil Country Tubular Goods from the Republic of Korea: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 87 FR 14248 (March 14, 2022) (*Korea Preliminary Determination*).

[5] *See Korea Final Determination,* 87 FR at 59057.

[6] *See Oil Country Tubular Goods from the Russian Federation: Preliminary Affirmative Countervailing Duty Determination, Preliminary Negative Critical Circumstances Determination, and Alignment of Final Determination with Final Antidumping Duty Determination* 87 FR 14249 (March 14, 2022) (*Russia Preliminary Determination*).

[7] Hyundai Steel Company must be both the producer and exporter of the subject merchandise for purposes of this rate application.

[8] Commerce has found the following company to be cross-owned with SeAH Steel Corporation: SeAH Steel Holding Corporation.

[9] Commerce has found the following companies to be cross-owned with Volzhsky Pipe Plant, Joint Stock Company: TMK Neftegasservice-Nizhnevartovsk, Joint Stock Company; TMK Neftegasservice-Buzuluk, Limited Liability Company; Russian Research Institute of the Tube & Pipe Industries, JSC; and Scientific and Technical Center TMK, LLC.

[10] Commerce has found the following companies to be cross-owned with JSC Vyska Steel Works: BusinessOptima; Metallolomaya Company OMK—Ecometall; United Metallurgical Company; and Joint-Stock Company Trubodetal.

[11] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

notice titled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[12] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[13]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available *at https://access.trade.gov,* within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [14]

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance,* the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [15] Accordingly, as stated above, the petitioners and the Governments of Korea and Russia should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioners and the Governments of Korea and Russia will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and the Governments of Korea and Russia are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the countervailing duty orders with respect to OCTG from Korea and Russia pursuant to section 706(a) of the Act. Interested parties can find a list of countervailing duty orders currently in effect at *https://enforcement.trade.gov/stats/iastats1.html.*

These countervailing orders are issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: November 16, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Orders

The merchandise covered by these orders is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of these orders also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of these orders if performed in the country of manufacture of the OCTG.

Excluded from the scope of these orders are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to these orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160, 7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to these orders may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of these orders is dispositive.

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BILLING CODE 3510–DS–P

[12] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[13] *Id.*

[14] This segment will be combined with the ACCESS Segment Specific Information (SSI) field, which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[15] *See Final Rule,* 86 FR at 52335.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–824, A–201–856, A–821–833]

Oil Country Tubular Goods From Argentina, Mexico, and the Russian Federation: Antidumping Duty Orders and Amended Final Affirmative Antidumping Duty Determination for the Russian Federation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing antidumping duty (AD) orders on oil country tubular goods (OCTG) from Argentina, Mexico, and the Russian Federation (Russia). In addition, Commerce is amending its final determination with respect to OCTG from Russia to correct a ministerial error.

DATES: Applicable November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov (Argentina), Yang Chun or Emily Bradshaw (Mexico), and George McMahon or Michael Heaney (Russia), AD/CVD Operations, Offices I and VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0665, (202) 482–5760, (202) 482–3986, (202) 482–1167, or (202) 482–4475, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended (the Act), on October 5, 2022, Commerce published its affirmative final determinations in the less-than-fair-value (LTFV) investigations of OCTG from Argentina, Mexico, and Russia.[1] In the investigation of OCTG from Russia, JSC Vyksa Steel Works (OMK/VSW) submitted a timely allegation that Commerce made a ministerial error in the final AD determination.[2] We reviewed the allegation and determined that we made a ministerial error in the final AD determination on OCTG from Russia. *See* ''Amendment to the Final Determination for Russia'' section below for further discussion. On November 14, 2022, the ITC notified Commerce of its final determinations, pursuant to section 735(d) of the Act, that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of OCTG from Argentina, Mexico, and Russia.[3]

Scope of the Orders

The products covered by these orders are OCTG from Argentina, Mexico, and Russia. For a complete description of the scope of these orders, *see* the appendix to this notice.

Amendment to the Final Determination for Russia

On September 30, 2022, OMK/VSW timely alleged that Commerce made a certain ministerial error in the *Russia Final Determination* with respect to the dumping margin assigned to OMK/VSW.[4] No other party made an allegation of ministerial errors or submitted a rebuttal to OMK/VSW's ministerial error allegation under 19 CFR 351.224(c)(3). Commerce reviewed the record and, on October 26, 2022, agreed that the error alleged by OMK/VSW constituted a ministerial error within the meaning of section 735(e) of the Act and 19 CFR 351.224(f).[5] Specifically, Commerce found that it made an inadvertent error in not converting into U.S. dollars a certification expense reported by OMK/VSW in Russian rubles.[6] Pursuant to 19 CFR 351.224(e), Commerce is amending the *Russia Final Determination* to reflect the correction of the ministerial error, as described in the Ministerial Error Memorandum.[7] Based on the correction, OMK/VSW's final dumping margin changed from 12.84 to 12.01 percent. As a result, we are also revising the all-others rate from 12.84 to 12.01 percent. The amended estimated weighted-average dumping margins are listed in the ''Estimated Weighted-Average Dumping Margins'' section below.

Antidumping Duty Orders

On November 14, 2022, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determinations in these investigations, in which it found that an industry in the United States is materially injured by reason of imports of OCTG from Argentina, Mexico, and Russia. Therefore, in accordance with section 735(c)(2) of the Act, Commerce is issuing these AD orders. Because the ITC determined that imports of OCTG from Argentina, Mexico, and Russia are materially injuring a U.S. industry, unliquidated entries of such merchandise from Argentina, Mexico, and Russia, entered or withdrawn from warehouse for consumption, are subject to the assessment of ADs.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, ADs equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of OCTG from Argentina, Mexico, and Russia. With the exception of entries occurring after the expiration of the provisional measures period and before publication of the ITC's final affirmative injury determinations, as further described below, antidumping duties will be assessed on unliquidated entries of OCTG from Argentina, Mexico, and Russia, entered, or withdrawn from warehouse, for consumption, on or after May 11, 2022, the date of publication of the *Preliminary Determinations*.[8]

Continuation of Suspension of Liquidation and Cash Deposits

Except as noted in the ''Provisional Measures'' section of this notice, in accordance with section 735(c)(1)(B) of

[1] *See Oil Country Tubular Goods from Argentina: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances,* 87 FR 59054 (September 29, 2022); *Oil Country Tubular Goods from Mexico: Final Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances,* 87 FR 59041 (September 29, 2022); and *Oil Country Tubular Goods from the Russian Federation: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Affirmative Critical Circumstances Determination, in Part,* 87 FR 59045 (September 29, 2022) (*Russia Final Determination*).

[2] *See* OMK/VSW's Letter, ''Oil Country Tubular Goods from the Russian Federation: OMK's Ministerial Error Comments,'' dated September 30, 2022 (Ministerial Error Allegation).

[3] *See* ITC's Letter, Investigation Nos. 701–TA–671–672 and 731–TA–1571–1573 (Final), dated November 14, 2022.

[4] *See* Ministerial Error Allegation.

[5] *See* Memorandum, ''Antidumping Duty Investigation of Oil Country Tubular Goods from the Russian Federation: Allegation of Ministerial Error in the Final Determination,'' dated October 26, 2022 (Ministerial Error Memorandum).

[6] *See* Memorandum, ''Amended Final Analysis Memorandum for JSC Vyksa Steel Works,'' dated October 26, 2022.

[7] *Id.*

[8] *See Oil Country Tubular Goods from Argentina: Preliminary Affirmative Determinations of Sales at* Less Than Fair Value and Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures, 87 FR 28801 (May 11, 2022); *Oil Country Tubular Goods from Mexico: Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 87 FR 28808 (May 11, 2022); and *Oil Country Tubular Goods from the Russian Federation: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Critical Circumstances Determination, Postponement of Final Determination, and Extension of Provisional Measures,* 87 FR 28804 (May 11, 2022) (collectively, *Preliminary Determinations*).

the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of OCTG from Argentina, Mexico, and Russia. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the estimated weighted-average dumping margins indicated in the tables below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determinations, CBP will require, at the same time as importers would normally deposit estimated duties on subject merchandise, a cash deposit equal to the rates listed in the table below. The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margin (percent)
Argentina:	
Siderca S.A.I.C	78.30
All Others	78.30
Mexico:	
Tubos de Acero de Mexico, S.A	44.93
All Others	44.93

Exporter or producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Russia:		
JSC Vyksa Steel Works	12.01	11.70
Volzhsky Pipe Plant, Joint Stock Company; Public Joint-Stock Company Trubnaya Metallurgicheskaya Kompaniya; Sinarsky Pipe Plant, Joint Stock Company; Seversky Pipe Plant, Joint Stock Company; Taganrog Metallurgical Plant, Joint Stock Company; Pervouralsk Pipe Plant, Joint Stock Company; Chelyabinsk Pipe Plant, Joint Stock Company; Orsky Machine Building Plant, Joint Stock Company *	184.21	184.21
All Others	12.01	11.87

* Rate based on adverse facts available.

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request that Commerce extend the four-month period to no more than six months. At the request of exporters that account for a significant proportion of OCTG from Argentina, Mexico, and Russia, Commerce extended the four-month period to six months in each of these investigations. Commerce published the *Preliminary Determinations* on May 11, 2022.[9]

The extended provisional measures period, beginning on the date of publication of the *Preliminary Determinations,* ended on November 6, 2022. Therefore, in accordance with section 733(d) of the Act and our practice,[10] Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of OCTG from Argentina, Mexico, and Russia entered or withdrawn from warehouse, for consumption after November 6, 2022, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determinations in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determinations in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[11] On September 27, 2021, Commerce also published the notice titled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[12] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[13]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available *at https://access.trade.gov,* within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and

[9] *Id.*

[10] *See, e.g., Certain Corrosion-Resistant Steel Products from India, India, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390, 48392 (July 25, 2016).

[11] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[12] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[13] *Id.*

under a specific segment type called ''AISL-Annual Inquiry Service List.'' [14]

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance,* the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [15] Accordingly, as stated above, the petitioners and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the AD orders with respect to OCTG from Argentina, Mexico, and Russia pursuant to section 736(a) of the Act. Interested parties can find a list of AD orders currently in effect at *https://www.trade.gov/data-visualization/adcvd-proceedings.*

The amended Russia final determination and these AD orders are published in accordance with sections 735(e) and 736(a) of the Act and 19 CFR 351.224(e) and 19 CFR 351.211(b).

Dated: November 16, 2022

Lisa W. Wang,

Assistant Secretary,for Enforcement and Compliance.

Appendix—Scope of the Orders

The merchandise covered by these orders is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than case iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of these orders also covers OCTG coupling stock.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise processed in a third country, including by performing any heat treatment, cutting, upsetting, threading, coupling, or any other finishing, packaging, or processing that would not otherwise remove the merchandise from the scope of these orders if performed in the country of manufacture of the OCTG.

Excluded from the scope of these orders are: casing, tubing, or coupling stock containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to these orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.1010, 7304.29.1020, 7304.29.1030, 7304.29.1040, 7304.29.1050, 7304.29.1060, 7304.29.1080, 7304.29.2010, 7304.29.2020, 7304.29.2030, 7304.29.2040, 7304.29.2050, 7304.29.2060, 7304.29.2080, 7304.29.3110, 7304.29.3120, 7304.29.3130, 7304.29.3140, 7304.29.3150, 7304.29.3160, 7304.29.3180, 7304.29.4110, 7304.29.4120, 7304.29.4130, 7304.29.4140, 7304.29.4150, 7304.29.4160, 7304.29.4180, 7304.29.5015, 7304.29.5030, 7304.29.5045, 7304.29.5060, 7304.29.5075, 7304.29.6115, 7304.29.6130, 7304.29.6145, 7304.29.6160, 7304.29.6175, 7305.20.2000, 7305.20.4000, 7305.20.6000, 7305.20.8000, 7306.29.1030, 7306.29.1090, 7306.29.2000, 7306.29.3100, 7306.29.4100, 7306.29.6010, 7306.29.6050, 7306.29.8110, and 7306.29.8150.

The merchandise subject to these orders may also enter under the following HTSUS item numbers: 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076, 7304.39.0080, 7304.59.6000, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, 7304.59.8070, 7304.59.8080, 7305.31.4000, 7305.31.6090, 7306.30.5055, 7306.30.5090, 7306.50.5050, and 7306.50.5070.

The HTSUS subheadings and specifications above are provided for convenience and customs purposes only. The written description of the scope of these orders is dispositive.

[FR Doc. 2022–25401 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–DS–P

[14] This segment will be combined with the ACCESS Segment Specific Information (SSI) field, which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[15] *See Final Rule,* 86 FR at 52335.

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 21, 2022.

SUMMARY: The U.S. Department of Commerce (Commerce) hereby publishes a list of scope rulings and circumvention determinations made during the period July 1, 2022, through September 30, 2022. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Marcia E. Short, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–1560.

SUPPLEMENTARY INFORMATION:

Background

Commerce regulations provide that it will publish in the **Federal Register** a list of scope rulings on a quarterly basis.[1] Our most recent notification of scope rulings was published on August 25, 2022.[2] This current notice covers all scope rulings and scope ruling/circumvention determination combinations made by Enforcement and

[1] *See* 19 CFR 351.225(o).

[2] *See Notice of Scope Rulings,* 87 FR 52359 (August 25, 2022).

Compliance between July 1, 2022, and September 30, 2022.

Scope Rulings Made July 1, 2022 Through September 30, 2022

People's Republic of China (China)

A–570–135 and C–570–136: Certain Chassis and Subassemblies Thereof From China

Requestor: Trans Texas Tire LLC. Wheel caps are not covered by the scope of the antidumping duty (AD) order on certain chassis and subassemblies thereof from China because these components are not used for further assembly with a finished or unfinished chassis and are utilized solely for marine trailers, utility trailers, and recreational vehicles; July 6, 2022.

A–570–106 and C–570–107: Wooden Cabinets and Vanities and Components Thereof From China

Requestor: AYC LLC. Chloe Styling Station is not covered by the scope of these orders because this product is a freestanding cabinet that is not for permanent installation. The scope of the orders covers wooden cabinets and vanities that are for permanent installation. Therefore, Chloe Styling Station is outside the scope of the orders. Further, Sanden Shampoo Cabinet (AYC Styling Station) is covered by the scope of the orders because this product requires permanent installation by attachment of plumbing and, thus, falls within the scope as a cabinet for permanent installation; August 1, 2022.

A–570–922: Raw Flexible Magnets From China

Requestor: Fasteners for Retail, Inc. dba Siffron. Siffron's plastic shelf dividers are outside the scope of the AD order on raw flexible magnets from China because the raw flexible magnet component of the plastic shelf dividers is rendered inflexible by attachment to a component plastic blade, and the order only pertains to flexible magnets. Therefore, Siffron's plastic shelf divider is not within the scope of the order; August 9, 2022.

A–570–090 and C–570–091: Certain Steel Wheels 12 to 16.5 Inches in Diameter From China

Requestor: Wheel Source, Inc. (Wheel Source). Passenger vehicle wheel model numbers X–76801 and 28860W, which are 16 inches in diameter, imported by Wheel Source are not covered by the scope of the AD and countervailing duty (CVD) orders on certain steel wheels 12 to 16.5 inches in diameter (steel wheels) from China because they have different hub bore sizes, offsets, and load ratings that make them unsuitable for use on trailer or towable equipment; August 26, 2022.

A–570–899: Certain Artist Canvas From China

Requestor: RV Print Factory LLC (RV Print). Certain polyester fabrics coated with ethylene-vinyl acetate (EVACPET) imported by RV Print are covered by the scope of the AD order on artist canvas from China because the fabrics are primed/coated with EVACPET to convert the fabric into a canvas and enter the United States as rolls that are converted/printed, varnished, framed, and shipped as artwork prints and custom photos; August 29, 2022.

Preliminary Scope Ruling/ Circumvention Determination Combinations Made July 1, 2022 Through September 30, 2022

China

A–570–051 and C–570–052: Certain Hardwood Plywood Products From China

Requestor: Coalition for Fair Trade in Hardwood Plywood. Commerce preliminarily found that hardwood plywood products assembled in Vietnam using certain inputs/ components sourced from China and exported to the United States are covered by the scope of the AD and CVD rders on hardwood plywood products from China.

Additionally, Commerce preliminarily determined that hardwood plywood products assembled in Vietnam using certain inputs/ components sourced from China and exported to the United States were not initially covered by the scope but were preliminarily found to be circumventing the orders; July 22, 2022.

A–570–042 and C–570–043: Stainless Steel Sheet and Strip (SSSS) From China

Self-initiated Scope/Circumvention Inquiry concerning SSSS from China, further processed in and exported from Vietnam. Preliminarily found that SSSS produced in China that meets all specifications of in-scope merchandise but is exported from Vietnam, is covered by the scope of the AD and CVD orders on SSSS from China because the scope includes language covering SSSS that is further processed in a third country (*e.g.,* Vietnam).

Additionally, preliminarily found that SSSS that meets all specifications of in-scope merchandise but is produced in Vietnam using certain non-subject stainless steel flat-rolled inputs of Chinese-origin were not initially covered by the scope, but were preliminarily found to be circumventing the AD and CVD orders on SSSS from China because the processing performed in Vietnam is minor or insignificant based on the totality of the factors under section 781(b)(2) of the Tariff Act of 1930, as amended; September 9, 2022.

Notification to Interested Parties

Interested parties are invited to comment on the completeness of this list of completed scope inquiries and scope/circumvention inquiry combinations made during the period July 1, 2022 through September 30, 2022. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to *CommerceCLU@trade.gov.*

This notice is published in accordance with 19 CFR 351.225(o).

Dated: November 16, 2022.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2022–25300 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Term Extension and Adjustment

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0020 Patent Term Extension and Adjustment. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before January 20, 2023.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business

Information or otherwise sensitive or protected information.

• *Email: InformationCollection@uspto.gov.* Include ''0651–0020 comment'' in the subject line of the message.

• *Federal Rulemaking Portal: https://www.regulations.gov.*

• *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3248; or by email at *parikha.mehta@uspto.gov* with ''0651–0020 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or United States Department of Agriculture (USDA). Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is 5 years. The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710–1.791.

This information collection covers information gathered in patent term extension applications submitted under 35 U.S.C. 156(d). Under this provision, an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the submission of information that enables the USPTO to determine the eligibility of the patent for extension, and the rights that will be derived from the extension, and information to enable the USPTO and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension. Additionally, 35 U.S.C. 156(d) requires the applicant for patent term extension to provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

This information collection also covers information gathered in requests for interim extensions pursuant to 35 U.S.C. 156(d)(5) and 156(e)(2). Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect. Under 35 U.S.C. 156(e)(2), an interim extension may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. In addition, this information collection covers requests for review of final eligibility decisions, and requests to withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases adjust the term of an original patent under the provisions of 35 U.S.C. 154 due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse USPTO determination of patentability. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701–1.705. The patent term provisions of 35 U.S.C. 154(b), as amended by Title IV, Subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, allow the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. This information collection covers information gathered in such a request.

In addition, this information collection covers information collected when the USPTO reduces the amount of a granted patent term adjustment if delays were caused by an applicant's failure to make a reasonable effort to respond to a communication from the USPTO within three months of the communication's mailing date. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period.

The title of this item has been changed from ''Patent Term Extension'' to ''Patent term Extension and Adjustment'' to better reflect the scope of actions available regarding Patent terms that are a part of this information collection.

II. Method of Collection

Electronically, by mail, or hand delivery to the USPTO.

III. Data

OMB Control Number: 0651–0020.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent's Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 915 respondents.

Estimated Number of Annual Responses: 915 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 1 hour and 25 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 6,113 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $2,659,155.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item name	Estimated annual respondents (a)	Respondents per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time per response (hour) (d)	Total annual hour burden (c) × (d) = (e)	Hourly cost burden rate [1] (f)	Total annual cost for time spent (e) × (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156.	146	1	146	25	3,650	$435	$1,587,750

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS—Continued

Item No.	Item name	Estimated annual respondents (a)	Respondents per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time per response (hour) (d)	Total annual hour burden (c) × (d) = (e)	Hourly cost burden rate [1] (f)	Total annual cost for time spent (e) × (f) = (g)
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2).	29	1	29	1	29	435	12,615
3	Petition to review final Eligibility Decision Under 37 CFR 1.750.	2	1	2	25	50	435	21,750
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5).	8	1	8	20	160	435	69,600
5	Subsequent Application for Interim Extension Under 37 CFR 1.790.	7	1	7	1	7	435	3,045
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period.	39	1	39	1	39	435	16,965
7	Response to Request to Identify Holder of Regulatory Approval.	2	1	2	2	4	435	1,740
8	Declaration to Withdraw an Application to Extend Patent Term.	1	1	1	2	2	435	870
9	Petition for Reconsideration of Patent Term Adjustment Determination.	631	1	631	3	1,893	435	823,455
10	Petition for Reinstatement of Reduced Patent Term Adjustment.	14	1	14	4	56	435	24,360
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term.	4	1	4	2	8	435	3,480
Totals		883		883		5,898		2,565,630

TABLE 2—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item name	Estimated annual respondents (a)	Respondents per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time per response (hour) (d)	Total annual hour burden (c) × (d) = (e)	Hourly cost burden rate [2] (f)	Total annual cost for time spent (e) × (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156.	4	1	4	25	100	$435	$43,500
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2).	1	1	1	1	1	435	435
3	Petition to review final Eligibility Decision Under 37 CFR 1.750.	1	1	1	25	25	435	10,875
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5).	1	1	1	20	20	435	8,700
5	Subsequent Application for Interim Extension Under 37 CFR 1.790.	1	1	1	1	1	435	435
6	Response to Requirement to Elect.	1	1	1	1	1	435	435
7	Response to Request to Identify Holder of Regulatory Approval.	1	1	1	2	2	435	870
8	Declaration to Withdraw an Application to Extend Patent Term.	1	1	1	2	2	435	870
9	Petition for Reconsideration of Patent Term Adjustment Determination.	19	1	19	3	57	435	24,795
10	Petition for Reinstatement of Reduced Patent Term Adjustment.	1	1	1	4	4	435	1,740
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term.	1	1	1	2	2	435	870

TABLE 2—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL AND HOUSEHOLD RESPONDENTS—Continued

Item No.	Item name	Estimated annual respondents (a)	Respondents per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time per response (hour) (d)	Total annual hour burden (c) × (d) = (e)	Hourly cost burden rate [2] (f)	Total annual cost for time spent (e) × (f) = (g)
Totals	.....	32	.....	32	.....	215	.....	93,525

Estimated Total Annual Respondent Non-hourly Cost Burden: $327,003.

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of filing fees ($326,920) and postage ($83), is $327,003.

Filing Fees

The items with filing fees are listed in the table below.

TABLE 3—FILING FEES

Item No.	Item	Annual estimated responses	Filing fee	Total cost
1	Application to Extend Patent Term Under 35 U.S.C. 156	150	$1,180	$177,000
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	10	440	4,400
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	10	230	2,300
9	Petition for Reconsideration of Patent Term Adjustment Determination	650	210	136,500
10	Petition for Reinstatement of Reduced Patent Term Adjustment	15	420	6,300
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term.	1	420	420
Totals	.....	836	.....	326,920

Postage

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO expects that approximately 1% of the 915 responses in this information collection will be submitted in the mail, resulting in 9 mailed submissions. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $9.25. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this information collection will total $83.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Adminstrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022–25314 Filed 11–18–22; 8:45 am]

BILLING CODE 3510–16–P

[1] 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F–27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is $435 per hour.

[2] Ibid.

COMMODITY FUTURES TRADING COMMISSION

Request for Nominations for the Energy Infrastructure Subcommittee and the Role of Metals Markets in Transitional Energy Subcommittee Under the Energy and Environmental Markets Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) is requesting nominations for membership on the Energy Infrastructure Subcommittee (Infrastructure Subcommittee) and the Role of Metals Markets in Transitional

Energy Subcommittee (Metals Market Subcommittee) under the Energy and Environmental Markets Advisory Committee (EEMAC). The EEMAC is an advisory committee established by the Dodd-Frank Wall Street Reform and Consumer Protection Act.

DATES: The deadline for submission of nominations is December 5, 2022.

ADDRESSES: Nominations should be emailed to *EEMAC_Submissions@cftc.gov* or sent by post to Lauren Fulks, EEMAC Secretary, Commodity Futures Trading Commission, 2600 Grand Boulevard, Suite 200, Kansas City, MO 64108. Please use the title ''EEMAC Subcommittees'' for any nominations you submit.

FOR FURTHER INFORMATION CONTACT: Lauren Fulks, EEMAC Secretary, at (816) 787–6297 or email *EEMAC_Submissions@cftc.gov.*

SUPPLEMENTARY INFORMATION: The Infrastructure Subcommittee was established to provide a report to the EEMAC that will evaluate what is required to ensure the energy markets in the United States remain resilient despite the numerous strains on the system globally. Topics and issues this subcommittee may consider in this regard include, but are not limited to, the following:

- Given the importance of predictable supply and reliable distribution of energy to effective energy derivatives markets, identifying the state of infrastructure of various energy markets, including but not limited to, oil, natural gas, and electricity, and examining how investment in infrastructure in recent years has contributed to the current state of infrastructure;
- Examining how the current state of energy infrastructure has impacted market fundamentals, such as supply and demand, price discovery, price volatility, and market participation;
- Identifying key issues facing energy derivatives markets that are related to or a result of energy market fundamentals and dynamics; and
- Examining if and how financial regulation can address current issues in the energy derivatives markets.

The Metals Market Subcommittee was established to provide a report to the EEMAC to examine the role of critical metals in transitional energy sources and their potential impact on derivatives markets. Within this charge, this subcommittee may consider, but is not limited to, the following issues and topics:

- Identifying metals that are used as components in transitional energy sources and their related derivatives markets, or lack thereof;
- Examining how the increased demand for certain metals impact existing derivatives markets;
- Examining the issues around creating new derivatives markets for metals that will be integral in transitional energy; and
- Examining if and how financial regulation should change given the increased demand on and need for metals derivatives markets.

The subcommittees will provide their reports directly to the EEMAC and will not provide their reports directly to the Commission. The subcommittees have no authority to make decisions on behalf of the EEMAC, and no determination of fact or policy will be made by the subcommittees on behalf of the Commission.

Subcommittee members will generally serve as representatives and provide advice reflecting the views of diverse stakeholder organizations and entities within the derivatives and financial markets. The subcommittees may also include regular government employees when doing so furthers their purposes. It is anticipated that the subcommittees will hold at least three in-person or telephonic meetings. Subcommittee members serve at the pleasure of the Commission. Subcommittee members do not receive compensation or honoraria for their services, and they are not reimbursed for travel and per diem expenses.

Subcommittee members will include individuals who are Members or Associate Members of the EEMAC and/or other individuals. For these other individuals, the Commission seeks nominations of individuals from a wide range of perspectives, including from industry, academia, the government, and public interest. To advise the EEMAC effectively, subcommittee members must have a high level of expertise and experience with: the energy and/or metals markets, the Commodity Exchange Act, Commission regulations, and guidance thereunder. To the extent practicable, and consistent with these objectives, the Commission will strive to include members reflecting wide ethnic, racial, gender, and age representation.

The Commission invites the submission of nominations for membership on the subcommittees. Each nomination submission should include the proposed member's name, title, organization affiliation, address, email address, and telephone number, as well as information that supports the individual's qualifications to serve on a subcommittee. The submission should also include the name, email address, and telephone number of the person nominating the proposed subcommittee member. Self-nominations are acceptable.

Submission of a nomination is not a guarantee of selection as a member of a subcommittee. The Commission will identify members for the subcommittees based on Commissioners' and Commission staff's professional knowledge of the energy and metals markets, consultation with knowledgeable persons outside of the CFTC, and requests received from organizations. The Commission, by vote, will authorize members to serve on the subcommittees.

Authority: 5 U.S.C. app. II.

Dated: November 16, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2022–25256 Filed 11–18–22; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0144]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Subpart K—Cash Management

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 20, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0144. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will*

not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Subpart K—Cash Management.

OMB Control Number: 1845–0038.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments; Individuals or Households.

Total Estimated Number of Annual Responses: 19,605,555.

Total Estimated Number of Annual Burden Hours: 861,393.

Abstract: This request is for an extension of the current information collection 1845–0038 that is expiring. This collection pertains to the recordkeeping requirements contained in the regulations related to the administration of the Subpart K—Cash Management section of the Student Assistance General Provisions. The regulatory language has not changed. These program regulations are designed to provide benefits to Title IV, HEA applicants, and protect the taxpayers' interest. The information collection requirements in these regulations are necessary to provide students with required information about their eligibility to receive funding under the federal student financial aid programs and to prevent fraud and abuse of program funds by allowing students to reduce or reject aid being offered as well as being made aware of when such funding can be expected to be available.

Dated: November 16, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–25254 Filed 11–18–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

U.S. Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: EIA submitted an information collection request for extension as required by the Paperwork Reduction Act of 1995. The information collection requests a three-year extension with changes to the Electric Power & Renewable Electricity Surveys (EPRES), OMB Control Number; 1905–0129. EPRES consists of nine surveys, including annual, monthly and one daily survey. These surveys collect data from entities involved in the production, transmission, delivery, and sale of electricity, and in maintaining the reliable operation of the power system. The data collected are the primary source of information on the nation's electric power system. The renewable energy survey collects information on the manufacture, shipment, import, and export of photovoltaic cells and modules, and is the primary national source of information on these topics.

DATES: Comments on this information collection must be received no later than December 21, 2022. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Paul McArdle, (202) 586–4445 email: *Electricity2023@eia.gov.* The forms and instructions are available on EIA's website at *https://www.eia.gov/survey/.*

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1905–0129;

(2) *Information Collection Request Title:* Electric Power & Renewable Electricity Surveys;

(3) *Type of Request:* Three-year extension with changes;

(4) *Purpose:* EIA's EPRES consists of the following nine surveys:

Form EIA–63B *Photovoltaic Module Shipments Report* tracks photovoltaic module manufacturing, shipments, technology types, revenue, and related information.

Form EIA–860 *Annual Electric Generator Report* collects data on existing and planned electric generation plants, and associated equipment including generators, boilers, cooling systems, and environmental control systems. Data are collected from all existing units and from planned units scheduled for initial commercial operation within ten years of the specified reporting period (depending on the type of power plant).

Form EIA–860M *Monthly Update to the Annual Electric Generator Report* collects data on the status of proposed new generators scheduled to begin commercial operation within the future 12-month period; and existing generators that have proposed modifications that are scheduled for completion within one month. The information is needed to ensure a complete and accurate inventory of the nation's generating fleet, for such purposes as reliability and environmental analysis.

Form EIA–861 *Annual Electric Power Industry Report* collects annual information on the retail sale, distribution, transmission, and generation of electric energy in the United States and its territories. The data include related activities such as energy efficiency and demand response programs. In combination with Form EIA–861S short form and the monthly Form EIA–861M, this annual survey provides coverage of sales to ultimate customers of electric power and related activities.

Form EIA–861S *Annual Electric Power Industry Report (Short Form)* collects a limited set of information annually from small companies involved in the retail sale of electricity. A complete set of annual data are collected from large companies on Form EIA–861. The small utilities that currently report on Form EIA–861S are required to complete Form EIA–861 once every eight years to provide updated information for the statistical estimation of uncollected data.

Form EIA–861M *Monthly Electric Power Industry Report* collects monthly information from a sample of electric utilities, energy service providers, and distribution companies that sell or deliver electric power to end users. Data included on this form includes sales and revenue for end-use sectors—residential, commercial, industrial, and transportation. Additionally, capacity data on net metering and non net-metered distributed generators is collected by technology type and used for the monthly small scale solar generation estimate. This survey is the monthly complement to the annual data collection from the universe of respondents that report on Form EIA–861 and Form EIA–861S.

Form EIA–923 *Power Plant Operations Report* collects information from electric power plants in the United States on electric power generation, energy source consumption, end of reporting period fossil fuel stocks, as well as the quality and cost of fossil fuel receipts.

Form EIA–930 *Balancing Authority Operations Report* collects a comprehensive set of the current day's system demand data on an hourly basis and the prior day's basic hourly electric system operating data on a daily basis. The data provide a basic measure of the current status of electric systems in the United States and can be used to compare actual system demand with the day-ahead forecast thereby providing a measure of the accuracy of the forecasting used to commit resources. In addition, the data can be used to address smart grid related issues such as integrating wind and solar generation, improving the coordination of natural gas and electric short-term operations and expanding the use of demand response, storage, and electric vehicles in electric systems operations.

Form EIA–930A *Balancing Authority Generator Inventory Report* is a new survey proposed under this clearance to collect an inventory of electric generating units from the 63 Balancing Authorities (BAs) in the contiguous United States on an annual basis.

(4a) Proposed Changes to Information Collection:

Form EIA–860 Annual Electric Generator Report

EIA proposes to add battery storage questions for proposed applications, including planned design attributes, energy storage capacity, and use case. For energy storage applications that are operationally connected to renewable technologies, EIA proposes to add a question that identifies the related plants and generators.

EIA also proposes to add 'bifacial' as a solar photovoltaic technology option.

Form EIA–861 Annual Electric Power Industry Report

EIA proposes to expand questions about battery storage on the net metering and non net-metered distributed generators schedules. EIA is dropping two questions on net metering 'storage' and adding six questions pertaining to batteries.

For non net-metered EIA is dropping one 'storage' question and adding two questions about batteries. EIA is proposing to add one question about Photovoltaic generators.

Form EIA–861M Monthly Electric Power Industry Report

EIA proposes to expand questions about battery storage on the net metering and non net-metered distributed generators schedules. EIA is dropping two questions on net metering 'storage' and adding six questions pertaining to batteries.

For non net-metered EIA is dropping one 'storage' question and adding two questions about batteries. EIA is proposing to add one question about Photovoltaic generators.

Form EIA–923 Power Plant Operations Report

EIA proposes to collect 12 months of operational data for annual respondents of renewable and energy storage power plants when respondents report their annual EIA–923 survey form. EIA also proposes to collect the cost, quality, and storage statistics for plants that utilize hydrogen as a fuel source for electricity generation.

Form EIA–930 Balancing Authority Operations Report

EIA proposes several improvements to the EIA–930 designed to enhance the submission process and EIA–930 data quality. First, EIA proposes that respondents provide a description of their submission method on an annual basis in order to ensure compliance with the Federal Information Security Modernization Act of 2014 (FISMA). Second, EIA proposes that BAs report all data as hourly integrated integer values in order to standardize data format across all respondents. Third, EIA proposes that respondents report hourly net generation separately for pumped hydro, geothermal, battery storage, integrated solar and battery units, integrated wind and battery units, and other energy storage technologies to obtain a better understanding of the charging/discharging patterns of these rapidly evolving generation sources. Fourth, EIA proposes that if a respondent cannot report accurate data within the required timeline, then they should submit their best estimate to meet the required timeline and correct the data with a scheduled resubmission as soon as accurate data are available. And, finally, EIA proposes in cases where respondents have been unable to remove the adjustments from dynamic transfer arrangements (either pseudo-ties or dynamic schedules), per the revised instructions, it is the responsibility of the impacted balancing authorities to reach an agreement with their counterparts on a consistent reporting of generation, demand, and interchange.

Form EIA–930A Annual Balancing Authority Generator Inventory Report

EIA proposes to improve the ability to reconcile Form EIA–930 data with data reported on Form EIA–860 and Form EIA–923 by collecting the plants and generators used by each balancing authority.

Pretesting Interviews

EIA would like to conduct up to 100 pretesting interviews each year for testing purposes. These methodologies will test or evaluate new terminology, unclear questions in surveys, unclear instructions, or questions that may be added to the Electric Power & Renewable Electricity Surveys. This will help improve ongoing surveys and reduce errors due to respondent confusion.

(5) *Annual Estimated Number of Respondents:* 23,737:

Form EIA–63B has 36 respondents;
Form EIA–860 has 5,716 respondents;
Form EIA–860M has 478 respondents;
Form EIA–861 has 1,735 respondents;
Form EIA–861S has 1,692 respondents;
Form EIA–861M has 650 respondents;
Form EIA–923 has 13,204 respondents;
Form EIA–930 has 63 respondents;
Form EIA–930A has 63 respondents;
Pretesting has 100 respondents;

(6) *Annual Estimated Number of Total Responses:* 84,838;

(7) *Annual Estimated Number of Burden Hours:* 202,320 hours;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $16,892,482 (202,320 burden hours times $83.38 per hour). EIA estimates that there are no additional costs to respondents associated with the surveys other than the costs associated with the burden hours since the information is maintained during normal course of business.

Statutory Authority: 15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*

Samson Adeshiyan,

Director, Office of Statistical Methods & Research, U.S. Energy Information Administration.

[FR Doc. 2022–25287 Filed 11–18–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–10–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 3, 2022, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed a prior notice request for authorization, in accordance with 18 CFR Sections 157.205, 157.213, and 157.216 of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act and Columbia's blanket certificate issued in Docket No. CP83–76–000, to install facilities and appurtenances, to abandon storage pipeline, and to make other modifications in its existing Pavonia Storage Field (Field), located in Ashland County, Ohio. Columbia states the project creates counter storage compression to mitigate the Field's intra-reservoir migration issues improving deliverability of the Field. Columbia states that the cost of the project will be $17,000,000, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002–2700, at (832) 320–5477 or *David_alonzo@tcenergy.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on January 13, 2023. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is January 13, 2023. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is January 13, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for

[1] 18 CFR (Code of Federal Regulations) § 157.9.

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before January 13, 2023. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP23–10–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP23–10–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002–2700, at (832) 320–5477 or *David_alonzo@tcenergy.com.*

Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: November 14, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–25221 Filed 11–18–22; 8:45 am]

BILLING CODE 6717–01–P

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–11–000]

Florida Gas Transmission Company, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 3, 2022, Florida Gas Transmission Company, LLC (FGT), 1300 Main St., Houston, Texas 77002, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.208 and 157.211 of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act (NGA), and FGT's blanket certificate issued in Docket No. CP82–553–000, for authorization to construct/modify, install, own, maintain, and operate certain natural gas pipeline facilities (including lateral looping) and appurtenant facilities in Pinellas County, Florida, and modify and install appurtenant facilities on the existing FGT Tampa West Lateral in Hillsborough County, Florida, to support the proposed Tampa West Project (Tampa West Project).

In its application, FGT states that the proposed Tampa West Project will enable FGT to decrease certain existing Peoples Gas System (PGS) delivery point capacity by 10,000 Million British Thermal Units per day (MMBtu/d) in PGS' St. Petersburg Division on FGT's system in Pinellas County, Florida, and to increase delivery point capacity by 10,000 MMBtu/d to PGS Tampa West in PGS' Tampa Division on the FGT system in Hillsborough County, Florida. FGT also states that this will allow the peak hourly flow rights to the PGS Tampa West delivery point to be increased from 360 Million British Thermal Units per hour (MMBtu/hr) to 667 MMBtu/hr, in Hillsborough County, Florida. FGT also states that there will be no change in the daily capacity of FGT's mainline system, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this prior notice request should be directed to Blair Lichtenwalter, Senior Director, Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas 77002, at (713) 989–2605, or by

email to *Blair.Lichtenwalter@energytransfer.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on January 13, 2023. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is January 13, 2023. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is January 13, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp*.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before January 13, 2023. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP23–11–000 in your submission:

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP23–11–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Protests and motions to intervene must be served on the applicant either by mail at: Blair Lichtenwalter, Senior Director, Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas 77002, or email (with a link to the document) at: *Blair.Lichtenwalter@energytransfer.com*. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

[1] 18 CFR (Code of Federal Regulations) § 157.9.

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

Tracking the Proceeding

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In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp*.

Dated: November 14, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–25220 Filed 11–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 8866–013]

Black Canyon Bliss, LLC; Notice Of Application Accepted For Filing, Intent To Waive Scoping, Soliciting Motions To Intervene and Protests, Ready For Environmental Analysis, and Soliciting Comments, Terms and Conditions, Recommendations, Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent License.

b. *Project No.:* 8866–013.

c. *Date filed:* February 28, 2022.

d. *Applicant:* Black Canyon Bliss.

e. *Name of Project:* Stevenson No.2 Hydroelectric Project.

f. *Location:* The existing project is located on an unnamed tributary to the Snake River in Gooding County, Idaho. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r)

h. *Applicant Contact:* Mr. David Jentzsch, 319 River Road, Bliss, ID 83314, Telephone (208) 431–1227.

i. *FERC Contact:* Maryam Zavareh, (202) 502–8474 or *maryam.zavareh@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, terms and conditions, recommendations, and prescriptions: 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, terms and conditions, recommendations, and prescriptions using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–8866–013.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The existing Black Canyon Bliss Hydro Project consists of: (1) a 735-foot-long, 18-inch-diameter underground concrete intake; (2) a concrete transition box; (3) a 303-foot-long, 18-inch-diameter above ground steel penstock; (4) a powerhouse containing a single generating unit with a rated capacity of 24 kW; (5) a 20-foot-long tailrace, (6) a 530-foot-long, 34.5 kV transmission line; and (7) appurtenant facilities. The project generates an annual average of 155 kilowatt-hours.

m. Due to the small size and location of this project, the applicant's close coordination with federal and state agencies during preparation of the application, and studies completed during pre-filing consultation, we intend to waive scoping and expedite the licensing process. Based on a review of the application and resource agency consultation letters filed to date, Commission staff does not anticipate that any new issues would be identified through additional scoping. Based on the issues identified during the pre-filing period, staff's National Environmental Policy Act (NEPA) document will consider the potential effects of project construction and operation on geology and soils, aquatic, terrestrial, threatened and endangered species, recreation, and cultural and historic resources.

n. A copy of the application can be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

Register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' ''COMPETING APPLICATION,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings

in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

p. The applicant must file no later than 60 days following the date of issuance of this notice: (1) a copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification. Please note that the certification request must comply with 40 CFR 121.5(b), including documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request. Please also note that the certification request must be sent to the certifying authority and to the Commission concurrently.

q. Procedural schedule: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Deadline for filing interventions, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions.	January 2023.
Deadline for filing reply comments	February 2023.

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: November 14, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–25222 Filed 11–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Loveland Area Projects—Rate Order No. WAPA–202

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order concerning firm electric service and sale of surplus products formula rates.

SUMMARY: The formula rates for the Rocky Mountain Region's (RMR) Loveland Area Projects (LAP) firm electric service and sale of surplus products have been confirmed, approved, and placed into effect on an interim basis (Provisional Formula Rates). LAP consists of the Fryingpan-Arkansas Project (Fry-Ark) and the Pick-Sloan Missouri Basin Program (P–SMBP)—Western Division, which were integrated for marketing and rate-making purposes in 1989. These new formula rates replace the existing formula rates for these services under Rate Schedules L–F11, Firm Electric Service, and L–M2, Sale of Surplus Products, which expire on December 31, 2022. The LAP firm electric service rate is increasing 16.5 percent. There are no changes to the formula rate for sale of surplus products.

DATES: The Provisional Formula Rates under Rate Schedules L–F12, Firm Electric Service, and L–M3, Sale of Surplus Products, are effective on the first day of the first full billing period beginning on or after January 1, 2023, and will remain in effect through December 31, 2027, pending confirmation and approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Barton V. Barnhart, Regional Manager, Rocky Mountain Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, or email: *lapfirmadj@wapa.gov,* or Sheila D. Cook, Rates Manager, Rocky Mountain Region, Western Area Power Administration, (970) 685–9562, or email: *scook@wapa.gov.*

SUPPLEMENTARY INFORMATION: On May 24, 2018, FERC confirmed and approved Formula Rate Schedules L–F11 and L–M2 under Rate Order No. WAPA–179, on a final basis through December 31, 2022.[1] These schedules apply to LAP firm electric service and sale of surplus products. Western Area Power Administration (WAPA) published a **Federal Register** notice (Proposed FRN) on May 25, 2022 (87 FR 31876), proposing increases to both the base component and the drought adder component of the LAP firm electric service rate and to put new 5-year rate schedules in place. The Proposed FRN also initiated a 90-day public consultation and comment period and set forth the dates and locations of the public information and public comment forums.

[1] Order Confirming and Approving Rate Schedules on a Final Basis, FERC Docket No. EF18–3–000, 163 FERC ¶ 62,115 (2018).

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and Department of Energy procedures for public participation in rate adjustments set forth at 10 CFR part 903.[2]

Following review of RMR's proposal, Rate Order No. WAPA–202, which provides the formula rates for LAP firm electric service and sale of surplus products, is hereby confirmed, approved, and placed into effect on an interim basis. WAPA will submit Rate Order No. WAPA–202 to FERC for confirmation and approval on a final basis.

Department of Energy

Administrator, Western Area Power Administration

In the Matter of: Western Area Power Administration, Rocky Mountain Region, Rate Adjustment for the Loveland Area Projects, Firm Electric Service and Sale of Surplus Products, Formula Rates.

Rate Order No. WAPA–202

Order Confirming, Approving, and Placing the Formula Rates for the Loveland Area Projects Into Effect on an Interim Basis

The formula rates in Rate Order No. WAPA–202 are established following section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).[3]

[2] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[3] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior

Continued

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the Western Area Power Administration (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to the Federal Energy Regulatory Commission (FERC). By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and DOE procedures for public participation in rate adjustments set forth at 10 CFR part 903.[4]

Acronyms, Terms, and Definitions

As used in this Rate Order, the following acronyms, terms, and definitions apply:

Base: A component of the firm electric service (FES) rate design that is a fixed revenue requirement that includes operation and maintenance expenses (O&M), investments and replacements, interest on investments and replacements, normal timing power purchases, and transmission costs.

Capacity: The electric capability of a generator, transformer, transmission circuit, or other equipment. It is expressed in kilowatts (kW) or megawatts (MW).

Capacity Rate: The rate which sets forth the charges for capacity. It is expressed in dollars per kilowatt-month (kWmonth) and applied to each kW of the Contract Rate of Delivery or CROD.

Composite Rate: The Power Repayment Study (PRS) rate for commercial firm power, which is the total annual revenue requirement for capacity and energy divided by the total annual energy sales. It is expressed in mills per kilowatt-hour (mills/kWh) and used only for comparison purposes.

Corp of Engineers Annual Operating Plan (AOP): The Corp of Engineers (Corps) water management guidelines designed to meet the reservoir regulation objectives.

Customer: An entity with a contract that is receiving Loveland Area Projects (LAP) firm electric service from WAPA.

Customer Rate Brochure: A document prepared for public distribution explaining the rationale and background for the information contained in the Proposed FRN and in this rate order.

Deficit(s): Deferred or unrecovered annual and/or interest expenses.

Drought Adder: A component of the FES rate design that is a formula-based revenue requirement that includes future power purchases above normal timing power purchases, previous purchase power drought-related Deficits, and interest on the purchase power drought-related Deficits.

Energy: Measured in terms of the work it is capable of doing over a period of time. Electric energy is expressed in kilowatt-hours (kWh).

Energy Charge: The charge under the rate schedule for energy. It is expressed in mills/kWh and applied to each kWh delivered to each Customer.

FRN: **Federal Register** Notice—a document published in the **Federal Register** in order for WAPA to provide information of public interest.

Firm: Power intended to be available at all times during the period covered by a guaranteed commitment to deliver, even under adverse conditions.

FY: WAPA's fiscal year; October 1 to September 30.

kW: Kilowatt—the electrical unit of capacity that equals 1,000 watts.

kWh: Kilowatt-hour—the electrical unit of energy that equals 1,000 watts in 1 hour.

kWmonth: Kilowatt-month—the electrical unit of the monthly amount of capacity.

LAP Marketing Plan: The Post-1989 General Power Marketing and Allocation Criteria for the Pick-Sloan Missouri Basin Program—Western Division (P–SMBP—WD) and the Fryingpan-Arkansas Project (Fry-Ark) (collectively known as Loveland Area Projects or LAP) (published in January 1986 and extended and amended per the LAP 2025 Power Marketing Initiative published on December 10, 2013 (78 FR 79444)) that provides the principles used to market LAP firm hydropower resources.

mills/kWh: Mills per kilowatt-hour—the unit of charge for energy (equal to one tenth of a cent or one thousandth of a dollar).

NEPA: National Environmental Policy Act of 1969, as amended.

Non-timing Power Purchases: Power purchases related to drought conditions, not related to operational constraints.

Normal Timing Power Purchases: Power purchases related to operational constraints (*e.g.,* management of endangered species habitat, water quality, navigation, balancing authority purposes, market events, etc.), not associated with drought conditions.

O&M: Operation and maintenance expenses.

OM&R: Operation, maintenance, and replacement expenses.

Order RA 6120.2: DOE Order outlining Power Marketing Administration financial reporting and rate-making procedures.

Power: Capacity and energy.

Power Factor: The ratio of real to apparent power at any given point and time in an electrical circuit. Generally, it is expressed as a percentage.

Power Repayment Study (PRS): Defined in Order RA 6120.2 as a study portraying the annual repayment of power production and transmission costs of a power system through the application of revenues over the repayment period of the power system. The study shows, among other items, estimated revenues and expenses, year by year, over the remainder of the power system's repayment period (based upon conditions prevailing over the cost evaluation period), the estimated amount of Federal investment amortized during each year, and the total estimated amount of Federal investment remaining to be amortized.

Preference: The provisions of Reclamation Law that require WAPA to first make Federal Power available to certain entities. For example, section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) states that preference in the sale of Federal Power shall be given to municipalities and other public corporations or agencies and also to cooperatives and other nonprofit organizations financed in whole or in part by loans made under the Rural Electrification Act of 1936.

Provisional Formula Rates: Formula rates confirmed, approved, and placed into effect on an interim basis by the Secretary of Energy or his/her designee.

Rate-setting PRS: The PRS used for the rate adjustment proposal.

Reclamation's Most Probable Inflow Operating Plan: The combination of the forecasted generation plans for the Bureau of Reclamation's (Reclamation) North Platte River, Buffalo Bill Reservoir, Boysen Reservoir, Colorado

and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) and section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s); and other acts that specifically apply to the projects involved.

[4] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

Big-Thompson Project, and Yellowtail Dam, assuming median generation.

Regional Transmission Organization (RTO): Organizations that operate bulk electric power systems across parts of North America. RTOs are independent, membership-based, non-profit organizations that ensure reliability and optimize supply and demand bids for wholesale electric power.

RTO West: A group of electricity service providers focusing on collaboratively developing long-term solutions that will improve market efficiencies in the West.

Regions: WAPA's Rocky Mountain Region (RMR) and Upper Great Plains Region (UGP).

Revenue Requirement: The revenue required by the PRS to recover annual expenses (such as O&M, purchase power, transmission service, interest, and deferred expenses) and repay Federal investments and other assigned costs.

Scheduling, Accounting, and Billing Procedures (SABPs): The SABP establish the parameters for scheduling, accounting, and billing procedures as they relate to LAP power deliveries. They are intended to implement the terms of a contract, not to modify or amend the contract.

Webex: Webex is an online secure invite-only meeting platform used by WAPA. The general website is *https://doe.webex.com.*

Western Energy Imbalance Service Market (WEIS Market): The market for imbalance energy administered by the Southwest Power Pool in the Western Interconnection. The market footprint encompasses the loads and resources that are located within a participating Balancing Authority Area. The Western Area Colorado Missouri Balancing Authority or WACM (operated by RMR) and the Western Area Upper Great Plains West Balancing Authority or WAUW (operated by UGP) are both participating Balancing Authority Areas.

Winter Storm Uri: A severe winter storm in February 2021 that had widespread impacts across the RMR and UGP regions.

Effective Date

The Provisional Formula Rate Schedules L–F12, Firm Electric Service, and L–M3, Sale of Surplus Products, will take effect on the first day of the first full billing period beginning on or after January 1, 2023, and will remain in effect through December 31, 2027, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

RMR followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in developing these formula rates. The steps RMR took to involve interested parties in the rate process include:

1. On May 25, 2022, a **Federal Register** notice (87 FR 31876) (Proposed FRN) announced the proposed formula rates and launched the 90-day public consultation and comment period.

2. On May 25, 2022, RMR notified Preference Customers and interested parties of the proposed rates and provided a copy of the published Proposed FRN.

3. On June 15, 2022, RMR held a public information forum via Webex. RMR's representatives explained the proposed formula rates, answered questions, and gave notice that more information was available in the Customer Rate Brochure.

4. On June 29, 2022, RMR held a public comment forum via Webex to provide an opportunity for customers and other interested parties to comment for the record.

5. RMR provided a website that contains important dates, letters, presentations, FRNs, Customer Rate Brochure, and other information about this rate process. The website is located at *www.wapa.gov/regions/RM/rates/Pages/2023-Rate-Adjustment-Firm-Power.aspx.*

6. During the 90-day consultation and comment period, which ended on August 23, 2022, RMR received one oral comment submission and four comment letters, encompassing a total of 22 individual comments. The individual comments and RMR's responses are addressed in the ''Comments'' section. All comments have been considered in the preparation of this Rate Order.

Oral comments were received from the following organization:

Mid-West Electric Consumers Association, Colorado

Written comments were received from the following organizations:

Loveland Area Customer Association, Colorado
Platte River Power Authority, Colorado
Mid-West Electric Consumers Association, Colorado
East River Electric Power Cooperative, Inc., South Dakota

Power Repayment Study—Firm Electric Service Rate Discussion

PRSs are prepared each FY to determine if revenues will be sufficient to repay, within the required time, all costs assigned to the Pick-Sloan Missouri Basin Program (P–SMBP) and the Fry-Ark. Repayment criteria are based on applicable laws and legislation, as well as policies including Order RA 6120.2. To meet the Cost Recovery Criteria outlined in Order RA 6120.2, RMR developed a rate adjustment to demonstrate sufficient revenues will be collected under the Provisional Formula Rates to meet future obligations. The revenue requirement of the Fry-Ark PRS is combined with the P–SMBP—WD revenue requirement, derived from the P–SMBP PRS, to develop one rate for LAP firm electric service. The revenue requirement and composite rate for LAP firm electric service are being increased, as indicated in Table 1:

TABLE 1—COMPARISON OF EXISTING AND PROVISIONAL REVENUE REQUIREMENTS AND COMPOSITE RATES

Firm electric service	Existing requirements under L–F11 as of January 1, 2018	Provisional requirements under L–F12 as of January 1, 2023	Percent change
LAP Revenue Requirement (million $)	$64.1	$74.7	16.5
Pick-Sloan—WD [1]	50.8	58.6	15.4
Fry-Ark	13.3	16.1	21.1
Composite Rate (mills/kWh)	31.44	36.61	16.4

[1] Additional information on the overall P–SMBP PRS and charge components can be found under Rate Order No. WAPA–203 and on UGP's website at *www.wapa.gov/regions/UGP/Rates/Pages/2023-firm-rate-adjustment.aspx.*

Firm Electric Service—Existing and Provisional Formula Rates

Under the current rate methodology, rates for LAP firm electric service are designed to recover an annual revenue requirement that includes investment repayment (including aid to irrigation), interest, purchase power, OM&R, and other expenses within the allowable period. The annual revenue requirement continues to be allocated equally between capacity and energy.

The Base component costs for the P–SMBP PRS have increased primarily due to: (1) increased OM&R from WAPA and the generating agencies; (2) increased purchase power, including during the Winter Storm Uri; (3) pricing volatility; (4) reduced surplus energy sales; and (5) the loss of certain balancing authority revenues for services that are no longer provided after RMR joined the WEIS Market. Winter Storm Uri was not a water or generation issue; therefore, its costs only impact the Base component.

The Base component costs for the Fry-Ark PRS have increased due to: (1) increased O&M from both WAPA and Reclamation; (2) increased purchase power, transmission, and ancillary services costs; (3) changes in costs related to Reclamation's Mt. Elbert Rehabilitation project; and (4) price volatility.

The driver behind the P–SMBP PRS Drought Adder component increase is the AOP projecting less than average generation for the next several years in the P–SMBP mainstem dams. Uncertainties with water inflows, hydro generation, and replacement energy prices continue to pose potential risks for meeting firm power contractual commitments.

The net effect of these changes to the PRS Base and Drought Adder components results in an overall increase to the LAP rate. A comparison of the existing and Provisional Formula Rates for firm electric service is shown in Table 2:

TABLE 2—COMPARISON OF EXISTING AND PROVISIONAL FORMULA RATES

Firm electric service	Existing charges under rate schedule L–F11 as of January 1, 2018	Provisional charges under rate schedule L–F12 as of January 1, 2023	Percent change
Firm Capacity Rate ($/kWmonth)	$4.12	$4.80	16.5
Firm Energy Rate (mills/kWh)	15.72	18.31	16.5

As a part of the existing and provisional rate schedule, RMR provides for a formula-based adjustment of the Drought Adder component, with an annual increase of up to 2 mills/kWh each year. The 2 mills/kWh cap places a limit on the amount the Drought Adder component can be adjusted upward relative to associated drought costs included in the Drought Adder formula rate for any 1-year cycle. The Drought Adder component may be adjusted downward by any amount. Continuing to identify the firm electric service revenue requirement using Base and Drought Adder components will assist the Regions in presenting the future impacts of droughts, demonstrate repayment of drought-related costs in the PRSs, and allow the Regions to be more responsive to changes caused by drought-related expenses. RMR will continue to charge and bill its customers firm electric service rates for energy and capacity, which are the sum of the Base and Drought Adder components.

Under Rate Schedule L–F12, RMR will continue to identify its LAP firm electric service revenue requirement using Base and Drought Adder components. The Base component is a fixed revenue requirement from each PRS that includes annual O&M, investment repayment and associated interest, Normal Timing Power Purchases, and transmission costs. RMR cannot adjust the Base component without a public process. The Drought Adder component is a formula-based revenue requirement from each PRS that includes costs attributable to drought conditions in the Regions. The Drought Adder component includes costs associated with future Non-timing Power Purchases to meet firm electric service contractual obligations not covered with available system generation due to a drought, previously incurred Deficits due to purchased power debt that resulted from Non-timing Power Purchases made during a drought, and the interest associated with drought-related Deficits. The Drought Adder component is designed to repay drought-related Deficits within 10 years from the time the Deficit was incurred, using balloon-payment methodology. For example, a drought-related Deficit incurred in FY 2022 will be repaid by FY 2032.

The annual revenue requirement calculation will continue to be summarized by the following formula: Annual Revenue Requirement = Base Revenue Requirement + Drought Adder Revenue Requirement.

The Provisional charge components update the Base component with present costs from a revenue requirement of $64.1 million to $67.8 million and increases the Drought Adder component revenue requirement. For rate year 2023, the Drought Adder revenue requirement increases from zero to $6.8 million.[5] A comparison of the existing and provisional components is shown in Table 3:

[5] The exact values are $64,143,960, $67,839,200, and $6,838,720 respectively.

TABLE 3—SUMMARY OF LAP EXISTING AND PROVISIONAL CHARGE COMPONENTS

Firm electric service	Existing charges under rate schedule L–F11 as of January 1, 2018			Provisional charges under rate schedule L–F12 as of January 1, 2023			Percent change
	Base component	Drought adder component	Total charge	Base component	Drought adder component	Total charge	
Firm Capacity ($/kWmonth)	$4.12	$0	$4.12	$4.36	$0.44	$4.80	16.5
Firm Energy (mills/kWh)	15.72	0	15.72	16.63	1.68	18.31	16.5

RMR reviews the inputs for the P–SMBP and Fry-Ark PRS Base and Drought Adder components after the annual PRSs are complete, generally in the first quarter of the calendar year. If an adjustment to the LAP Base component is necessary, or if an incremental upward adjustment to the LAP Drought Adder component greater than the equivalent of 2 mills/kWh to the LAP Rate is necessary, RMR will initiate a public process pursuant to 10 CFR part 903 prior to making an adjustment.

In accordance with the approved annual Drought Adder adjustment process, the PRS Drought Adder components are reviewed annually in early summer to determine if drought costs differ from those projected in the PRSs. In October, RMR will determine if a change to the LAP Drought Adder component is necessary, either incremental or decremental. Any incremental adjustment to the Drought Adder component, up to 2 mills/kWh, or decremental adjustment will be implemented in the following January billing cycle. Although decremental adjustments to the Drought Adder component will occur as drought costs are repaid, the adjustments cannot result in a negative Drought Adder component. Implementing the Drought Adder component adjustment on January 1 of each year will help keep the drought-related Deficits from escalating as quickly, will lower the interest expense due to drought-related Deficits, will demonstrate responsible Deficit management, and will provide prompt drought-related Deficit repayments.

Statement of Revenue and Related Expenses

The following Table 4 provides a summary of the projected revenue and expense data for the Fry–Ark revenue requirement during the 5-year rate-setting periods:

TABLE 4—FRY-ARK COMPARISON OF 5-YEAR RATE PERIODS TOTAL REVENUES AND EXPENSES

	Existing rate FY2018–FY2022 ($000)	Provisional rate FY2023–FY2027 ($000)	Difference ($000)
Total Revenues	$91,392	$114,466	$23,074
Revenue Distribution:			
Expenses.			
O&M	31,334	38,760	7,426
Purchase Power	724	1,378	654
Transmission	18,302	20,182	1,880
Ancillary Services	979	6,513	5,534
Interest	14,779	12,446	−2,333
Total Expenses	66,118	79,279	13,161
Principal Payments:			
Capitalized Expenses (Deficits)	0	0	0
Original Project and Additions	14,893	12,873	−2,020
Replacements	10,381	22,314	11,933
Total Principal Payments	25,274	35,187	9,913
Total Revenue Distribution	91,392	114,466	23,074

The summary of the P–SMBP projected revenues and expenses for the 5-year rate-setting periods is included in the P–SMBP Statement of Revenue and Related Expenses that is part of Rate Order No. WAPA–203.

Sale of Surplus Products Rate Discussion

The sale of surplus products rate schedule is formula-based, providing for LAP Marketing Office to sell LAP surplus energy and capacity products. If LAP surplus products are available, as specified in the rate schedule, the charge will be based on market rates plus administrative costs. The customer will be responsible for acquiring transmission service necessary to deliver the product(s) for which a separate charge may be incurred. Rate Schedule L–M2 is being superseded by the Provisional Rate Schedule L–M3 and continues to allow for the sale of energy, frequency response, regulation, and reserves.

Comments

RMR received a total of 22 individual oral and written comments during the public consultation and comment period. The comments expressed have been paraphrased and/or combined,

where appropriate, without compromising the meaning of the comments:

A. *Comment:* A customer association and a Customer commented that WAPA contends that its participation in the WEIS Market is increasing the cost to the LAP Customers in the form of administrative fees and lost ancillary service revenue. With the recent addition of Colorado Springs Utilities, and, in April 2023, the utilities that comprise the Public Service Company of Colorado balancing authority area members, the WEIS Market Footprint will increase in size and resource diversity. Thus, there is a reasonable expectation that benefits could accrue to LAP in the form of a reduced administrative fee and co-optimized real-time energy dispatch. WAPA and the Customers should regularly monitor the WEIS Market for net benefits accrued to LAP and should refrain from assuming the Drought Adder will be required until WAPA has experience in the WEIS Market. They request a commitment to evaluate a downward rate adjustment should these anticipated benefits accrue.

Response: Participation in the WEIS Market required RMR to change some of the Base component projections in the Fry-Ark and Pick-Sloan PRSs, for both revenue and expense. These changes are a very small contributor to the Base component increases in comparison to other contributors, such as O&M and Normal Timing Power Purchases and has no impact on the need for, or the size of, the P–SMBP Drought Adder. RMR has and will continue to monitor the WEIS Market for potential benefits, but due to the nature of the LAP Marketing Plan, LAP has very little surplus generation that can be bid into the WEIS Market. Also, RMR has been actively working to ensure the costs, and any benefits, we accrue through our participation are recovered in the appropriate rate design(s) as soon as practical. RMR, in coordination with UGP, is committed to developing rates that are the lowest possible, consistent with sound business principles, which includes an annual evaluation of the Base components and a biannual evaluation of the Drought Adder components. The Drought Adder components can be annually reduced without a cap, or increased subject to a 2 mills/kWh cap, without a public process, based on this evaluation.

B. *Comment:* A customer association and a Customer noted the P–SMBP PRS assumed a below average generation profile on a median runoff scenario from the Corps, factoring in unit and transmission outages. Their understanding is that this outcome was used to calculate the Drought Adder component for the P–SMBP—WD, resulting from a projected deficit of generation that will be replaced by purchased power over the study period. They stated they would like the Regions to rerun the PRS to assess the impact to the proposed Drought Adder using an average generation profile in the P–SMBP—WD to satisfy the cost recovery criteria under Order RA 6120.2. Alternatively, the Regions could follow its normal formula rate process to account for actual generation, rather than working from assumptions that presume a deficit of generation.

Response: As standard practice, the P–SMBP PRS includes separate generation projections for the P–SMBP—ED and the P–SMBP—WD and the resulting power purchases and surplus energy sales are assigned to the overall P–SMBP revenue requirement. The overall P–SMBP revenue requirement is then allocated between P–SMBP—ED and P–SMBP—WD based on the ratio of each division's fixed amount of annual marketable energy to the total P–SMBP marketable energy, regardless of which component the revenue requirement is identified.

UGP has historically relied upon the AOP as the source document for projecting the P–SMBP—ED's future purchase power needs and surplus energy sales in the PRS for a 5-year projection period. After this 5-year period, the PRS assumes average P–SMBP—ED generation and no generation-related P–SMBP—ED power purchases or surplus energy sales are projected. RMR has historically relied upon Reclamation's most recent update to their Most Probable Inflow Operating Plan for projecting the P–SMBP—WD's future purchase power needs and surplus energy sales in the PRS for a 2-year projection period. After this 2-year period, the PRS assumes average P–SMBP—WD generation and no generation-related P–SMBP—WD power purchases or surplus energy sales are projected. The 2023 Rate-setting PRS continues these historical practices.

The 2023 Rate-setting PRS utilized the Corp's Final 2021–2022 AOP dated December 17, 2021, that projected nearly 20 percent lower generation for FYs 2022 and 2023 and just under or at normal generation for FYs 2024–2027 (to our knowledge, the AOP does not factor in transmission outages as stated in the comment) and Reclamation's 2022–2024 plans, received in December 2021, that projected 24 percent lower generation for FY 2022 and just under average generation for FYs 2023–2024. Reclamation's plans took into consideration reservoir inflows that were 67 percent of average and reservoir storage that was at 99 percent of average as of October 2021 and unit and transmission maintenance schedules.

Utilizing these generation plans, the 2023 Rate-setting PRS includes higher levels of power purchases to meet UGP firm contractual commitments, a reduced amount of surplus energy sales for P–SMBP—ED, and Normal Timing Power Purchases and surplus energy sales for P–SMBP—WD (since P–SMBP—WD was not formally considered to be in a drought condition). Since the P–SMBP—ED was considered to be in a drought condition, in accordance with our established methodology, a second or ''base'' study was completed. This ''base'' study removed the P–SMBP—ED's future drought-related power purchase costs and added back in the P–SMBP—ED's Normal Timing Power Purchases and normal surplus energy sales (essentially simulating what the PRS would look like under a non-drought, or normal, condition for both P–SMBP—ED and P–SMBP—WD). The revenue requirement difference between these two PRSs is the revenue requirement for the proposed Drought Adder. There is no need to rerun these PRSs to assess the impact to the proposed Drought Adder using an average generation profile in the P–SMBP—WD since the PRSs already utilize Normal Timing Power Purchases and normal surplus energy sales for P–SMBP—WD.

C. *Comment:* A customer association suggests that concurrent with this rate adjustment, the Regions perform a comparison of the unpaid federal investment balances versus the depreciated balances of the P–SMBP investments to determine if the unpaid investments balances are greater than the depreciated balances at the present point in the asset service lives. They would appreciate the opportunity to review this analysis to gauge the reasonableness of the Drought Adder approach. They note the Regions have performed analyses such as these in the past, and they believe that it would be beneficial again when analyzing both Deficits and rate adders. Given the pressures to consumers, they believe that this information could be useful to avoid excessive Drought Adders and keep rates stable, and to allow the system to function as intended. They contend that based on conversations and points raised during informal discussions, they believe that there is a sensitivity to taking drought-related Deficits in the PRSs, and that Deficits may be considered bad financial practice to those reviewing rate

activities. Taking reasonable Deficits for purchased power is a longstanding practice that is based on the fact that historic shortages and surpluses occur over time, and that over the long run, these Deficits have always been paid, even during extreme droughts over the past 30–40 years. They are part of the financial flexibility necessary because WAPA is unable to accumulate rate stabilization funds during good water years and can only use surpluses to pay existing investments ahead of time. Without accumulated funds, taking Deficits provides a counterbalance that keeps rates stable and are part of good financial practice for short periods of time. Key to these Deficits is knowing when they continue to be reasonable and when they can no longer be sustained.

Response: As noted, Deficits are an integral and longstanding component of WAPA's repayment methodology and the Regions do utilize them in the PRSs when appropriate (in accordance with Order RA 6120.2). The P–SMBP PRS incurred a $92.7 million Base-related Deficit in FY 2021 as the result of various issues related to Winter Storm Uri. Also in FY 2021, P–SMBP—ED had lower than normal generation, though no adjustment to the Drought Adder component was implemented. The P–SMBP—ED projected generation for FY 2022 utilized in the 2023 Rate-setting PRS is estimating a $76.6 million drought-related Deficit in FY 2022. Payments toward these two Deficits are projected to be made over a 7-year time frame with final repayment projected in FY 2028. During this 7-year repayment plan, the 2023 Rate-setting PRS is projecting annual interest payments associated with these Deficits. The Regions agree it would be beneficial to prepare an analysis of the unpaid balances compared to the depreciated balances of the P–SMBP investments and will provide Customers/customer groups with an opportunity to review once the analysis is completed.

D. *Comment:* A customer association commented that they believe the current proposal may be an overly sensitive reaction to water conditions and may lead to rate instability as Drought Adders continue to be taken on and off, sometimes with significant rate increases like this one. At present, they note that there is no drought-related Deficits to which these added revenues could really be applied (pending final purchases and the application of revenues for FY 2022). They urge the Regions to use caution in implementing a practice that may eventually preclude the taking of Deficits, with a replacement policy of covering any drought-related purchases during the year of occurrence, regardless of the effects of good water over time. Paid-ahead investments may become a standard with no offsetting consideration.

Response: The commentor is correct that at present, there are no actual drought-related Deficits in the P–SMBP 2023 Rate-setting PRS, only the projected $76.6 million drought-related Deficit in FY 2022. The proposed rates will not be effective until January 2023, and the AOP is projecting lower-than-average generation in FY 2023, with FY 2023 being the third consecutive year of lower-than-average generation on the P–SMBP mainstem. A review of the Regions' actual purchase power costs at a point more than halfway through FY 2022 indicates the projected costs for FY 2022 may be conservative, which will likely result in a larger than estimated Deficit for FY 2022.

During the rate formulation timeframe (end of 2021/beginning of 2022), the Regions ran multiple PRS scenarios using various purchase power and surplus energy sales assumptions (based on hydrology, generation outlook, and price volatility information available at that time), while also considering the fact there are required investment payments coming due within the cost evaluation period. The Regions ultimately settled on a profile that resulted in a projected drought-related Deficit being incurred in FY 2022, before the proposed Drought Adders could take effect in January 2023. The Regions appreciate the commentor's concerns over rate stability and rate-making decisions. The Region's decision to implement the proposed Drought Adder did consider risks and impacts and was in no way an attempt to preclude the taking of Deficits, which are an integral part of WAPA's repayment methodology, and which is evident in the FY 2021 Base-related Deficit as well as the projected FY 2022 drought-related Deficit. In fact, the Regions chose to implement the full amount of the P–SMBP Drought Adder through the rate process, rather than implement 2 mills/kWh of it through the Drought Adder adjustment process, so there would be transparency and opportunity for public input.

E. *Comment:* A customer association and a Customer commented that they support the comments of their member utilities, fellow customer associations, and other customer groups.

Response: The Regions appreciate the commentors' feedback. The Regions conducted a combined public process for the rate adjustments under Rate Order Nos. WAPA–202 and WAPA–203 and have coordinated all responses. Comments received specifically by UGP for the P–SMBP—ED rate process are recognized as being addressed in UGP's Rate Order No. WAPA–203.

F. *Comment:* A customer association and a Customer provided various comments related to the Mt. Elbert Powerplant such as: (1) they are aware that Mt. Elbert is experiencing increased maintenance costs and will very likely require future major maintenance that will put an upward pressure on rates, (2) the form in which customers can use Mt. Elbert through the SABPs may be out of alignment with the West's changing energy market paradigms; for example, Mt. Elbert may be better used to meet resource adequacy requirements, and (3) they support having ongoing discussions and want to ensure that future costs to rehabilitate Mt. Elbert come with commensurate benefits to the whole, which may require a change in how Mt. Elbert's value is captured in an organized energy market and appropriately credited to customers.

Response: The SABPs, Customers' use of Mt. Elbert, and potential future organized energy markets are outside the scope of this rate process; however, RMR appreciates the comments and is committed to ongoing discussions related to the use of Mt. Elbert and how to address future rehabilitation costs and potential benefits.

G. *Comment:* A Customer commented that benefits may be realized, and costs mitigated, in a future RTO like Southwest Power Pool's RTO West. The full picture of both costs and benefits from participation are unknown today, but the customer suggests the Regions wait to assess the need for a Drought Adder until the impacts of the future RTO West are known.

Response: The possibility of participation in an RTO is outside of the scope of this rate process; however, RMR appreciates the comment and recognizes there could be benefits from participation in an RTO and is actively engaged in exploring various market opportunities. Since WAPA has not made a decision on joining a RTO West market, RMR has not included estimated operations costs, estimated benefits, or estimated implementation costs. In the meantime, implementation of a Drought Adder under the formula rate is not dependent on potential future uncertain events and timelines. The design of the Drought Adder formula is flexible enough to be reduced each year should any such benefits reduce the need for the Drought Adder.

H. *Comment:* A customer association and member utility commented that

they understand a rate increase is warranted due to several factors: (1) persistent low water conditions in the P–SMBP—ED, (2) increasing market power pricing, (3) costs incurred during the Winter Storm Uri, and (4) inflation on O&M and capital investments for the system. They encourage WAPA to continue focus on identifying and reducing controllable costs within the Regions and at WAPA's Headquarters.

Response: The Regions appreciate the commentors' recognition of the specific costs and repayment obligations of the PRSs and the need for the rate adjustments. The Regions are committed to developing rates that are the lowest possible, consistent with sound business principles.

I. *Comment:* A customer association commented that they recommend the Rates staff and Regional leadership continue to meet regularly with the Mid-West Electric Consumers Association's (Mid-West) Water and Power Committee on a quarterly basis to update and advise the members on the latest information on hydrology outlook, power supply costs, system storage, and potential need for future adjustments as this will allow more advance notice for dealing with future issues.

Response: Customer meeting attendance is outside the scope of this rate process; however, the Regions do intend to continue communication with our Customers and customer groups as appropriate.

J. *Comment:* A customer association and member utility request WAPA staff continue transparent engagements with the Customers and customer groups to better understand WAPA's efforts to control and mitigate costs, rate impacts, impacts of drought conditions, importance of rate stability, and need for risk mitigation through regular meetings with the Mid-West Water and Power Committee and impacted customer groups. The strong collaboration between customers and WAPA benefits everyone and improves the value we all provide to the consumer-owners at the end of the line.

Response: The Regions appreciate the support of our Customers and customer groups and agree that collaboration is vital when faced with uncertain drought conditions and other impacts to the firm power rates. The Regions intend to continue communication with our Customers and customer groups as appropriate.

K. *Comment:* The customer association and member utility commented that they appreciated the efforts of the UGP and RMR Rates staff for understanding Customer concerns regarding the rate.

Response: The Regions thank the commentors for recognizing the UGP and RMR Rates staff and their efforts to ensure Customer concerns are addressed.

L. *Comment:* A customer association and a member utility commented their customers are already feeling the impacts of the current drought in the P–SMBP—ED and understand the need for the Drought Adder and the process for the Drought Adder evaluation. They requested debt strategy and rate design options be discussed with customers before any final decisions are made as a part of the annual Drought Adder review process.

Response: The Regions agree with the need for continued transparency regarding debt strategy and rate options related to the annual Drought Adder adjustment process. The proposed rates did not reflect any change to the Regions' existing rate designs or annual Drought Adder adjustment process. Changes to the rate designs or adjustment process would require a separate rate process where Customers and interested parties would have the opportunity to participate in the process. The 2007 rate orders implementing the Drought Adder component provided the framework for the annual Drought Adder adjustment process, which hasn't been modified in subsequent rate orders.

M. *Comment:* The member utility encourages WAPA to focus on its core function of marketing and delivering Preference Power to Preference Customers.

Response: The Regions appreciate the comment and intend to continue to fulfill our mission of marketing to Preference Power Customers consistent with current marketing plans.

N. *Comment:* The customer association and member utility appreciated the opportunity to comment on the rate process, stating that any rate increase has a direct impact on the energy affordability of the members it serves.

Response: The Regions recognize the impact of the rate increases on Customers and strive to find ways to mitigate impacts of the drought and operational costs to keep rates as low as possible.

Certification of Rates

I have certified that the Provisional Formula Rates for LAP firm electric service under Rate Schedule L–F12 and LAP sale of surplus products under Rate Schedule L–M3 are the lowest possible rates, consistent with sound business principles. The Provisional Formula Rates were developed following administrative policies and applicable laws.

Availability of Information

Information about this rate adjustment, including the Customer Rate Brochure, PRSs, comments, letters, memorandums, and other supporting materials that were used to develop the Provisional Formula Rates, is available for inspection and copying at the Rocky Mountain Regional Office located at 5555 East Crossroads Boulevard, Loveland, Colorado. Many of these documents are also available on RMR's website at *www.wapa.gov/regions/RM/rates/Pages/2023-Rate-Adjustment---Firm-Power.aspx.*

Ratemaking Procedure Requirements

Environmental Compliance

WAPA has determined that this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021.410: B4.3 (Electric power marketing rate changes). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.[6] A copy of the categorical exclusion determination is available on WAPA's website at *www.wapa.gov/regions/RM/environment/Pages/CX2022.aspx.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Formula Rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA–202. The rates will remain in effect on an interim basis until: (1) FERC confirms and approves them on a final basis; (2) subsequent rates are confirmed

[6] The determination was done in compliance with NEPA (42 U.S.C. 4321–4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

and approved; or (3) such rates are superseded.

Signing Authority

This document of the Department of Energy was signed on November 9, 2022, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 16, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

Rate Schedule L–F12

(Supersedes Rate Schedule L–F11)

Effective January 1, 2023

United States Department of Energy

Western Area Power Administration

Rocky Mountain Region

Loveland Area Projects

Firm Electric Service

(Approved Under Rate Order No. WAPA–202)

Effective

The first day of the first full billing period beginning on or after January 1, 2023, and extending through December 31, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Available

Within the marketing area served by the Loveland Area Projects (LAP) (consisting of the Fryingpan-Arkansas Project and the Pick-Sloan Missouri Basin Program—Western Division, which were integrated for marketing and rate-making purposes in 1989); parts of Colorado, Kansas, Nebraska, and Wyoming.

Applicable

To the LAP firm electric service delivered at specific point(s) of delivery, as established by contract.

Character

Alternating current, 60 hertz, three phase, delivered and metered at the voltages and points established by contract.

Formula Rate and Charge Components

LAP Firm Electric Service Rate (Rate) = Base component + Drought Adder component

Monthly Charge as of January 1, 2023, Under the Rate

Capacity Charge: $4.80 per kilowatt per month (kWmonth) of billing capacity.

Energy Charge: 18.31 mills per kilowatt-hour (kWh) of monthly entitlement.

Billing Capacity: Unless otherwise specified by contract, the billing capacity will be the seasonal contract rate of delivery.

Charge Components

Base Component: A fixed revenue requirement that includes operation and maintenance expense, investments and replacements, interest on investments and replacements, normal timing power purchases (purchases due to operational constraints, not associated with drought), and transmission costs. Any proposed change to the Base component will require a public process. The Base revenue requirement is $67,839,200 and the charges under the formulas are:

$$\text{Base Capacity} = \frac{50\% \text{ X Base Revenue Requirement}}{\text{Firm Billing Capacity}} = \$4.36/\text{kWmonth}$$

$$\text{Base Energy} = \frac{50\% \text{ X Base Revenue Requirement}}{\text{Annual Energy}} = 16.63 \text{ mills/kWh}$$

Drought Adder Component: A formula-based revenue requirement that includes future power purchases above normal timing power purchases, previous purchase power drought-related deficits, and interest on the purchase power drought-related deficits. As of January 1, 2023, the Drought Adder component revenue requirement is $6,838,720 and the charges under the formulas are:

$$\text{Drought Adder Capacity} = \frac{50\% \text{ X Drought Adder Revenue Requirement}}{\text{Firm Billing Capacity}} = \$0.44/\text{kWmonth}$$

$$\text{Drought Adder Energy} = \frac{50\% \text{ X Drought Adder Revenue Requirement}}{\text{Annual Energy}} = 1.68 \text{ mills/kWh}$$

Annual Drought Adder Adjustment Process

The Drought Adder component may be adjusted annually using the above formulas for any costs attributed to drought of less than or equal to the equivalent of 2 mills/kWh to the Rate. Any planned incremental upward adjustment to the Drought Adder component greater than the equivalent of 2 mills/kWh to the Rate will require a public process.

The annual review process is initiated in early summer when the Rocky Mountain Region (RMR) reviews the Drought Adder component and provides notice of any estimated change to the Drought Adder component charge under the formula. In October, RMR will make a final determination of any change to the Drought Adder component charge, either incremental or decremental. If a Drought Adder component change is required, a modified Drought Adder revenue requirement and the associated charges will become effective the following January 1 and will be identified in a Drought Adder modification update. RMR will inform customers of updates by letter and post updates to RMR's external website.

Adjustments

For Transformer Losses: If delivery is made at transmission voltage but metered on the low-voltage side of the substation, the meter readings will be increased to compensate for transformer losses as provided for in the contract.

For Power Factor: None. Customers will be required to maintain a power factor within the range of 95-percent leading to 95-percent lagging, measured at the point of interconnection.

Rate Schedule L–M3

(Supersedes Rate Schedule L–M2)

Effective January 1, 2023

United States Department of Energy

Western Area Power Administration

Rocky Mountain Region

Loveland Area Projects

Sale of Surplus Products

(Approved Under Rate Order No. WAPA–202)

Effective

The first day of the first full billing period beginning on or after January 1, 2023, and extending through December 31, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Loveland Area Projects (LAP) Marketing and is applicable to the sale of the following LAP surplus energy and capacity products: energy, frequency response, regulation, and reserves. If any of the above LAP surplus products are available, LAP can make the product(s) available for sale, providing entities enter into separate agreement(s) with LAP Marketing which will specify the terms of sale(s).

Formula Rate

The charge for each product will be determined at the time of the sale based on market rates, plus administrative costs. The customer will be responsible for acquiring transmission service necessary to deliver the product(s), for which a separate charge may be incurred.

[FR Doc. 2022–25266 Filed 11–18–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Pick-Sloan Missouri Basin Program—Eastern Division-Rate Order No. WAPA–203

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order concerning firm power service, firm peaking power service, and sale of surplus products formula rates.

SUMMARY: The formula rates for the Upper Great Plains Region (UGP) Pick-Sloan Missouri Basin Program—Eastern Division (P–SMBP—ED) firm power service, firm peaking power service, and sale of surplus products have been confirmed, approved, and placed into effect on an interim basis (Provisional Formula Rates). These new formula rates replace the existing formula rates for these services under Rate Schedules P–SED–F13, P–SED–FP13, and P–SED–M1, which expire on December 31, 2022. The P–SMBP—ED firm power service composite rate is increasing 16.3 percent. There are no changes to the formula rate for sale of surplus products.

DATES: The Provisional Formula Rates under Rate Schedules P–SED–F14, Firm Power Service; P–SED–FP14, Firm Peaking Power Service; and Rate Schedule P–SED–M2, Sale of Surplus Products, are effective on the first day of the first full billing period beginning on or after January 1, 2023, and will remain in effect through December 31, 2027, pending confirmation and approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Lloyd Linke, Regional Manager, Upper Great Plains Region, Western Area Power Administration, 2900 4th Avenue North, 6th Floor, Billings, MT 59101–1266, or email: *ugpfirmrate@wapa.gov,* or Linda Cady-Hoffman, Rates Manager, Upper Great Plains Region, Western Area Power Administration, (406) 255–2920, or email: *cady@wapa.gov* or *ugpfirmrate@wapa.gov.*

SUPPLEMENTARY INFORMATION: On April 16, 2018, FERC confirmed and approved Formula Rate Schedules P–SED–F13, P–SED–FP13, and P–SED–M1, under Rate Order No. WAPA–180, on a final basis through December 31, 2022.[1] These schedules apply to P–SMBP—ED firm power service, firm peaking power service, and sale of surplus products. Western Area Power Administration (WAPA) published a **Federal Register** notice (Proposed FRN) on May 25, 2022 (87 FR 31878), proposing increases to both the base component and the drought adder component of the P–SMBP—ED firm power service and firm peaking power service and to put new 5-year rate schedules in place. The Proposed FRN also initiated a 90-day public consultation and comment period and set forth the dates and locations of the public information and public comment forums.

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and

[1] Order Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. EF18–2–000, 163 FERC ¶ 62,039 (2018).

Department of Energy procedures for public participation in rate adjustments set forth at 10 CFR part 903.[2]

Following review of UGP's proposal, Rate Order No. WAPA–203, which provides the formula rates for the P–SMBP—ED firm power service, firm peaking power service, and sale of surplus products, is hereby confirmed, approved, and placed into effect on an interim basis. WAPA will submit Rate Order No. WAPA–203 to FERC for confirmation and approval on a final basis.

Department of Energy Administrator, Western Area Power Administration

In the Matter of: Western Area Power Administration, Upper Great Plains Region, Rate Adjustment for the Pick-Sloan Missouri Basin Program—Eastern Division, Firm Power Service, Firm Peaking Power Service, and Sale of Surplus Products Formula Rates

Rate Order No. WAPA–203

Order Confirming, Approving, and Placing the Formula Rates for the Pick-Sloan Missouri Basin Program—Eastern Division Into Effect on an Interim Basis

The formula rates in Rate Order No. WAPA–203 are established following section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).[3]

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the Western Area Power Administration (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to the Federal Energy Regulatory Commission (FERC). By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and DOE procedures for public participation in rate adjustments set forth at 10 CFR part 903.[4]

Acronyms, Terms, and Definitions

As used in this Rate Order, the following acronyms, terms, and definitions apply:

Base: A component of the firm power and firm peaking power rate design that is a fixed revenue requirement that includes operation and maintenance expenses (O&M), investments and replacements, interest on investments and replacements, normal timing power purchases, and transmission costs.

Capacity: The electric capability of a generator, transformer, transmission circuit, or other equipment. It is expressed in kilowatts (kW) or megawatts (MW).

Capacity Rate: The rate which sets forth the charges for capacity. It is expressed in dollars per kilowatt-month (kWmonth) and applied to each kW of the Contract Rate of Delivery or CROD.

Composite Rate: The Power Repayment Study (PRS) rate for commercial firm power, which is the total annual revenue requirement for capacity and energy divided by the total annual energy sales. It is expressed in mills per kilowatt-hour (mills/kWh) and used only for comparison purposes.

Corps of Engineers Annual Operating Plan (AOP): The Corps of Engineers water management guidelines designed to meet the reservoir regulation objectives.

Customer: An entity with a contract that is receiving Pick-Sloan Missouri Basin Program—Eastern Division (P–SMBP—ED) firm power service from WAPA.

Customer Rate Brochure: A document prepared for public distribution explaining the rationale and background for the information contained in the Proposed FRN and in this rate order.

Deficit(s): Deferred or unrecovered annual and/or interest expenses.

Demand: The rate at which electric energy is delivered to or by a system or part of a system, generally expressed in kilowatts (kW) or megawatts (MW), at a given instant or averaged over any designated interval of time.

Drought Adder: A component of the firm power and firm peaking power rate design that is a formula-based revenue requirement that includes future power purchases above normal timing power purchases, previous purchase power drought-related Deficits, and interest on the purchase power drought-related Deficits.

Energy: Measured in terms of the work it is capable of doing over a period of time. Electric energy is expressed in kilowatt-hours (kWh).

Energy Charge: The charge under the rate schedule for energy. It is expressed in mills/kWh and applied to each kWh delivered to each Customer.

Firm: Power intended to be available at all times during the period covered by a guaranteed commitment to deliver, even under adverse conditions.

FRN: **Federal Register** Notice—a document published in the **Federal Register** *in order for* WAPA to provide information of public interest.

FY: WAPA's fiscal year; October 1 to September 30.

kW: Kilowatt—the electrical unit of capacity that equals 1,000 watts.

kWh: Kilowatt-hour—the electrical unit of energy that equals 1,000 watts in 1 hour.

kWmonth: Kilowatt-month—the electrical unit of the monthly amount of capacity.

mills/kWh: Mills per kilowatt-hour—the unit of charge for energy (equal to one tenth of a cent or one thousandth of a dollar).

NEPA: National Environmental Policy Act of 1969, as amended.

Non-timing Power Purchases: Power purchases related to drought conditions, not related to operational constraints.

Normal Timing Power Purchases: Power purchases related to operational constraints (*e.g.,* management of endangered species habitat, water quality, navigation, balancing authority purposes, market events, etc.), not associated with drought conditions.

O&M: Operation and maintenance expenses.

OM&R: Operation, maintenance, and replacement expenses.

Order RA 6120.2: DOE Order outlining Power Marketing Administration (PMA) financial reporting and rate-making procedures.

Power: Capacity and energy.

Power Factor: The ratio of real to apparent power at any given point and time in an electrical circuit. Generally, it is expressed as a percentage.

Power Repayment Study (PRS): Defined in Order RA 6120.2 as a study portraying the annual repayment of power production and transmission costs of a power system through the application of revenues over the repayment period of the power system.

[2] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[3] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) and section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s); and other acts that specifically apply to the projects involved.

[4] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

The study shows, among other items, estimated revenues and expenses, year by year, over the remainder of the power system's repayment period (based upon conditions prevailing over the cost evaluation period), the estimated amount of Federal investment amortized during each year, and the total estimated amount of Federal investment remaining to be amortized.

Preference: The provisions of Reclamation Law that require WAPA to first make Federal Power available to certain entities. For example, section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) states that preference in the sale of Federal Power shall be given to municipalities and other public corporations or agencies and also to cooperatives and other nonprofit organizations financed in whole or in part by loans made under the Rural Electrification Act of 1936.

Provisional Formula Rates: Formula rates confirmed, approved, and placed into effect on an interim basis by the Secretary of Energy or his/her designee.

Rate-setting PRS: The PRS used for the rate adjustment proposal.

Regions: WAPA's Upper Great Plains Region (UGP) and Rocky Mountain Region (RMR).

Revenue Requirement: The revenue required by the PRS to recover annual expenses (such as O&M, purchase power, transmission service, interest, and deferred expenses) and repay Federal investments and other assigned costs.

Webex: Webex is an online secure invite-only meeting platform used by WAPA. The general website is *https://doe.webex.com.*

Western Energy Imbalance Service Market (WEIS Market): The market for imbalance energy administered by the Southwest Power Pool in the Western Interconnection. The market footprint encompasses the loads and resources that are located within a participating Balancing Authority Area. The Western Area Colorado Missouri Balancing Authority or WACM (operated by RMR) and the Western Area Upper Great Plains West Balancing Authority or WAUW (operated by UGP) are both participating Balancing Authority Areas.

Winter Storm Uri: A severe winter storm in February 2021 that had widespread impacts across UGP and RMR regions.

Effective Date

The Provisional Formula Rate Schedules P–SED–F14, Firm Power Service; P–SED–FP14, Firm Peaking Power Service; and P–SED–M2, Sale of Surplus Products, will take effect on the first day of the first full billing period beginning on or after January 1, 2023, and will remain in effect through December 31, 2027, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

UGP followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in developing these formula rates. The steps UGP took to involve interested parties in the rate process include:

1. On May 25, 2022, a **Federal Register** notice (87 FR 31878) (Proposed FRN) announced the proposed formula rates and launched the 90-day public consultation and comment period.
2. On May 25, 2022, UGP notified Preference Customers and interested parties of the proposed rates and provided a copy of the published Proposed FRN.
3. On June 15, 2022, UGP held a public information forum via Webex. UGP's representatives explained the proposed formula rates, answered questions, and gave notice that more information was available in the Customer Rate Brochure.
4. On June 29, 2022, UGP held a public comment forum via Webex to provide an opportunity for customers and other interested parties to comment for the record.
5. UGP provided a website that contains important dates, letters, presentations, FRNs, Customer Rate Brochure, and other information about this rate process. The website is located at *www.wapa.gov/regions/UGP/rates/pages/2023-firm-rate-adjustment.aspx.*
6. During the 90-day consultation and comment period, which ended on August 23, 2022, UGP received 2 oral comment submissions and 16 written comment letters. The comments and UGP's responses are addressed in the ''Comments'' section. All comments have been considered in the preparation of this Rate Order.

Oral comments were received from the following organizations:

Missouri River Energy Services (MRES), South Dakota
Mid-West Electric Consumers Association, Colorado

Written comments were received from the following organizations:

Missouri River Energy Services (MRES), South Dakota
Worthington Public Utilities, Minnesota
Valley City Public Works, North Dakota
Lakota Municipal Utilities, North Dakota
Elbow Lake Municipal Power, Minnesota
Hartley Municipal Utilities, Iowa
Hawarden Municipal Utilities, Iowa
City of Wadena, Minnesota
City of Vermillion Light & Power, South Dakota
Jackson, Minnesota
Willmar Municipal Utilities, Minnesota
Denison Municipal Utilities Denison, Iowa
Orange City, Iowa
City of Melrose Public Utility, Minnesota
East River Electric Power Cooperative, Inc., South Dakota
Mid-West Electric Consumers Association, Colorado

Power Repayment Study—Firm Power Service Rate Discussion

A PRS is prepared each FY to determine if revenues will be sufficient to repay, within the required time, all costs assigned to the Pick-Sloan Missouri Basin Program (P–SMBP). Repayment criteria are based on applicable laws and legislation as well as policies including Order RA 6120.2. To meet the Cost Recovery Criteria outlined in Order RA 6120.2, UGP developed a rate adjustment to demonstrate sufficient revenues will be collected under the Provisional Formula Rates to meet future obligations. The revenue requirement for P–SMBP is recovered by both the UGP in the P–SMB—ED rates and by RMR in the Loveland Area Projects (LAP) rate. The revenue requirement and composite rate for P–SMBP—ED firm power service are being increased, as indicated in Table 1:

TABLE 1—COMPARISON OF EXISTING AND PROVISIONAL REVENUE REQUIREMENTS AND COMPOSITE RATES

Firm power service	Existing requirements under P–SED–F13 as of January 1, 2018	Provisional requirements under P–SED–F14 as of January 1, 2023	Percent change
P–SMBP—ED Revenue [1/] Requirement (million $)	$230.1	$268.4	16.6
P–SMBP—ED Composite Rate (mills/kWh)	24.00	27.91	16.3

[1/] The Pick-Sloan—WD revenue requirement is recovered under the LAP rate schedule, which can be found under Rate Order No. WAPA–202 and on RMR's website at *www.wapa.gov/regions/RM/rates/Pages/2023-Rate-Adjustment---Firm-Power.aspx.*

Firm Power Service—Existing and Provisional Formula Rates

Under the current rate methodology, rates for P–SMBP—ED firm power and firm peaking power services are designed to recover an annual revenue requirement that includes investment repayment (including aid to irrigation), interest, purchase power, OM&R, and other expenses within the allowable period. The annual revenue requirement continues to be allocated equally between demand and energy.

The Base component costs for the P–SMBP PRS have increased primarily due to: (1) increased OM&R from WAPA and the generating agencies; (2) increased purchase power, including during the Winter Storm Uri; (3) pricing volatility; (4) reduced surplus energy sales; and (5) the loss of certain balancing authority revenues for services that are no longer provided after RMR joined the WEIS Market. Winter Storm Uri was not a water or generation issue; therefore, its costs only impact the Base component.

The driver behind the P–SMBP PRS Drought Adder component increase is the AOP projecting less than average generation for the next several years in the P–SMBP mainstem dams. Uncertainties with water inflows, hydro generation, and replacement energy prices continue to pose potential risks for meeting firm power contractual commitments.

The net effect of these changes to the PRS Base and Drought Adder components results in an overall increase to the P–SMBP—ED rate. A comparison of the existing and Provisional Formula Rates for firm power and firm peaking power service is shown in Table 2:

TABLE 2—COMPARISON OF EXISTING AND PROVISIONAL FORMULA RATES

Firm power & firm peaking power service	Existing charges under rate schedule P–SED–F13 & P–SED–FP13 as of January 1, 2018	Provisional charges under rate schedule P–SED–F14 & P–SED–FP14 as of January 1, 2023	Percent change
Firm Demand ($/kWmonth)	$5.25	$6.20	18.1
Firm Energy (mills/kWh)	13.27	15.27	15.1
Firm Peaking Demand ($/kWmonth)	4.75	5.70	20.0
Firm Peaking Energy [1/] (mills/kWh)	13.27	15.27	15.1

[1/] Firm Peaking Energy is normally returned. This charge will be assessed in the event Firm Peaking Energy is not returned.

As a part of the existing and provisional rate schedules, UGP provides for a formula-based adjustment of the Drought Adder component, with an annual increase of up to 2 mills/kWh each year. The 2 mills/kWh cap places a limit on the amount the Drought Adder component can be adjusted upward relative to associated drought costs included in the Drought Adder formula rate for any 1-year cycle. The Drought Adder component may be adjusted downward by any amount. Continuing to identify the firm power service revenue requirement using Base and Drought Adder components will assist the Regions in presenting the future impacts of droughts, demonstrate repayment of drought-related costs in the PRS, and allow the Regions to be more responsive to changes caused by drought-related expenses. UGP will continue to charge and bill its customers firm power and firm peaking power service rates for energy and demand, which are the sum of the Base and Drought Adder components.

Under Rate Schedule P–SED–F14, UGP will continue to identify its P–SMBP—ED firm power service revenue requirement using Base and Drought Adder components. The Base component is a fixed revenue requirement that includes annual O&M, investment repayment and associated interest, Normal Timing Power Purchases, and transmission costs. UGP cannot adjust the Base component without a public process. The Drought Adder component is a formula-based revenue requirement that includes costs attributable to drought conditions in the Regions. The Drought Adder component includes costs associated with future Non-timing Power Purchases to meet firm power service contractual obligations not covered with available system generation due to a drought, previously incurred Deficits due to purchased power debt that resulted from Non-timing Power Purchases made during a drought, and the interest associated with drought-related Deficits. The Drought Adder component is designed to repay drought-related Deficits within 10 years from the time the Deficit was incurred, using balloon-payment methodology. For example, a drought-related Deficit incurred in FY 2022 will be repaid by FY 2032.

The annual revenue requirement calculation will continue to be summarized by the following formula: Annual Revenue Requirement = Base Revenue Requirement + Drought Adder Revenue Requirement.

The Provisional charge components update the Base component with present costs from a revenue

requirement of $230.1 million to $235.4 million and increases the Drought Adder component revenue requirement. For rate year 2023, the Drought Adder revenue requirement increases from zero to $33 million. A comparison of the existing and provisional components is shown in Table 3:

TABLE 3—SUMMARY OF P–SMBP—ED EXISTING AND PROVISIONAL CHARGE COMPONENTS

Firm power & firm peaking power service	Existing charges under rate schedules P–SED–F13 & P–SED–FP13 as of January 1, 2018			Provisional charges under rate schedules P–SED–F14 & P–SED–FP14 as of January 1, 2023			Percent change
	Base component	Drought adder component	Total charge	Base component	Drought adder component	Total charge	
Firm Demand (/kWmonth)	$5.25	$0.00	$5.25	$5.45	$0.75	$6.20	18.1
Firm Energy (mills/kWh)	13.27	0.00	13.27	13.36	1.91	15.27	15.1
Firm Peaking Demand ($/kWmonth)	4.75	0.00	4.75	5.00	0.70	5.70	20
Firm Peaking Energy [1/] (mills/kWh)	13.27	0.00	13.27	13.36	1.91	15.27	15.1

[1/] Firm peaking energy is normally returned. This charge will be assessed in the event firm peaking energy is not returned.

The Regions review the inputs for the P–SMBP Base and Drought Adder components after the annual PRS is complete, generally in the first quarter of the calendar year. If an adjustment to the P–SMBP Base component is necessary, or if an incremental upward adjustment to the P–SMBP PRS Drought Adder component greater than the equivalent of 2 mills/kWh to the P–SMBP Composite Rate is necessary, the Regions will initiate a public process pursuant to 10 CFR part 903 prior to making adjustments.

In accordance with the approved annual Drought Adder adjustment process, the Drought Adder component is reviewed annually in early summer to determine if drought costs differ from those projected in the PRS. In October, the Regions will determine if a change to the Drought Adder component is necessary, either incremental or decremental. Any incremental adjustment to the Drought Adder component, up to 2 mills/kWh, or any decremental adjustment will be implemented by the Regions in the following January billing cycle. Although decremental adjustments to the Drought Adder component will occur as drought costs are repaid, the adjustments cannot result in a negative Drought Adder component. Implementing the Drought Adder component adjustment on January 1 of each year will help keep the drought-related Deficits from escalating as quickly, will lower the interest expense due to drought-related Deficits, will demonstrate responsible Deficit management, and will provide prompt drought-related Deficit repayments.

Statement of Revenue and Related Expenses

The following Table 4 provides a summary of the projected revenue and expense data for the P–SMBP revenue requirement during the 5-year rate-setting periods:

TABLE 4—P–SMBP COMPARISON OF 5-YEAR RATE PERIODS TOTAL REVENUES AND EXPENSES

	Existing rate FY2018–FY2022 ($000)	Provisional rate FY2023–FY2027 ($000)	Difference ($000)
Total Revenues	$2,720.2	$3,185.8	$465.6
Revenue Distribution.			
Expenses			
O&M	1,158.9	1,376.5	217.6
Purchase Power	124.8	288.0	163.2
Transmission	461.0	845.2	384.2
Interest	556.3	516.5	(39.8)
Total Expenses	2,301.0	3,026.2	725.2
Principal Payments:			
Capitalized Expenses (Deficits)	113.4	111.2	(2.2)
Original Project and Additions	187.2	38.2	(149.0)
Irrigation Aid	45.7	0.0	(45.7)
Replacements	72.9	10.2	(62.7)
Total Principal Payments	419.2	159.6	(259.6)
Total Revenue Distribution	2,720.2	3,185.8	465.6

Sale of Surplus Products Rate Discussion

The sale of surplus products rate schedule is formula-based, providing for P–SMBP—ED Marketing Office to sell P–SMBP—ED surplus energy and demand products. If P–SMBP—ED surplus products are available, as specified in the rate schedule, the charge will be based on market rates plus administrative costs. The customer will be responsible for acquiring transmission service necessary to deliver the product(s) for which a separate charge may be incurred. Rate

Schedule P–SED–M1 is being superseded by the Provisional Rate Schedule P–SED–M2 and continues to allow for the sale of energy, frequency response, regulation, and reserves.

Comments

UGP received 2 oral and 16 written submissions during the public consultation and comment period. Comments expressed have been paraphrased and/or combined, where appropriate, without compromising the meaning of the comments:

A. *Comment:* The customer association, member utility, and the action agency commented that they understand a rate increase is warranted due to several factors: (1) persistent low water conditions in the P–SMBP—ED, (2) increasing market power pricing, (3) costs incurred during the Winter Storm Uri, and (4) inflation on O&M and capital investments for the system. They encourage WAPA to continue focus on identifying and reducing controllable costs within the Regions and at WAPA's Headquarters. The action agency understands the full rate increase of 16.3 percent is necessary in 2023.

Response: The Regions appreciate the commentors' recognition of the specific costs and repayment obligations of the PRS and the need for the rate adjustments. The Regions are committed to developing rates that are the lowest possible, consistent with sound business principles.

B. *Comment:* The action agency commented that they understand the need to cover expenses necessary to provide firm, reliable service that is sustainable, and wants to ensure that proper planning is in place in order to guarantee the solvency of the system and not get into the situation the P–SMBP—ED experienced during the last drought.

Response: UGP appreciates the commentor's understanding of the impacts of drought conditions in the P–SMBP—ED. UGP intends to continue transparency and data sharing to encourage a strong working relationship with our Customers as we continue to provide products that are reliable and sustainable and meet repayment obligations of the power system.

C. *Comment:* Several Customers commented that this rate adjustment is substantial for the communities they serve, and they would have preferred for this increase to be implemented in multiple stages rather than one large increase beginning in 2023. They stated perhaps this could have been achieved by starting a few years earlier in planning for rate adjustments.

Response: The 10-month timeline associated with a public process is a major factor when initiating rate adjustments. Given the required timeline, in addition to the timing of the data to effectively evaluate impacts to the rate, UGP was as timely as could be when initiating this rate adjustment. UGP did notify Customers in both the spring 2021 and fall 2021 Drought Adder review letters that the rate schedules were expiring December 31, 2022, and that we would be in a formal rate process in 2022 to put new rates in place.

D. *Comment:* The action agency and customer association commented that they recommend the Rate's staff and Regional leadership continue to meet regularly with the Mid-West Electric Consumers Association's (Mid-West) Water and Power Committee on a quarterly basis to update and advise the members on the latest information on hydrology outlook, power supply costs, system storage, and potential need for future adjustments as this will allow more advance notice for dealing with future issues.

Response: Customer meeting attendance is outside the scope of this rate process; however, the Regions do intend to continue communication with our Customers and customer groups, as appropriate.

E. *Comment:* The action agency commented they prefer WAPA return to meeting with Customers/customer groups in person, as many in the industry have been meeting face-to-face for several months (post-COVID), and that it is important to have those in-person meetings to deal with issues more fully as this is the means to further understanding and to more efficiently resolve issues.

Response: Customer meeting attendance is outside the scope of this rate process; however, the Regions appreciate the comments and strive to communicate as broadly as possible with our Customers. It is the Regions' observation that the virtual meetings held for this rate process had greater attendance than when in person meetings were held prior to March 2020.

F. *Comment:* The action agency commented that the Regions should provide for more comprehensive and rigorous scenario analysis as part of the PRS and show details related to the assumptions and the results to Customers/customer groups. It also was noted that the new PRS system utilized by WAPA does not have the transparency promised and has not been as successful or open to customer access through the PRS customer portal.

Response: UGP intends to continue transparency and data sharing to encourage a strong working relationship with our Customers/customer groups. The PRS software tool is outside the scope of this rate process; however, WAPA's Information Technology (IT) and Rates staff have been evaluating the concerns with the PRS software. IT has contacted the vendor to address the issues and developed a plan to hopefully address the interface issue for external entity interfacing.

G. *Comment:* The action agency, customer association, and member utility request WAPA staff continue transparent engagements with the Customers and customer groups to better understand WAPA's efforts to control and mitigate costs, rate impacts, impacts of drought conditions, importance of rate stability, and need for risk mitigation through regular meetings with the Mid-West Water and Power Committee and impacted customer groups. The strong collaboration between customers and WAPA benefits everyone and improves the value we all provide to the consumer-owners at the end of the line.

Response: The Regions appreciate the support of our Customers and customer groups and agree that collaboration is vital when faced with uncertain drought conditions and other impacts to the firm power rates. The Regions intend to continue communication with our Customers and customer groups as appropriate.

H. *Comment:* The customer association and member utility commented that they appreciated the efforts of the UGP and RMR Rates staff for understanding Customer concerns regarding the rate.

Response: The Regions thank the commentors for recognizing the UGP and RMR Rates staff and their efforts to ensure Customer concerns are addressed.

I. *Comment:* A customer association and a member utility commented their customers are already feeling the impacts of the current drought in the P–SMBP—ED and understand the need for the Drought Adder and the process for the Drought Adder evaluation. They requested debt strategy and rate design options be discussed with customers before any final decisions are made as a part of the annual Drought Adder review process.

Response: The Regions agree with the need for continued transparency regarding debt strategy and rate options related to the annual Drought Adder adjustment process. The proposed rates did not reflect any change to the Regions' existing rate designs or annual

Drought Adder adjustment process. Changes to the rate designs or adjustment process would require a separate rate process where Customers and interested parties would have the opportunity to participate in the process. The 2007 rate orders implementing the Drought Adder component provided the framework for the annual Drought Adder adjustment process, which has not been modified in subsequent rate orders.

J. *Comment:* The member utility encourages WAPA to focus on its core function of marketing and delivering Preference Power to Preference Customers.

Response: The Regions appreciate the comment and intend to continue to fulfill our mission of marketing to Preference Power Customers consistent with current marketing plans.

K. *Comment:* The customer association commented that they support the comments of their member utilities and fellow customer groups.

Response: The Regions appreciate the commentor's feedback. The Regions conducted a combined public process for the rate adjustments under Rate Order Nos. WAPA–202 and WAPA–203 and have coordinated all responses. Comments received specifically by RMR for the LAP rate process are recognized as being addressed in RMR's Rate Order No. WAPA–202.

L. *Comment:* The customer association and member utility appreciated the opportunity to comment on the rate process, stating that any rate increase has a direct impact on the energy affordability of the members it serves.

Response: The Regions recognize the impact of the rate increases on Customers and strive to find ways to mitigate impacts of the drought and operational costs to keep rates as low as possible.

Certification of Rates

I have certified that the Provisional Formula Rates for P–SMBP—ED firm power service under Rate Schedule P–SED–F14, P–SMBP—ED firm peaking power service under Rate Schedule P–SED–FP14, and P–SMBP—ED sale of surplus products under Rate Schedule P–SED–M2 are the lowest possible rates, consistent with sound business principles. The Provisional Formula Rates were developed following administrative policies and applicable laws.

Availability of Information

Information about this rate adjustment, including the Customer Rate Brochure, PRSs, comments, letters, memorandums, and other supporting materials that were used to develop the Provisional Formula Rates, is available for inspection and copying at the Upper Great Plains Regional Office located at 2900 4th Avenue North, 6th Floor, Billings, Montana. Many of these documents are also available on UGP's website at *www.wapa.gov/regions/UGP/rates/Pages/2023-firm-rate-adjustment.aspx*

Ratemaking Procedure Requirements

Environmental Compliance

WAPA has determined that this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021.410: B4.3 (Electric power marketing rate changes). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.[5] A copy of the categorical exclusion determination is available on WAPA's website at *www.wapa.gov/regions/UGP/Environment/Pages/CX2022.aspx.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Formula Rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA–203. The rates will remain in effect on an interim basis until: (1) FERC confirms and approves them on a final basis; (2) subsequent rates are confirmed and approved; or (3) such rates are superseded.

Signing Authority

This document of the Department of Energy was signed on November 9, 2022, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 16, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

Rate Schedule P–SED–F14 (Supersedes Rate Schedule P–SED–F13): Effective January 1, 2023

United States Department of Energy, Western Area Power Administration

Upper Great Plains Region Pick-Sloan Missouri Basin Program—Eastern Division

Firm Power Service (Approved Under Rate Order No. WAPA–203)

Effective

The first day of the first full billing period beginning on or after January 1, 2023, through December 31, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Available

Within the marketing area served by the Eastern Division of the Pick-Sloan Missouri Basin Program, within Montana, North Dakota, South Dakota, Minnesota, Iowa, and Nebraska.

Applicable

To the power and energy delivered to customers as firm power service, as established in the contract for service.

Character

Alternating current, 60 hertz, three phase, delivered and metered at the voltages and points established by contract.

Formula Rate and Charge Components

Rate = Base component + Drought Adder component

Monthly Charge as of January 1, 2023, under the Rate:

CAPACITY CHARGE: $6.20 for each kilowatt per month (kWmonth) of billing capacity.

[5] The determination was done in compliance with NEPA (42 U.S.C. 4321–4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

ENERGY CHARGE: 15.27 mills for each kilowatt-hour (kWh) for all energy delivered as firm power service.

BILLING CAPACITY: The billing capacity will be as defined by the power sales contract.

Charge Components

Base Component: A fixed-revenue requirement that includes operation and maintenance expense, investments and replacements, interest on investments and replacements, normal timing power purchases (purchases due to operational constraints, not associated with drought), and transmission costs. Any proposed change to the Base component will require a public process. As of January 1, 2023, the Base component revenue requirement is $213.8 million and the charges under the formulas are:

$$\text{Base Capacity} = \frac{50\% \text{ X Base Revenue Requirement}}{\text{Firm Metered Billing Units}} = \$5.45/\text{kWmonth}$$

$$\text{Base Energy} = \frac{50\% \text{ X Base Revenue Requirement}}{\text{Annual Energy}} = 13.36 \text{ mills/kWh}$$

Drought Adder Component: A formula-based revenue requirement that includes future power purchases above normal timing power purchases, previous purchase power drought-related deficits, and interest on the purchase power drought-related deficits. As of January 1, 2023, the Drought Adder component revenue requirement is $30.0 million and the charges under the formulas are:

$$\text{Drought Adder Capacity} = \frac{50\% \text{ X Drought Adder Revenue Requirement}}{\text{Firm Metered Billing Units}} = 0.75/\text{kWmonth}$$

$$\text{Drought Adder Energy} = \frac{50\% \text{ X Drought Adder Revenue Requirement}}{\text{Annual Energy}} = 1.91 \text{ mills/kWh}$$

Annual Drought Adder Adjustment Process

The Drought Adder component may be adjusted annually using the above formulas for any costs attributed to drought of less than or equal to the equivalent of 2 mills/kWh to the Pick-Sloan Missouri Basin Program Power Repayment Study (PRS) composite rate. Any planned incremental upward adjustment to the Drought Adder component greater than the equivalent of 2 mills/kWh to the PRS composite rate will require a public process.

The annual review process is initiated in early summer when the Upper Great Plains Region (UGP) reviews the Drought Adder component and provides notice of any estimated change to the Drought Adder component charge under the formula. In October, UGP will make a final determination of any change to the Drought Adder component charge, either incremental or decremental. If a Drought Adder component change is required, a modified Drought Adder revenue requirement and the associated charges will become effective the following January 1 and will be identified in a Drought Adder modification update. UGP will inform customers of updates by letter and post updates to UGP's external website.

Adjustments

For Billing of Unauthorized Overruns: For each billing period in which there is a contract violation involving an unauthorized overrun of the contractual firm power and/or energy obligations, such overrun shall be billed at 10 times the formula rate.

For Power Factor: None. Customers will be required to maintain a power factor within the range of 95-percent leading and 95-percent lagging, measured at the point of interconnection.

Rate Schedule P–SED–FP14 (Supersedes Rate Schedule P–SED–FP13): Effective January 1, 2023

United States Department of Energy, Western Area Power Administration

Upper Great Plains Region Pick-Sloan Missouri Basin Program—Eastern Division

Firm Peaking Power Service (Under Rate Order No. WAPA–203)

Effective

The first day of the first full billing period beginning on or after January 1, 2023, through December 31, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Available

Within the marketing area served by the Eastern Division of the Pick-Sloan Missouri Basin Program, within Montana, North Dakota, South Dakota, Minnesota, Iowa, and Nebraska.

Applicable

To the power sold to customers as firm peaking power service, as established in the contract for service.

Character

Alternating current, 60 hertz, three phase, delivered and metered at the voltages and points established by contract.

Formula Rate and Charge Components

Rate = Base component + Drought Adder component

Monthly Charge as of January 1, 2023, under the Rate:

CAPACITY CHARGE: $5.70 for each kilowatt per month (kWmonth) of the effective contract rate of delivery for peaking power or the maximum amount scheduled, whichever is greater.

ENERGY CHARGE: 15.27 mills for each kilowatt-hour (kWh) for all energy scheduled for delivery without return.

Charge Components

Base Component: A fixed revenue requirement that includes operation and maintenance expense, investments and replacements, interest on investments and replacements, normal timing power purchases (purchases due to operational constraints, not associated with

drought), and transmission costs. Any proposed change to the Base component will require a public process. As of January 1, 2023, the Base component revenue requirement is $21.6 million and the charges under the formulas are:

$$\text{Base Capacity} = \frac{\text{Base Peaking Capacity Revenue Requirement}}{\text{Peaking CROD Billing Units}} = \$5.00/\text{kWmonth}$$

Drought Adder Component: A formula-based revenue requirement that includes future power purchases above normal timing power purchases, previous purchase power drought-related deficits, and interest on the purchase power drought-related deficits. As of January 1, 2023, the Drought Adder component revenue requirement is $3.0 million and the charges under the formulas are:

$$\text{Drought Adder Capacity} = \frac{\text{Drought Adder Peaking Capacity Revenue Requirement}}{\text{Peaking CROD Billing Units}} = 0.70/\text{kWmonth}$$

Annual Drought Adder Adjustment Process

The Drought Adder may be adjusted annually using the above formulas for any costs attributed to drought of less than or equal to the equivalent of 2 mills/kWh to the Pick-Sloan Missouri Basin Program Power Repayment Study (PRS) composite rate. Any planned incremental upward adjustment to the Drought Adder greater than the equivalent of 2 mills/kWh to the PRS composite rate will require a public process.

The annual review process is initiated in early summer when the Upper Great Plains Region (UGP) reviews the Drought Adder component and provides notice of any estimated change to the Drought Adder component charge under the formula. In October, UGP will make a final determination of any change to the Drought Adder component charge, either incremental or decremental. If a Drought Adder component change is required, a modified Drought Adder revenue requirement and the associated charges will become effective the following January 1 and will be identified in a Drought Adder modification update. UGP will inform customers of updates by letter and post updates to UGP's external website.

BILLING CAPACITY: The billing capacity will be the greater of (1) the highest 30-minute integrated capacity measured during the month up to, but not in excess of, the delivery obligation under the power sales contract, or (2) the contract rate of delivery.

Adjustments

Billing for Unauthorized Overruns: For each billing period in which there is a contract violation involving an unauthorized overrun of the contractual obligation for peaking capacity and/or energy, such overrun shall be billed at 10 times the above rate.

Rate Schedule P–SED–M2 (Supersedes Rate Schedule P–SED–M1): Effective January 1, 2023

United States Department of Energy, Western Area Power Administration

Upper Great Plains Region Pick-Sloan Missouri Basin Program—Eastern Division

Sale of Surplus Products (Under Rate Order No. WAPA–203)

Effective

The first day of the first full billing period beginning on or after January 1, 2023, through December 31, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Pick-Sloan Missouri Basin Program—Eastern Division (P–SMBP—ED) Marketing and is applicable to the sale of the following P–SMBP—ED surplus energy and capacity products: energy, frequency response, regulation, and reserves. If any P–SMBP—ED surplus energy and capacity products are available, the Upper Great Plains Region (UGP) can make the product(s) available for sale, providing entities enter into a separate agreement(s) with the UGP Marketing Office which will specify the terms of sale(s).

Formula Rate

The charge for each product will be determined at the time of the sale based on market rates, plus administrative costs. The customer will be responsible for acquiring transmission services necessary to deliver the product(s), for which a separate charge may be incurred.

[FR Doc. 2022–25267 Filed 11–18–22; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0631; FRL–10433–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Residential Lead-Based Paint Hazards Disclosure Requirements (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Residential Lead-Based Paint Hazards Disclosure Requirements (EPA ICR Number 1710.09, OMB Control Number 2070–0151) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2022. Public comments were previously requested via the **Federal Register** on March 1, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments must be received on or before December 21, 2022.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OPPT–2017–0631, online *www.regulations.gov* (our preferred method), by email to *www.epa.gov/dockets,* or by mail to: EPA Docket Center, Environmental Protection

Agency, Mail Code 2821T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Regulatory Support Branch (7101M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1204; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's dockets, visit *https://www.epa.gov/dockets.*

Abstract: This ICR covers the information collection activities associated with the reporting and recordkeeping requirements for sellers, lessors, and their agents' disclosure activities in target housing including the allowance of up to ten days for an optional risk assessment or inspection before being obligated under a purchase or lease contract.

Form Numbers: 9600–040 and 9600–041.

Respondents/Affected Entities: Persons engaged in selling or leasing certain residential dwellings built before 1978. The North American Industrial Classification System (NAICS) codes associated with industries most likely affected by the paperwork requirements are provided in the ICR.

Respondent's obligation to respond: Mandatory, 40 CFR part 745.

Estimated number of respondents: 16,793,558 (total).

Frequency of response: On occasion.

Total estimated burden: 5,481,069 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $133,320,708 (per year), includes $0 annualized capital or operation and maintenance costs.

Changes in the Estimates: There is a decrease of 471,275 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. As explained in more detail in the ICR, this decrease reflects revisions to the estimated number of respondents based on updates to data sources, revisions to time burden estimates due to technological change (*e.g.,* widespread use of electronic real estate transacting and documentation), and revisions based on market factors (*e.g.,* declines in the numbers of rentals and declines in the amount of owner-occupied target housing in the market).

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–25282 Filed 11–18–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and of the Board's Regulation LL (12 CFR 238.31) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 6, 2022.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org*:

1. *The Estate of Steven B. Schnall, Sherri Silver Schnall as Preliminary Executor, both of New York, New York;* to retain voting shares of Quontic Bank Acquisition Corp., and Quontic Bank Holdings Corp., and thereby indirectly retain voting shares of Quontic Bank, all of New York, New York.

In addition, the Schnall Disclaimer Trust A, Sherri Silver Schnall, individually and as co-trustee, both of New York, New York, with Amie Hoffman, as co-trustee, New Hope, Pennsylvania; the Sherri S. Schnall Family Irrevocable Trust, Amie Hoffman as trustee, both of New Hope, Pennsylvania; to acquire voting shares of Quontic Bank Acquisition Corp., and Quontic Bank Holdings Corp., and thereby indirectly acquire voting shares of Quontic Bank. Accordingly, all notificants in this notice to become a group acting in concert.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–25351 Filed 11–18–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/*

request.htm. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than December 5, 2022.

A. Federal Reserve Bank of New York (Ivan J. Hurwitz, Head of Bank Applications) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org*:

1. *PL Capital, LLC; Goodbody/PL Capital, LLC; Financial Edge Fund, L.P.; Financial Edge-Strategic Fund, L.P.; PL Capital/Focused Fund, L.P.; Goodbody/PL Capital, L.P.; PL Capital Advisors, LLC; and John W. Palmer and Richard J. Lashley, as principals and managing members of PL Capital Advisors, LLC, PL Capital, LLC, and Goodbody/PL Capital LLC, all of Naples, Florida;* as a group acting in concert, to acquire additional voting shares of Evans Bancorp, Inc., and thereby indirectly acquire additional voting shares of Evans Bank, N.A., both of Williamsville, New York.

B. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street, NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org*:

1. *Strategic Value Investors, LP; Strategic Value Bank Partners, LLC; Strategic Value Opportunities, LP; Strategic Value Private Partners, LLC; and Benjamin Mackovak and Martin Adams, each a managing member of Strategic Value Bank Partners, LLC and Strategic Value Private Partners, LLC, all of Cleveland, Ohio;* as a group acting in concert, to acquire additional voting shares of FineMark Holdings, Inc., and thereby indirectly acquire voting shares of FineMark National Bank & Trust, both of Fort Myers, Florida.

C. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org*:

1. *The James C. Keaster III Revocable Trust, James C. Keaster, as trustee, the Rebecca R. Keaster Revocable Trust, Rebecca R. Keaster, as trustee, and James Keaster IV, all of Greenville, Illinois; Benjamin Keaster, and Marie Keaster, both of Spring Arbor, Michigan;* as a group acting in concert to retain voting shares of Bradford Bancorp, Inc., and thereby indirectly retain voting shares of The Bradford National Bank of Greenville, both of Greenville, Illinois.

D. Federal Reserve Bank of Minneapolis (Stephanie Weber, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org*:

1. *Eunice M. Moody Trust, Robert H. Moody and Michael Moody, individually and as co-trustees, Kathleen Moody, Elizabeth Moody, and Patricia Moody, all of River Falls, Wisconsin;* to become the Moody Family Shareholder Group, a group acting in concert, to retain voting shares of River Falls Bancshares, Inc., and thereby indirectly retain voting shares of River Falls State Bank, both of River Falls, Wisconsin.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–25286 Filed 11–18–22; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. R611004]

Energy Labeling Rule; Correction

AGENCY: Federal Trade Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Trade Commission (''Commission'') published a document in the **Federal Register** of October 12, 2022, concerning the Energy Labeling Rule. Soon after publication, Commission staff learned that the document contained an incorrect number. The Commission is issuing this correction to reflect the corrected number.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome (202–326–2889), Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Room CC–9528, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The final rule document submitted by Commission staff for publication contained a typographical error; specifically, a decimal point was omitted from the price-per-gallon figure for liquid propane in the table for revised appendix K1.

Correction

In final rule FR Doc. 2022–22036 appearing at 87 FR 61465 in the **Federal Register** of Wednesday, October 12, 2022, make the following correction. On page 61477, in the table in appendix K1, in the second column of the entry for ''Propane'', ''$223/gallon [8]'' is corrected to read ''$2.23/gallon [8]''.

Dated: November 16, 2022.

April J. Tabor,

Secretary.

[FR Doc. 2022–25307 Filed 11–18–22; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0310; Docket No. 2022–0001; Sequence No. 17]

Information Collection; Nondiscrimination in Federal Financial Assistance Programs, GSA Form 3702

AGENCY: Office of Civil Rights, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an existing information collection requirement regarding OMB Control No: 3090–0310; Nondiscrimination in Federal Financial Assistance Programs, GSA 3702. This information is needed to facilitate nondiscrimination in GSA's Federal Financial Assistance Programs, consistent with Federal civil rights laws and regulations that apply to recipients of Federal financial assistance.

DATES: Submit comments on or before: January 20, 2023.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, via *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702'' on your attached document. If your comment cannot be submitted using regulations.gov, call or email the points of contact in the **FOR FURTHER**

INFORMATION CONTACT section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Stephanie Stoltzfus Treier, Deputy Associate Administrator, Office of Civil Rights, at telephone 202–501–0767 or via email to *civilrights@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA has mission responsibilities related to monitoring and enforcing compliance with Federal civil rights laws and regulations that apply to Federal financial assistance programs administered by GSA. Specifically, those laws provide that no person on the ground of race, color, national origin, disability, sex or age shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program in connection with which Federal financial assistance is extended under laws administered in whole, or in part, by GSA.

These mission responsibilities generate the requirement to request and obtain certain data from recipients of Federal surplus property for the purpose of determining compliance, such as the number of individuals that speak non-English languages encountered by the recipient's program(s) and how the recipient is addressing meaningful access for individuals that are Limited English Proficient; whether the recipients provide disability access in compliance with applicable laws and standards; whether there has been complaints or lawsuits filed against the recipient based on prohibited discrimination; whether there has been any findings of discrimination; and whether the recipient's facilities are accessible to qualified individuals with disabilities.

B. Annual Reporting Burden

Respondents: 1,200.
Responses per Respondent: 1.
Total Responses: 1,200.
Hours per Response: 2.
Total Burden Hours: 2,400.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702, in all correspondence.

Beth Anne Killoran,
Deputy Chief Information Officer.

[FR Doc. 2022–25277 Filed 11–18–22; 8:45 am]
BILLING CODE 6820–34–P

GENERAL SERVICES ADMINISTRATION

[Notice–ID–2022–02; Docket No. 2022–0002; Sequence No. 29]

Privacy Act of 1974; Notice of a Modified System of Records

AGENCY: Office of the Chief Privacy Officer, General Services Administration (GSA).

ACTION: Notice of a modified system of records.

SUMMARY: GSA proposes to modify a system of records subject to the Privacy Act of 1974, as amended. *Login.gov* is a secure sign-in service with the capability to authenticate and identity proof users before the user is granted access to participating government websites or applications. GSA is modifying the categories of records in the system, the policies and practices for retrieval and routine uses of records, and removing outdated references to National Institute of Standards and Technology (NIST) technical standards. This modification is intended to revise and replace all notices previously describing this system of records.

DATES: Submit comments on or before: December 21, 2022.

ADDRESSES: Submit comments identified by ''Notice–ID–2022–02, Notice of Modified System of Records'' via. Submit comments via *https://www.regulations.gov,* the Federal eRulemaking portal, by searching for Notice–ID–2022–02, Notice of Modified System of Records. Select the link ''Comment Now'' that corresponds with ''Notice–ID–2022–02, Notice of Modified System of Records.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Notice–ID–2022–02, Notice of Modified System of Records'' on your attached document.

FOR FURTHER INFORMATION CONTACT: Richard Speidel, Chief Privacy Officer, GSA, by email at *gsa.privacyact@gsa.gov* or by phone at 202–969–5830.

SUPPLEMENTARY INFORMATION: GSA proposes to alter language in this system of records to remove an outdated NIST technical standard, and instead use plain language to describe the system's authentication and identity proofing process.

In 2019, the Office of Management and Budget (OMB) published Memorandum 2019–17 (M–19–17), which withdrew Memorandum 2004–04 (M–04–04) and specified the most recent version of NIST SP 800–63 as authoritative for defining levels associated with the rigor of various digital identity related functions. OMB directed agencies to transition from the prior use of Levels of Assurance (LOAs) from M–04–04 in favor of Authentication Assurance Levels (AALs), Identity Assurance Levels (IALs), and Federation Assurance Levels (FALs).

To prevent future potential misalignment between Federal guidance and this system of record notice (SORN), this revision removes references to NIST standards and instead uses plain language descriptions of *Login.gov*'s authentication and identity proofing process. This revision also adds categories of records and two new routine uses related to research studies and fraud prevention operations, and details the records management practices for those new records.

Specifically:

- references to Level of Assurance (LOA) are removed because that is an outdated NIST technical standard and *Login.gov* instead uses plain language descriptions of its authentication and identity proofing process;
- use of records to increase coverage and access to authentication and identity proofing services to the public, including studies evaluating impacts to equitable access by identity verification.
- use of records to support fraud prevention operations to preserve

integrity of the authentication and identity proofing system.

Richard Speidel,

Chief Privacy Officer, Office of the Deputy Chief Information Officer, General Services Administration.

SYSTEM NAME AND NUMBER:

GSA/TTS–1 (*Login.gov*)

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

General Services Administration owns *Login.gov,* which is housed in secure data centers in the continental United States. Contact the System Manager listed below for additional information.

SYSTEM MANAGER(S):

Daniel Lopez-Braus, Director, *Login.gov,* TTS, Office of Solutions, General Services Administration, 1800 F Street NW, Washington, DC 20405. *https://www.Login.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E-Government Act of 2002 (Pub. L. 107–347, 44 U.S.C. 3501 note), 6 U.S.C. 1523 (b)(1)(A)–(E), and 40 U.S.C. 501.

PURPOSES(S) OF THE SYSTEM:

The purposes of the system are:

- to provide a secure sign-in service with the capability to authenticate and identity proof users before the user is granted access to participating government websites or applications;
- to prevent fraud and to protect the integrity of the *Login.gov* system; and
- to conduct studies into enhancements to the secure sign-in service, including demographic studies of the equitable performance of new technologies.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system of records include members of the public seeking electronic access to a website or application from a federal, state, or local agency that has integrated with *Login.gov* (''partner agency'') and participants in studies commissioned by GSA to evaluate equitable performance of new identity verification and fraud prevention technologies.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains information provided by individuals who create and use *Login.gov* accounts. There are two types of accounts in the *Login.gov* system: records related to the process of authenticating a *Login.gov* user's account, and records related to the process in which an individual's identity is verified.

For accounts for which *Login.gov* is authenticating the user, the system collects and maintains:

- email address,
- password,
- and phone number (optionally).

For accounts that require a verified identity, the system collects and maintains:

- photographs of their government-issued ID, to include all personal information and images on the ID. Photographs are stored in an encrypted format, and are only accessed to investigate suspected or confirmed fraud;
- Social Security Number (SSN); and
- phone number or postal address.

Each third-party identity proofing service will send information back to *Login.gov* about its attempt to identity proof the user, including:

- Transaction ID;
- pass/fail indicator;
- date/time of transaction; and
- status codes associated with the transaction data.

Each partner agency whose services the user accesses via *Login.gov* may add its own unique identifier to that user's account information.

To protect the public and the integrity of the system, *Login.gov* needs to detect and prevent fraud while providing redress to users who were unable to complete identity verification. To that end, *Login.gov* will also obtain a collection of information about the device (a ''Device ID'') including, for example browser type and internet protocol (IP) address) and usage patterns (*e.g.,* keyboard, mouse, or touchscreen behavior) used to access their *Login.gov* account. The Device ID and usage patterns are assessed by a third-party fraud prevention service along with the other information collected by *Login.gov.* The third-party fraud prevention services provide *Login.gov* risk scores for all of the information assessed, and also provide other identifying attributes that have been associated with that same Device ID in the past. Those identifying attributes include, but are not limited to, names, addresses, phone numbers, and SSNs that have been associated with the Device ID.

Separate from *Login.gov's* active sign-on service, GSA may also conduct studies in which it temporarily collects information from voluntary participants to evaluate the equitable performance of new technologies and guide service improvements. In addition to the categories of records previously described, collection of information for studies could include, but is not limited to:

- demographic information such as race, ethnicity, gender, income, age, and education; and
- biometric information to verify that the applicant matches the identity documents (*e.g.,* a photograph or video of the user).

RECORD SOURCE CATEGORIES:

The sources for information in the system include individual *Login.gov* users, participants in GSA-commissioned studies, third-party identity-proofing services, partner agencies, and third-party fraud prevention services. Individual users and research participants provide information needed to authenticate themselves, verify their identity, or voluntarily respond to research surveys. Each third-party identity proofing service provides transaction details about their attempt to identity proof a user. Partner agencies may provide their own unique identifier to that user's account information. Third party fraud prevention services provide risk scores and identity attributes associated with a user's Device ID.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside GSA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (a) GSA or any component thereof, or (b) any employee of GSA in his/her official capacity, or (c) any employee of GSA in his/her individual capacity where DOJ or GSA has agreed to represent the employee, or (d) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and GSA determines that the records are both relevant and necessary to the litigation.

b. To third parties providing remote or in-person authentication and identity proofing services, inclusive of other federal agencies providing such services, as necessary to authenticate and/or identity proof an individual for access to a participating government website or application;

c. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate

authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

d. To a Member of Congress or his or her staff in response to a request made on behalf of and at the request of the individual who is the subject of the record.

e. To the Office of Management and Budget (OMB), Office of Inspector General (OIG), and the Government Accountability Office (GAO) in accordance with their responsibilities for evaluation or oversight of Federal programs.

f. To an expert, consultant, or contractor of GSA in the performance of a federal duty to which the information is relevant.

g. To the National Archives and Records Administration (NARA) for records management purposes.

h. To appropriate agencies, entities, and persons when (1) GSA suspects or has confirmed that there has been a breach of the system of records; (2) GSA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, GSA (including its information systems, programs and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with GSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

i. To another Federal agency or Federal entity, when GSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

j. To the Government Publishing Office (GPO), when *Login.gov* needs to mail a user an address confirmation form or if a user requests mailed notifications of account changes or of proofing attempts.

k. To other federal agencies and third-party fraud prevention services as necessary to detect and investigate suspected fraud, including providing redress to users.

l. To third-party identity proofing services and fraud prevention services when participating in studies commissioned by the GSA to evaluate the equitable performance of new technologies and guide service improvements.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records are stored electronically in databases. User account information is encrypted in transit and at rest.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records retrieval practices vary based on the type or category of record in the system.

a. When a user logs in, *Login.gov* retrieves their email and phone number (if provided) to send the user a one-time passcode.

b. When a user accesses a participating government website or application that requires the user's identity attributes, the following retrieval practice occurs:

i. The user successfully logs into their account (enabling decryption and retrieval of certain records);

ii. *Login.gov* decrypts and retrieves the user's verified personal information (full name, date of birth, postal address, and Social Security Number); and

iii. *Login.gov* requests that the user provide consent to share the personal information requested by the participating government site.

c. When a user with verified identity is recovering access to their account, the following retrieval practice occurs:

i. The user successfully authenticates their account when requesting to reset their *Login.gov* password;

ii. The user provides their personal recovery code (enabling decryption and retrieval of the records) and selects a new password;

iii. *Login.gov* retrieves the user's verified personal information (full name, date of birth, postal address, and Social Security Number);

iv. These attributes are then encrypted with the user's new password.

d. When *Login.gov* is performing fraud investigation and redress, the following retrieval practices occur:

i. Only trained *Login.gov* fraud operations personnel have access to records maintained specifically for fraud prevention purposes. This includes Device IDs and usage patterns associated with personal identifiers and risk scores as described in the Categories of Records in the System.

ii. *Login.gov* fraud operations personnel retrieve personal information (full name, date of birth, postal address and Social Security Number) from third-party identity proofing services while completing a manual review of a user's identity proofing transaction.

e. When GSA is conducting studies into enhancements to the secure sign-in service, data from voluntary participants' surveys and identity-proofing transactions are retrieved by GSA and third-party contractors to conduct statistical analysis of the performance of new technologies. Data from *Login.gov's* active service is not retrieved during these studies.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposal policies and practices vary based on the type or category of record in the system.

a. Records related to active user authentication and validated user identities will be retained and disposed of in accordance with NARA's General Records Schedule (GRS) 3.2 (Transmittal 26), item 31 ''System access records'' covering user profiles, log-in files, password files, audit trail files and extracts, system usage files, and cost-back files used to assess charges for system use. The guidance instructs, ''Destroy 6 years after password is altered or user account is terminated, but longer retention is authorized if required for business use.''

b. Records related to identity verification attempts (photographs of government IDs, personal information entered by the user) may be retained by *Login.gov* to aid in fraud investigation, redress, or product improvement.

c. Records related to fraud prevention operations, such as Device IDs and user behaviors with associated identity attributes and risk scores, are maintained by a third party on behalf of GSA for up to three years.

d. For studies commissioned by GSA, third-party proofing services will discard any information collected within 24 hours of collection. GSA will maintain the information for the duration of the study after which it will be preserved for 6 years as required by the GSA's retention schedule for Customer Research and Reporting Records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse through a combination of administrative, technical, and physical security measures. Administrative measures include but are not limited to

policies that limit system access to individuals within an agency with a legitimate business need, and regular review of security procedures and best practices to enhance security. Technical security measures within GSA include restrictions on computer access to authorized individuals, required use of passphrases and regular review of security procedures and best practices to enhance security. Access to the *Login.gov* database is maintained behind an industry-standard firewall and information in the database is encrypted. As noted above, other than email address, neither the system nor the system operators can retrieve the user's personal account information without the user supplying a password or recovery code. Trained and cleared *Login.gov* fraud operations personnel are able to cross-reference personal information used by third party or federal agency identity proofing services to validate a user's identity attributes as part of a manual review of identity proofing transactions. Records related to studies are kept separate from records related to *Login.gov*'s active users.

RECORD ACCESS PROCEDURES:

Requests for access to records should be directed to the system manager. Individuals seeking access to their records in this system of records may submit a request by following the instructions provided in 41 CFR part 105–64, subpart 105–64.2.

CONTESTING RECORD PROCEDURES:

During identity proofing, an individual can use the *Login.gov* fraud operations redress mechanism to contest records used by third party identity proofing services. After identity proofing or participating in a study, individuals wishing to contest the content of records about themselves contained in this system of records should contact the system manager at the address above. See 41 CFR part 105–64, subpart 105–64.4 for full details on what to include in a Privacy Act amendment request.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should contact the system manager at the address above. Follow the procedures on accessing records in 41 CFR part 105–64, subpart 105–64.2 to request such notification.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

82 FR 6552; 82 FR 37451

[FR Doc. 2022–25420 Filed 11–18–22; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0024; Docket No. 2022–0053; Sequence No. 22]

Submission for OMB Review; Buy American, Trade Agreements, and Duty-Free Entry

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision of a previously approved information collection requirement regarding Buy American, associated with implementation of Federal Acquisition Regulation (FAR) rule 2021–008, Amendments to the FAR Buy American Act Requirements.

DATES: Submit comments on or before December 21, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

Additionally, submit a copy to GSA through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, at telephone 703–605–2868, or *mahruba.uddowla@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0024, Buy American, Trade Agreements, and Duty-Free Entry.

B. Needs and Uses

This clearance covers the information that an offeror must submit in response to the requirements of the provisions and clauses in Federal Acquisition Regulation (FAR) part 25 that relate to the following:

* The Buy American statute (41 U.S.C. chapter 83) and Executive Orders (E.O.s) 10582 and 14005.

* The Trade Agreements Act (19 U.S.C. 2501–2515), including the World Trade Organization Government Procurement Agreement and various free trade agreements.

* The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (Recovery Act).

* Subchapters VIII and X of Chapter 98 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

a. 52.225–2, Buy American Certificate. This provision requires the offeror to identify in its proposal supplies that do not meet the definition of domestic end product and whether those supplies exceed 55% domestic content. This provision also requires offerors to identify in its proposal domestic end products that contain a critical component.

b. 52.225–4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate. This provision requires a separate list of foreign products that are eligible under a trade agreement, and a list of all other foreign end products and whether those supplies exceed 55% domestic content. This provision also requires offerors to identify in its proposal domestic end products that contain a critical component.

c. 52.225–6, Trade Agreements Certificate. This provision requires the offeror to certify that all end products are either U.S.-made or designated country end products, except as listed in paragraph (b) of the provision. Offerors are not allowed to provide other than a U.S.-made or designated country end product, unless the requirement is waived.

d. 52.225–8, Duty-Free Entry. This clause requires contractors to notify the

contracting officer when they purchase foreign supplies, in order to determine whether the supplies should be duty-free. The notice shall identify the foreign supplies, estimate the amount of duty, and the country of origin. The contractor is not required to identify foreign supplies that are identical in nature to items purchased by the contractor or any subcontractor in connection with its commercial business, and segregation of these supplies to ensure use only on Government contracts containing duty-free entry provisions is not economical or feasible. In addition, all shipping documents and containers must specify Start Printed Page 8915certain information to assure the duty-free entry of the supplies.

e. Construction provisions and clauses:

- 52.225–9, Buy American—Construction Materials
- 52.225–10, Notice of Buy American Requirement—Construction Materials
- 52.225–11, Buy American—Construction Materials Under Trade Agreements
- 52.225–12, Notice of Buy American Requirement—Construction Materials under Trade Agreements
- 52.225–21, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials
- 52.225–23, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials Under Trade Agreements

The listed provisions and clauses provide that an offeror or contractor requesting to use foreign construction material due to unreasonable cost of domestic construction material shall provide adequate information to permit evaluation of the request.

C. Annual Burden

Respondents: 16,478.
Total Annual Responses: 69,165.
Total Burden Hours: 43,469.

D. Public Comment

A 60-day notice was published within the proposed FAR rule (2021–008, Amendments to the FAR Buy American Act Requirements) in the **Federal Register** at 86 FR 40980, on July 30, 2021. The proposed FAR rule included information collection requirements that were additional to the paperwork burden previously approved under OMB Control Number 9000–0024 as well as a new information collection requirement that would have required clearance under a new OMB Control Number (i.e., ''Domestic Content Reporting Requirement''). However, as explained in the published final FAR rule at 87 FR 12780, on March 7, 2022, the FAR will not be implementing the information collection for domestic content reporting until a future FAR rule but the final rule did proceed with the information collection requirements that are additional to the paperwork burden previously approved under OMB Control Number 9000–0024. As such, the Regulatory Secretariat Division is proceeding with seeking OMB approval of the revised information collection requirements under OMB Control Number 9000–0024 but has withdrawn its request for approval of a new information collection requirement concerning ''Domestic Content Reporting Requirement.''

No comments to the 60-day notice specifically cited this OMB Control Number but two respondents did comment on the requirement for offerors to identify whether any of their end products/construction material contain critical components.

a. One respondent commented that the establishment of a separate representation process can create administrative burden and cost for vendors, as associated compliance mechanisms will be required to assure the accuracy of such separate representations. The respondent did not appear to be aware that the FAR Council acknowledged the additional burden associated with this new representation and sought an increase to the estimated burdens associated through this clearance. Since no feedback was provided on the FAR Council's proposed calculations for the associated burden, no revisions are being made to the estimates previously provided.

b. One respondent commented that contractors are unable to comply with the ''reporting requirements.'' Since no feedback was provided on the FAR Council's proposed calculations for the associated burden, no revisions are being made to the estimates previously provided.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2022–25236 Filed 11–18–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0024]

CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), announces the availability of the *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022* (2022 Clinical Practice Guideline). The 2022 Clinical Practice Guideline updates and expands the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (2016 Guideline) and provides evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients age 18 years and older with: acute pain (duration less than 1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of more than 3 months). The recommendations in the 2022 Clinical Practice Guideline do not apply to pain management related to sickle cell disease, cancer-related pain treatment, palliative care, or end-of-life care. The 2022 Clinical Practice Guideline finalizes the draft clinical practice guideline issued on February 10, 2022.

DATES: The 2022 Clinical Practice Guideline is available November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Arlene I. Greenspan, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S106–9, Atlanta, GA 30341; Telephone: 770–488–4696. Email: *opioids@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In the 2016 Guideline, CDC communicated the intent to evaluate and reassess evidence and recommendations for opioid prescribing for adult patients as new evidence became available and to determine when new evidence would prompt an update. To achieve these aims, CDC funded the Evidence-based Practice Centers at the Agency for Healthcare Research and Quality (AHRQ) to conduct systematic reviews of the scientific evidence in the following five areas: (1) noninvasive (*e.g.,* exercise, physical therapy, psychological therapies), nonpharmacological treatments for chronic pain; (2) nonopioid pharmacologic treatments for chronic pain; (3) opioid treatments for chronic pain; (4) treatments for acute pain; and (5) acute treatments for episodic migraine. Based on the evidence described in these reviews, an update to the 2016 Guideline was warranted.

CDC developed the 2022 Clinical Practice Guideline recommendations using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework, which specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. Recommendations were made based on systematic reviews of the available scientific evidence while considering benefits and harms; patient, caregiver, and clinician values and preferences for pain treatment; and resource allocation (*e.g.,* costs to patients or health systems, including clinician time). CDC drafted recommendation statements in the 2022 Clinical Practice Guideline to assist clinicians in determining whether or not to initiate opioids for pain, selecting opioids and determining opioid dosages, deciding duration of initial opioid prescription and conducting follow-up, and assessing risk and addressing potential harms of opioid use.

The 2022 Clinical Practice Guideline includes recommendations for primary care clinicians (including physicians, nurse practitioners, and physician assistants) as well as for outpatient clinicians in other specialties (including those managing dental and postsurgical pain in outpatient settings and emergency clinicians providing pain management for patients being discharged from emergency departments).

The 2022 Clinical Practice Guideline is not a regulation or a law. It is a set of voluntary recommendations intended to support clinicians as they work in consultation with their patients to address pain. It is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making. It *is not* intended to be applied as inflexible standards of care across patient populations by healthcare professionals, health systems, third-party payers, organizations, or governmental jurisdictions. The 2022 Clinical Practice Guideline is intended to achieve the following: improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

To help ensure the 2022 Clinical Practice Guideline's integrity, credibility, and consideration of patient, caregiver, and clinician values and preferences, CDC obtained input through individual conversations with patients, caregivers, experts, clinicians, through public comment opportunities, and a federally chartered advisory committee, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). CDC also obtained feedback from a panel of external peer reviewers who are experts in topics related to opioid prescribing.

Summary of Public Comment and CDC Response

On February 10, 2022, CDC published a notice in the **Federal Register** announcing the availability of the draft clinical practice guideline (87 FR 7838). The notice gave the public an opportunity to submit comments by April 10, 2022. CDC received approximately 5,500 unique comments (including one comment submitted with 28,322 additional signatories) from the public, including patients with acute and chronic pain, caregivers, and clinicians. Comments also included organizational perspectives from medical associations, professional organizations, academic institutions, state and local governments, and advocacy and industry groups.

CDC carefully catalogued, reviewed, and qualitatively analyzed all comments submitted by members of the public. All public comments were carefully reviewed and considered when revising the draft clinical practice guideline. Most comments submitted to the public docket for the draft clinical practice guideline were submitted by individuals living with pain and their caregivers, families, and friends.

CDC highly values insights gained from these public comments and especially thanks those patients living with pain who shared their personal experiences in this public forum.

Themes from the comments included: (1) concerns about the 2016 Guideline; (2) overall considerations for the 2022 Clinical Practice Guideline; (3) considerations for Recommendation Statements in the 2022 Clinical Practice Guideline; and (4) suggestions for scientific articles to include in supporting rationales to supplement information from the systematic reviews about acute and chronic pain management.

(1) Concerns about the 2016 Guideline

Respondents shared their personal experiences with pain care, including with misinterpretation and misapplication of the 2016 Guideline. In particular, they mentioned issues with misapplication related to prescribed dosing limits and forced tapers.

CDC Response

- CDC added language to the 2022 Clinical Practice Guideline emphasizing that it provides voluntary clinical practice recommendations that are not intended to be inflexible standards of care or implemented as absolute limits of policy or practice for patients by clinicians, healthcare systems, or government entities.
- CDC added language throughout the document that further emphasizes that both the benefits and the risks of continuing opioid therapy should be considered by clinicians when providing pain care for patients.
- CDC added discussion throughout the document pertaining to changes related to dosage thresholds and appropriate application. For example, the following was added to the Rationale:

Importantly, to discourage the misapplication of opioid pain medication dosage thresholds as inflexible standards, revised recommendation statement language emphasizes principles such as avoiding increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. More specific considerations related to dosage have been moved to implementation considerations that follow each recommendation statement, where more nuance is offered to inform clinical decision-making and individualized patient care.

(2) Overall Considerations for the 2022 Clinical Practice Guideline

Respondents focused on the importance of clinician judgment that promotes flexible opioid prescribing practices focused on the individual patient. They were appreciative of CDC's inclusion of language emphasizing open communication between patients and clinicians and updated language to discourage forced tapers. Regarding the latter, respondents encouraged CDC to further emphasize and strengthen this language.

Many respondents expressed concern that mention of specific morphine milligram equivalents in the 2022 Clinical Practice Guideline would lead to hard limits on opioid prescriptions. Respondents also were concerned that specific pain conditions were called out as conditions to which the draft clinical practice guideline was not applicable while others went unmentioned.

Respondents noted that the length of the draft clinical practice guideline was a barrier to end users. However, respondents also noted that several organizational features of the draft clinical practice guideline were helpful, such as a call-out box that summarizes its intended use, including conditions for which it is not applicable. Respondents suggested that additional detail in these boxes would be beneficial for those who may not read beyond this content. In addition, professional organizations suggested the development of supplemental one-pagers and supporting materials to further increase the utility of the document.

Finally, some respondents providing comments on behalf on individuals with non-pain related conditions that use opioids for treatment (*e.g.,* ostomy-related conditions and restless leg syndrome [RLS]) proposed that the 2022 Clinical Practice Guideline title should be adjusted to better reflect its content and intended use.

CDC Response

- CDC added language throughout the document to emphasize that the 2022 Clinical Practice Guideline provides voluntary clinical practice recommendations that are not intended to be inflexible standards of care or implemented as absolute limits of policy or practice for patients by clinicians, healthcare systems, or government entities.
- CDC added discussion throughout the document pertaining to changes related to dosage thresholds and appropriate application. For example, the following was added to the Rationale:

Importantly, to discourage the misapplication of opioid pain medication dosage thresholds as inflexible standards, revised recommendation statement language emphasizes principles such as avoiding increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. More specific considerations related to dosage have been moved to the Implementation Considerations that follow each recommendation statement, where more nuance is offered to inform clinical decision-making and individualized patient care.

- CDC revised language in the scope and audience section to further emphasize that all types of pain need effective treatment:

Although some principles in this clinical practice guideline might be helpful in the management of pain related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care, some recommendations might not be relevant for pain management in these contexts. Other guidelines more specifically address pain management in these situations; therefore, this clinical practice guideline does not apply to patients experiencing pain associated with these conditions or types of care. This does not imply that any other types of pain are more or less worthy of effective treatment, only that clinicians are referred to existing clinical guidelines that more specifically address unique considerations for management of pain related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care.

- CDC added call-out boxes to the document to highlight critical information:
  - Box 1. Executive summary of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 2022
  - Box 2. Intended use of CDC's Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 2022
  - Box 3. Recommendations for prescribing opioids for outpatients with pain, excluding pain management for sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care; recommendation categories; and evidence types, CDC Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 2022
  - Box 4. Guiding principles for implementation of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 2022 recommendations
  - Box 5. Areas for additional research to build the evidence base for optimal pain management
- CDC is developing translation and communication materials to support accurate implementation of the 2022 Clinical Practice Guideline. These resources will be short references and ''at-a-glance'' materials to support appropriate application and interpretation.
- CDC changed the name of the document from the *CDC Clinical Practice Guideline for Prescribing Opioids* to the *CDC Clinical Practice Guideline for Prescribing Opioids for Pain* to further emphasize its focus on prescription opioids for the treatment of pain.

(3) Considerations for Recommendation Statements in the 2022 Clinical Practice Guideline

Respondents noted that frequent follow-up appointments, office visits, and drug screening requirements were barriers to care and health equity. They also expressed concern about stigma related to toxicology testing.

CDC Response

- CDC added language to address health equity and additional considerations and context related to health equity, such as language about using virtual follow-up visits for patients for whom virtual visits are part of standard care (*e.g.,* in remote areas where distance or other context makes follow-up visits challenging) or for patients for whom in-person follow-up visits are challenging (*e.g.,* frail patients) under Recommendation 7's implementation considerations and supporting text.
- The second sentence of Recommendation 7 has been changed from ''Clinicians should evaluate benefits and risks of continued therapy with patients every 3 months or more frequently'' to ''Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients.'' Of note, the more specific ''3-month'' time frame is still discussed in the Implementation Considerations and Supporting Rationale, where more nuanced considerations for flexibility are discussed.
- CDC augmented language in the implementation considerations for Recommendation 10 to state:

Toxicology testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Clinicians should not

dismiss patients from care on the basis of a toxicology test result. Dismissal could have adverse consequences for patient safety, potentially including the patient obtaining opioids or other drugs from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

(4) Suggestions for Scientific Articles About Acute and Chronic Pain Management

Some respondents submitted scientific articles about acute and chronic pain management for CDC to consider citing as additional informative references in the supporting rationales. CDC carefully reviewed each submitted comment and made edits or added additional citations to the draft clinical practice guideline where appropriate. Some examples of recommended sources and revisions are below.

- To demonstrate the undertreatment of sickle cell disease due to stigma and racism, the organization Sick Cells recommended that CDC cite this reference: Phillips S, Chen Y, Masese R, Noisette L, Jordan K, et al. (2022) Perspectives of individuals with sickle cell disease on barriers to care. PLOS ONE 17(3): e0265342. *https://doi.org/10.1371/journal.pone.026534.*
- The Michigan Opioid Prescribing Engagement Network suggested that CDC cite its OPEN Prescribing Recommendations as an additional reference for Recommendation 1. This reference was already included in the document: Michigan Opioid Prescribing Engagement Network. Prescribing recommendations. Ann Arbor, MI: Michigan Opioid Prescribing Engagement Network. *https://michigan-open.org/prescribing-recommendations.*
- The American Geriatric Society noted that a reference to its 2009 *American Geriatric Society Recommendations for Chronic Pain Medications in Older Adults* (AGS Guideline) was not current and recommended CDC cite different sources for its discussion of the use of acetaminophen for the treatment of pain among adults aged 18 and over.
- The National Pain Advocacy Center stated that several studies finding adverse outcomes after opioid stoppage, dose reduction, or dose variation were not cited or were cited inaccurately.
- The American Academy of Addiction Psychiatry recommended the inclusion of the Alcohol Use Disorders Identification Consumption Test (AUDIT–C), as done by the Veterans Health Administration, instead of the full Alcohol Use Disorders Identification Test (AUDIT).
- The American College of Obstetrics and Gynecology (ACOG) recommended that other critical concepts regarding family planning and contraceptive counseling from additional resources be included in the document. ACOG also recommended an additional reference with safety data regarding buprenorphine/naloxone combination use in pregnancy: Link HM, Jones H, Miller L, Kaltenbach K, Seligman N. Buprenorphine-naloxone use in pregnancy: a systematic review and metaanalysis. Am J Obstet Gynecol MFM. 2020 Aug;2(3):100179. doi: 10.1016/j.ajogmf.2020.100179. Epub 2020 Jul 3. PMID: 33345863.

CDC Response

- CDC included Phillips et. al. in the references section.
- CDC added a citation to the Open Prescribing Recommendations again in reference to Recommendation 1.
- CDC deleted reference to the 2009 American Geriatric Society Guideline throughout the document.
- CDC added the references from the National Pain Advocacy Center. Several recommended references were already included in the draft clinical practice guideline.
  - Hallvik SE, El Ibrahimi S, Johnston K, et al. Patient outcomes after opioid dose reduction among patients with chronic opioid therapy. Pain. 2022;163(1):83–90.
  - Binswanger IA, Glanz JM, Faul M, et al. The Association between Opioid Discontinuation and Heroin Use: A Nested Case-Control Study. Drug and Alcohol Dependence. 2020;217:108248.
  - Perez HR, Buonora M, Cunningham CO, Heo M, Starrels JL. Opioid Taper Is Associated with Subsequent Termination of Care: a Retrospective Cohort Study. J Gen Intern Med. 2020;35(1):36–42.
- CDC modified its inclusion from full AUDIT to AUDIT–C in the Supporting Rationale for Recommendation 7.
- CDC added additional family planning and contraceptive planning concepts and the following sources:
  - ACOG Committee Opinion No. 762. American College of Obstetricians and Gynecologists. Obstet Gynecol 2019;133:e78–89.
  - Patient-Centered Contraceptive Counseling. Committee Statement No. 1. American College of Obstetricians and Gynecologists. Obstet Gynecol 2022;139:349–53.
  - Interpregnancy care. Obstetric Care Consensus No. 8. American College of Obstetricians and Gynecologists. Obstet Gynecol 2019;133:e51–72.
- CDC added Link. et al.

For more information about CDC's response to peer reviewers' and public comments, please see the Supporting & Related Materials tab of this docket.

For more information about the 2022 Clinical Practice Guideline or the process of updating it, please visit *https://www.cdc.gov/opioids/guideline-update/index.html.*

Supporting and Related Material in the Docket

The docket contains the following supporting and related materials: (1) the 2022 Clinical Practice Guideline; (2) the GRADE tables; (3) CDC's response to peer review of the draft clinical practice guideline; (4) CDC's response to public comments on the draft clinical practice guideline; (5) the draft clinical practice guideline released for public comment on February 10, 2022; (6) the Opioid Workgroup (OWG) Report, prepared at the request of the BSC/NCIPC and which the BSC/NCIPC unanimously voted to have CDC adopt, and CDC's response to observations outlined in the OWG Report; and (7) an Overview of Community Engagement and Public Comment Opportunities, which describes key themes that emerged about participant values and preferences regarding pain management, as well as CDC's response to input obtained from these efforts.

The GRADE tables include clinical evidence review ratings of the evidence for the key clinical questions. The OWG Report describes the workgroup's findings and observations about an initial draft clinical practice guideline presented to the BSC/NCIPC at a public meeting on July 16, 2021. The OWG, comprising three BSC/NCIPC members in accordance with federal advisory committee policy, as well as patients with pain, caregivers, and family members of patients with pain, and clinicians and subject matter experts with a variety of relevant pain management expertise, was designed to provide independent, broad, external, and transparent input to the BSC/NCIPC on the diverse and complex issues addressed in the draft clinical practice guideline. OWG meetings were coordinated by an NCIPC subject matter expert who served as the Designated Federal Official. CDC's response to the OWG Report reflects and describes how CDC incorporated OWG observations and comments in the revised draft clinical practice guideline.

The *Overview of Community Engagement and Public Comment Opportunities* document provides a summary of efforts implemented throughout the clinical practice

guideline update process to better understand the lived experiences and perspectives of community members and to ensure additional input from patients, caregivers, clinicians, and the public. This document also summarizes CDC's response to the themes and findings that emerged throughout the community engagement and public comment opportunities and describes how CDC carefully considered and incorporated diverse perspectives and input from multiple sources into the draft clinical practice guideline that was posted for public comment.

Availability of the 2022 Clinical Practice Guideline

The *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022* can be found in the Supporting & Related Materials tab of this docket on the Federal eRulemaking Portal: identified by Docket No. CDC–2022–0024 and at *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–25264 Filed 11–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1163]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''CDC Fellowship Programs Assessments'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 22, 2022, to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Data Collection for CDC Fellowship Programs (OMB Control No. 0920–1163, Exp. 3/31/2023)—Extension—Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's mission is to protect America from health, safety, and security threats, both foreign and in the U.S. To ensure a competent, sustainable, and empowered public health workforce prepared to meet these challenges, CDC plays a key role in developing, implementing, and managing a large number of fellowship programs. A fellowship is defined as a training or work experience lasting at least one month and consisting of primarily experiential (*i.e.,* on-the-job) learning, in which the trainee has a designated mentor or supervisor. CDC fellowships are intended to develop public health professionals, enhance the public health workforce, and strengthen collaborations with partners in public health and healthcare organizations, academia, and other stakeholders in governmental and non-governmental organizations. Assessing fellowship activities is essential to ensure that the public health workforce is equipped to promote and protect the public's health.

CDC requests a three-year extension of a Generic Clearance to collect data about its fellowship programs, as they relate to public health workforce development. Data collections will allow for ongoing, collaborative, and actionable communications between CDC fellowship programs and stakeholders (*e.g.,* fellows, supervisors/mentors, alumni). These collections might include short surveys, interviews, and focus groups. Intended use of the resulting information is to:

- inform planning, implementation, and continuous quality improvement of fellowship activities and services;
- improve efficiencies in the delivery of fellowship activities and services; and
- determine to what extent fellowship activities and services are achieving established goals.

Collection and use of information about CDC fellowship activities will help ensure effective, efficient, and satisfying experiences among fellowship program participants and partners.

This Extension ICR contains a change in burden estimate from the previously approved package. This change is the result of a review and evaluation of CDC programming and fellowship needs. CDC estimates that annually, approximately one quarter of all CDC fellowships (23 of 91) will conduct a GenIC under this umbrella. This estimate reflects the usage rate for CFPA in its most recent approval period. Burden estimates assume that a given fellowship program will conduct one query each with one of the three respondent groups: fellowship applicants or fellows; mentors, supervisors, or employers; and alumni.

OMB approval is requested for three years. CDC requests OMB approval for an estimated 1,546 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number respondents	Number of responses per respondent	Average burden per response (in hours)
Applicants or fellows	Fellowship Data Collection Instrument	966	1	30/60
Mentors, supervisors, or employers	Fellowship Data Collection Instrument	193	1	30/60
Alumni	Fellowship Data Collection Instrument	1932	1	30/60

Jeffery M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–25244 Filed 11–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–0950; Docket No. CDC–2022–0133]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the information collection project titled National Health and Nutrition Examination Survey (NHANES). NHANES produces descriptive statistics, which measure the health and nutrition status of the general population.

DATES: CDC must receive written comments on or before January 20, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0133 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all Federal comments through the Federal eRulemaking portal (*www.regulations.gov*) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB Control No. 0920–0950, Exp. 04/30/2023)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

The National Health and Nutrition Examination Survey (NHANES) has been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics (NCHS), CDC.

NHANES produces descriptive statistics, which measure the health and nutrition status of the general population. With physical examinations, laboratory tests, and interviews, NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors and is used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time.

In this Revision, the program is not considering any substantial changes to NHANES content or procedures. The proposed changes being requested

include modifications previously approved via non-substantive change requests in addition to a request for three years of approval. As in previous years, the base sample will remain at approximately 5,000 interviewed and examined individuals annually. It is possible that the survey may have to adapt its plans in response to the novel Coronavirus Disease (COVID–19) or related concerns.

NCHS collects personally identifiable information (PII). Participant level data items will include basic demographic information, name, address, Social Security number, Medicare number and participant health information to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services (CMS).

A variety of agencies sponsors data collection components on NHANES. To keep burden down and respond to changing public health research needs, NCHS cycles in and out various components. The 2021–22 NHANES physical examination includes the following components: anthropometry (all ages), liver elastography (ages 12 and older), standing balance (ages 20–69), 24-hour dietary recall via phone (all ages), blood pressure measurement (ages eight and older), and dual X-ray absorptiometry (DXA) (ages 8–69, total body scan). While at the examination center, additional interview questions are asked of participants and a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3–10 days later.

The 2021–22 survey is similar to what was fielded in 2019–20. NHANES may conduct developmental projects, with a focus on planning for NHANES 2024 and beyond. These may include activities such as tests of new equipment, crossover studies between current and proposed methods, test of different study modes, settings or technology, outreach materials, incentive strategies, sample storage and processing or sample designs. The biospecimens collected for laboratory tests include urine and blood. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. Consent to store DNA is continuing in NHANES.

Beginning in 2021, NHANES added the following laboratory tests: Acetylcholinesterase Enzyme Activity in whole blood; an Environmental Toxicant in Washed Red Blood Cells (Hemoglobin Adducts); Environmental Toxicants in serum (seven terpenes); Environmental Toxicants in urine (seven volatile organic compound (VOC) metabolites); Infectious Disease Markers in serum (Enterovirus 68 (EV–D68) and Human Papilloma Virus (HPV) in serum); Nutritional Biomarkers in plasma (Four trans-fatty acids (TFA)); and two Nutritional Biomarkers in serum.

Additionally, at the start of the 2021 survey year, the following Laboratory Tests were modified: Steroid hormones in serum (eleven steroid hormones). Cycling out of NHANES is the Blood Pressure Methodology Study and laboratory tests of Adducts of Hemoglobin (Acrylamide, Glycidamide) and Urine flow rate.

Most sections of the NHANES interviews provide self-reported information to be used in combination with specific examination or laboratory content, as independent prevalence estimates, or as covariates in statistical analysis (*e.g.,* socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition-monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and weight history/self-image related behavior.

NHANES will continue multi-mode screening and electronic consent procedures. Our yearly goal for interview, exam and post exam components is 5,600 participants. To achieve this goal, we may need to screen up to 8,300 individuals annually. Burden for individuals will vary based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults. This is because young people may have fewer health conditions or medications to report so their interviews take less time or because certain exams are only conducted on individuals 18 and older. In addition, adults often serve as proxy respondents for young people in their families.

Participation in NHANES is voluntary and confidential. CDC requests OMB approval for a three-year extension, with 65,630 annualized burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals in households	Screener	8,300	1	10/60	1,383
Individuals in households	Household Interview	5,600	1	1	5,600
Individuals in households	MEC Interview & Examination	5,600	1	2.5	14,000
Individuals in households	Telephone Dietary Recall & Dietary Supplements.	5,600	1	1.3	7,280
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up.	5,600	1	20/60	1,867
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	24-hour wearable device projects	1,000	1	25	25,000
Total					65,630

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–25245 Filed 11–18–22; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–23–0010]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 1, 2022 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS) (OMB Control No. 0920–0010, Exp. 2/28/2023)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect. Birth defects contributed to more than one million hospital stays in the U.S. in 2013, resulting in $22.9 billion in hospital costs. Birth defects are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

For most birth defects, the causes are not known, making prevention efforts challenging to develop. To date, primary preventive measures are available for only a few birth defects. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the newborn can be prevented by appropriate medical practice, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or permanently disabling neural tube defects such as anencephaly and spina bifida.

This continued burden justifies reasonable attempts to reduce the prevalence of birth defects. To help reduce birth defects among U.S. babies, in 1996 Congress directed the CDC to establish Centers of Excellence for Birth Defects Research and Prevention. The mandate was formalized with passage of the Birth Defects Prevention Act of 1998. This Act amended Section 317C of the Public Health Service Act (42 U.S.C. 247b–4) and authorized CDC to: (1) collect, analyze, and make available data on birth defects; (2) operate regional centers that will conduct applied epidemiological research for the prevention of birth defects; and (3) provide the public with information on preventing birth defects.

In response to this mandate, the Division of Birth Defects and Infant Disorders (DBDID) obtained OMB clearance for data collection that is carried out by the Centers for Birth Defects Research and Prevention (CBDRP). The CBDRP's first research effort was the National Birth Defects Prevention Study (NBDPS), which began data collection in 1997 and ended in 2013. The CBDRPs transitioned from NBDPS to the Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS), which began data collection in 2014. One of the main activities for each Center is to conduct BD–STEPS in their state, and the purpose of BD–STEPS is to evaluate factors associated with the occurrence of birth defects and stillbirths, and ultimately to work to prevent major birth defects and stillbirths associated with maternal risk factors.

CDC requests OMB approval for an estimated 4,473 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers (Interview)	Core Computer Assisted Telephone Interview.	3,030	1	55/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers (Consent)	Linkage to Reportable Infectious Disease Consent.	2,590	1	15/60
Mothers (Consent for Residual Newborn Bloodspot Retrieval).	Residual Newborn Bloodspot Consent.	1,850	1	15/60
Mothers (Online Questionnaire).	Online Occupational Questionnaire.	830	1	20/60
Mothers of AR/MA Stillbirths and Controls (Interview).	Supplemental Computer Assisted Telephone Interview.	640	1	25/60
Mothers of AR/MA Stillbirths with Specimens available for Testing.	Authorization Form for Stillbirth COVID–19 Sub-Study.	157	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–25243 Filed 11–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22FT]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 2, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

People experiencing homelessness are at higher risk for respiratory infectious diseases. However, the causes of these infections are not well understood. This project involves enhanced surveillance for organisms that cause respiratory illness in congregate and non-congregate homeless shelters to provide evidence to improve public health for people who are experiencing homelessness in Anchorage, Alaska.

The project team will collect an upper respiratory specimen (*e.g.,* nasopharyngeal swab) from people experiencing respiratory symptoms who are accessing shelters. A member from the project team will complete demographic questions and a short symptom questionnaire with the participant. Swabs obtained from study participants will be tested for multiple respiratory pathogens to: (1) estimate the burden of pathogen-specific respiratory infections among people experiencing homelessness; (2) inform infection control; and (3) determine the vaccination status of people in this population.

CDC requests OMB approval for an estimated 500 annual burden hours for this collection. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per respons (in hours)
Persons with Respiratory Symptoms Experiencing Homelessness.	Enrollment in Symptom Screening ..	1,000	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–25242 Filed 11–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID). This virtual meeting is open to the public via Zoom, limited only by the number of web conference lines available (500 lines). Pre-registration is required by accessing the link below in the addresses section.

DATES: The meeting will be held on December 7, 2022, from 9:00 a.m. to 5:15 p.m., EST, and December 8, 2022, from 8:30 a.m. to 1:00 p.m., EST.

ADDRESSES: Zoom virtual meeting. Pre-registration is required by accessing the link at *https://cdc.zoomgov.com/webinar/register/WN_PbAc34lET9uD2RN8lopzig.* Instructions to access the meeting will be provided following registration.

FOR FURTHER INFORMATION CONTACT: Laura Hughes-Baker, Ph.D., Designated Federal Officer, CDC, 1600 Clifton Road NE, Mailstop H24–12, Atlanta, Georgia 30329–4027; Telephone: (404) 639–1402; Email: *LHughesBaker@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The BSC, DDID provides advice and guidance to the Secretary, Department of Health and Human Services; the Director, CDC; the CDC Deputy Director for Infectious Diseases; and the Directors of the National Center for Emerging and Zoonotic Infectious Diseases, the National Center for HIV, Viral Hepatitis, STD, and TB Prevention, and the National Center for Immunization and Respiratory Diseases, CDC, concerning strategies, goals, and priorities for the programs and research within the national centers and monitors the overall strategic direction and focus of DDID and the national centers.

Matters to be Considered: The agenda will include updates and discussions on recent outbreaks and affected populations, as well as brief reports from two of the Board's workgroups: the Food Safety Modernization Act Surveillance Working Group and the Acute Flaccid Myelitis Task Force. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–25276 Filed 11–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Administration for Children and Families Program Instruction—Children's Justice Act (OMB #0970–0425)

AGENCY: Children's Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF Program Instruction—Children's Justice Act (Office of Management and Budget (OMB) #0970–0425, expiration 6/30/2023). There are no changes proposed to the Program Instruction.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Program Instruction, prepared in response to the enactment of the Children's Justice Act, Title II of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the states and territories to accomplish the purposes of assisting states in developing, establishing, and operating programs designed to improve: (1) the assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child's family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The

information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate, and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Application and Annual Report	52	1	60	3,120

Estimated Total Annual Burden Hours: 3,120.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 5106c Sec. 107 (b)4; and 42 U.S.C. 5106 Sec. 107 (B)5.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–25223 Filed 11–18–22; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Animal Drug User Fee Act.'' The purpose of the public meeting is to discuss the proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA V) for fiscal years 2024 through 2028.

DATES: The public meeting will be held virtually on December 7, 2022, from 1 p.m. to 3 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by December 19, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and further information.

ADDRESSES: The public meeting will be hosted via a live virtual webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 19, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0656 for ''Animal Drug User Fee Act; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Transcripts of the meeting will be available on FDA's website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *lisa.kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of ADUFA, which authorizes FDA to collect user fees and use them for the process of reviewing new animal drug applications and associated submissions. The authority for ADUFA expires September 30, 2023. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal drug review process for future fiscal years. Section 740A(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholder, and before transmitting the Agency's final recommendation to Congress for the reauthorized program (ADUFA V), we do the following: (1) present the recommendation to the relevant Congressional committees, (2) publish such recommendations in the **Federal Register**, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) consider such public views and comments and revise such recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADAs) to be central to the Agency's mission to protect and promote human and animal health. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act of 2003 (Pub. L. 108–130; hereinafter referred to as ''ADUFA I'') authorized FDA to collect user fees dedicated to the timely review of new animal drug applications in accordance with certain performance goals and to expand and modernize the new animal drug review program from fiscal year (FY) 2004 to 2008. The Agency agreed, under ADUFA I, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process by 30 percent in ADUFA I.

With the reauthorization of ADUFA for an additional 5 years under ADUFA II (FY 2009 to FY 2013), FDA agreed to further enhance and improve the review process. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews. The ADUFA programs have enabled FDA to meet performance timeframes for application review for new animal drugs without compromising the quality of the Agency's review.

The ADUFA III reauthorization (FY 2014 to FY 2018) maintained the FY 2013 review timeframes for key submissions in addition to enhancements to the program. Enhancements included: replacing the End Review Amendment with a short, second-round review; reducing time for microbial food safety hazard characterization submissions to 100 days; and changes to the financial structure. There were also chemistry, manufacturing, and controls (CMC) enhancements, including developing guidance for a two-phased CMC technical section submission and review process under the investigational new animal drug file.

Most recently, ADUFA was reauthorized for an additional 5 years under ADUFA IV (FY 2019 to FY 2023). The ADUFA IV authorization enhancements included adding new performance goals for presubmission conferences and tissue residue method trial demonstrations, requiring 100 percent electronic submissions, and requiring an ''approved by FDA'' statement along with a NADA number on approved animal drugs by September 30, 2023. Additionally, a new provision was added that any excess collections would be used to offset workload adjuster or shortfall fee increases, if invoked.

FDA has published a number of reports that provide useful background on ADUFA I, II, III, and IV. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.*

II. Topics for Discussion at the Public Meeting

In preparing the proposed recommendation to Congress for ADUFA reauthorization, we conducted discussions with the regulated industry, and consulted with stakeholders as required by the law. We began the ADUFA reauthorization process with a public meeting held on May 20, 2021 (86 FR 18989, April 12, 2021). Following the May 2021 public meeting, FDA conducted negotiations with regulated industry and continued regular consultations with public stakeholders from October 2021 through August 2022. As directed by Congress, FDA posted minutes of these discussions on its website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

The proposed enhancements in ADUFA V will address priorities identified by stakeholders, regulated industry, and FDA. The full description of these proposed recommendations can be found in the proposed ADUFA V Performance Goals and Procedures Letter. FDA intends to post the full text of the proposed ADUFA V Performance Goals and Procedures Letter at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings,* no later than 1 week prior to the public meeting. FDA will post the agenda approximately 5 days before the meeting at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online at *https://fda.zoomgov.com/webinar/register/WN_DBPaDGi5QXaaCoxkJkx7g* no later than December 5, 2022. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Also, please self-identify as a member of one of the following stakeholder categories: scientific or academic experts, veterinary professionals, patients and consumer advocacy groups, or the regulated industry, and whether you are requesting a scheduled presentation.

Early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

If you need special accommodations due to a disability, please contact Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 1, 2022.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by December 5, 2022. All requests to make oral presentations must be received by December 1, 2022, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 5, 2022. No commercial or promotional material will be permitted to be presented at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25274 Filed 11–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2826]

Allergan Sales, LLC, et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040099	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 5 milligrams (mg)/325 mg.	Allergan Sales, LLC, U.S. Agent for Allergan Pharmaceuticals International Limited, 5 Giralda Farms, Madison, NJ 07940.
ANDA 040148	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg, 10 mg/325 mg, and 10 mg/500 mg.	Do.
ANDA 076434	Chlorhexidine Gluconate Solution, 0.12%	Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195.
ANDA 079076	Ranitidine Hydrochloride (HCl) Injection, Equivalent to (EQ) 25 mg base/milliliters (mL).	Mylan Pharmaceuticals Inc., a Viatris Company, U.S. Agent for Mylan Laboratories Limited, 3711 Collins Ferry Rd., Morgantown, WV 26505.
ANDA 090054	Ranitidine HCl Syrup, EQ 15 mg base/mL	Tolmar Inc., 701 Centre Ave., Fort Collins, CO 80526.
ANDA 201804	Letrozole Tablets, 2.5 mg	Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713.
ANDA 201832	Nimodipine Capsules, 30 mg	Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180.
ANDA 203419	Donepezil HCl Tablets, 23 mg	Indicus Pharma, LLC.
ANDA 203519	Morphine Sulfate Solution, 20 mg/5 mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 206151	Abacavir Sulfate and Lamivudine Tablets, EQ 600 mg base; 300 mg.	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Limited, 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 21, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on December 21, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25315 Filed 11–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Input on the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans: Request for Information

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This Request for information (RFI) invites comments and suggestions on the *National Strategy for the Prevention and Control of Vector-Borne Diseases.* The *Strategy* represents the Federal Government's priorities for addressing vector-borne disease (VBD) threats.

DATES: To be assured consideration, comments must be received via the method provided below, no later than midnight Eastern Time (ET) on December 21, 2022. Submissions received after the deadline will not be reviewed.

ADDRESSES: Comments, including mass comment submissions, must be submitted electronically at *http://www.regulations.gov.* Search for this RFI by typing a keyword in the search field on the homepage. Click on the ''Comment Now'' button on RFI and you can submit your comments including attachments in a window titled, ''Your Information.'' For help finding this RFI and/or submitting comments, please visit *https://www.regulations.gov/help.*

FOR FURTHER INFORMATION CONTACT: Dr. Kristen Honey, Chief Data Scientist and Executive Director of InnovationX, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, *vectorbornedisease@hhs.gov,* (202) 853–7680.

SUPPLEMENTARY INFORMATION: It is important to read this entire RFI notice to ensure an adequate response is prepared and to have a full understanding of how your response will be acknowledged and used. Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

The Federal Government is developing a national strategy for the prevention and control of vector-borne diseases (VBD) in humans.

The Federal Government has identified 5 goals and 19 strategic priorities which were developed using the framework of the previously released National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans:

- *Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs).*
  - ○ *Strategic Priority 1:* Better understand vectors, the pathogens they transmit, and the potential effects of a changing climate.
  - ○ *Strategic Priority 2:* Modernize and maintain surveillance systems for vectors, reservoirs, and VBDs.
  - ○ *Strategic Priority 3:* Better understand the risk factors for and effects of VBDs on humans.
- *Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.*
  - ○ *Strategic Priority 1:* Identify and characterize novel VBD pathogens and their clinical manifestations.
  - ○ *Strategic Priority 2:* Develop, evaluate, and improve diagnostic tests for VBDs.
  - ○ *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD diagnosis in humans.
  - ○ *Strategic Priority 4:* Develop, maintain, and distribute non-commercial diagnostic resources to facilitate VBD testing.
- *Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases.*
  - ○ *Strategic Priority 1:* Develop, evaluate, and improve safe and effective VBD prevention tools such as vaccines, vector control strategies, and health communication tools and products that are tailored for communities that are disproportionately affected.
  - ○ *Strategic Priority 2:* Develop and evaluate data-driven and adaptive predictive models and decision support tools for VBDs.
  - ○ *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD prevention.
  - ○ *Strategic Priority 4:* Develop and evaluate tools and processes for responding to public health emergencies.
- *Goal 4: Develop and assess drugs and treatment strategies for VBDs.*
  - ○ *Strategic Priority 1:* Identify, develop, and evaluate safe and effective drugs and treatment strategies (regimens) for VBDs.
  - ○ *Strategic Priority 2:* Develop evidence-based recommendations and guidelines on the treatment and management of VBDs.
  - ○ *Strategic Priority 3:* Evaluate drug and treatment use patterns.
- *Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats.*
  - ○ *Strategic Priority 1:* Disseminate evidence-based information about VBD prevention and control, guidelines, and recommendations to partners and the public.
  - ○ *Strategic Priority 2:* Ensure current and future capacity to implement and adequately and equitably scale safe, effective, and publicly accepted VBD prevention and control programs.
  - ○ *Strategic Priority 3:* Monitor and evaluate evidence-based public health programs and tools.
  - ○ *Strategic Priority 4:* Respond to public health emergencies resulting from VBD threats.
  - ○ *Strategic Priority 5:* Clarify, facilitate, and improve processes to bring regulated diagnostic tests, treatment strategies, vaccines, and vector control products to market.

A detailed copy of the goals and strategic priorities of this strategy can be found in the next section of this RFI.

The focus areas listed above are not exhaustive but represent the Federal Government's priorities for preventing and controlling VBDs. Although critical to public health and wellness, healthcare utilization, access to care, and reimbursement or payment for clinical services are outside the scope of this prevention and control strategy.

HHS/OASH recognizes the extensive work of the Tick-Borne Disease Working Group, including the two (2) reports delivered to Congress as of the release of this Request for Information. These reports included 55 recommendations, which have been cross-walked against the Goals and Strategies of the *National Strategy for the Prevention and Control of Vector-Borne Diseases.* This crosswalk reflects the alignment between the TBDWG recommendations and the *Strategy.* A copy of this crosswalk can be found in the last section of this RFI.

II. Information Requested/Questions

HHS/OASH invites input from stakeholders throughout the scientific research, advocacy, and clinical practice communities, as well as the general public, on the proposed national strategy. This input is a valuable component in finalizing the strategy, and the community's time and consideration are appreciated.

HHS/OASH also invites thoughts on preferred strategies for partner engagement as the strategy is further developed and modified over time (*e.g.,* webinars, listening sessions, additional RFIs, etc.).

HHS/OASH encourages organizations (*e.g.,* patient advocacy groups, professional organizations) to submit a single response reflective of the views of the organization/membership as a whole when possible.

III. How To Submit Your Response

Please respond concisely, in plain language, and in narrative format. You may respond to some or all of the topic areas covered in the RFI, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file.

Please note that this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h) (4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

HHS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property; they will not be returned, and we may publish some of their non-proprietary content.

Dated: November 15, 2022.

Kristen Honey,

Chief Data Scientist and Executive Director of InnovationX, Office of the Assistant Secretary for Health, Department of Health and Human Services.

National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans

Vision

A nation where vector-borne diseases no longer threaten human health and well-being.

Mission

Protect people from illness, suffering, and death due to vector-borne diseases.

Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs)

STRATEGIC PRIORITY 1—BETTER UNDERSTAND VECTORS, THE PATHOGENS THEY TRANSMIT, AND THE POTENTIAL EFFECTS OF A CHANGING CLIMATE

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Determine how vector-borne pathogens are transmitted to humans:	*DHHS (CDC, NIH).*
• *Sub-objective 1:* Develop animal and vector models for VBD research.	*USDA.*
• *Sub-objective 2:* Identify key animal reservoirs for vector-borne pathogens.	*DOI.*
• *Sub-objective 3:* Identify the factors associated with the ability of vectors to effectively transmit pathogens to humans.	*DOD.*
• *Sub-objective 4:* Determine if co-infections within vectors and animal reservoirs impact transmission to humans.	
Objective 2: Identify the environmental factors associated with vector and animal reservoir populations:	*DHHS (CDC, NIH).*
• *Sub-objective 1:* Identify key factors, such as climate and ecological factors, associated with the distribution and abundance of vectors and animal reservoirs.	*DOD.*
• *Sub-objective 2:* Identify key factors, such as climate and ecological factors, associated with the seasonality of vectors and animal reservoirs.	*DOI.*
	NOAA.
	NASA.
	USDA (APHIS).

STRATEGIC PRIORITY 1—BETTER UNDERSTAND VECTORS, THE PATHOGENS THEY TRANSMIT, AND THE POTENTIAL EFFECTS OF A CHANGING CLIMATE—Continued

Objectives and sub-objectives	Federal entities with accountability
Objective 3: Determine which vectors found outside the United States and its territories pose the greatest near-term risk of becoming established in the United States and its territories: • *Sub-objective 1:* Conduct assessments and develop a list of vectors that pose the highest risk for establishment in the United States and its territories. • *Sub-objective 2:* Develop habitat suitability models for the potential distribution of vectors based on their distribution outside the United States and its territories.	*DHHS (CDC, NIH).* *DOD.* *DOI (USGS, NISC, NPS).* *NOAA.* *USDA (APHIS).*

Goal 1: Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases

STRATEGIC PRIORITY 2—MODERNIZE [1] AND MAINTAIN SURVEILLANCE SYSTEMS FOR VECTORS, RESERVOIRS, AND VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Evaluate, improve, and maintain surveillance systems for vectors, reservoirs, pathogens, and VBDs in humans and animals: • *Sub-objective 1:* Identify existing complementary public and private surveillance systems. • *Sub-objective 2:* Evaluate existing surveillance systems to identify gaps both within and across systems. • *Sub-objective 3:* Address surveillance gaps within and across existing surveillance systems. • *Sub-objective 4:* Increase usability of surveillance data by expanding data access and timeliness and enhancing data visualizations of data from VBD systems. • *Sub-objective 5:* Evaluate the utility of alternative data sources and tools (*e.g.,* artificial intelligence, citizen science, crowdsourcing, patient registries) and use these evaluations to leverage relevant systems to further inform surveillance.	*DHHS (CDC, NIH).* *USDA.* *DOI (USGS, NPS).*
Objective 2: Increase data integration of and data sharing across surveillance systems: • *Sub-objective 1:* Identify opportunities for and challenges to increase the integration of and data sharing across surveillance systems. • *Sub-objective 2:* Implement steps to increase data integration and interoperability of surveillance systems.	*DHHS (CDC, NIH).* *DOD.* *USDA.* *USGS.*

Goal 1: Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases

STRATEGIC PRIORITY 3—BETTER UNDERSTAND THE RISK FACTORS FOR AND EFFECTS OF VBDS ON HUMANS

Objectives and sub objectives	Federal entities with accountability
Objective 1: Determine the social, behavioral, and environmental factors for human exposure to VBD pathogens: • *Sub-objective 1:* Determine the social determinants of health [2] and associated with human exposure to VBD pathogens. • *Sub-objective 2:* Determine the environmental factors, including the built environment,[3] associated with human exposure to VBD pathogens. • *Sub-objective 3:* Determine the knowledge, attitudes, and behaviors influencing and impacting human exposure to VBD pathogens, including differences among population groups. • *Sub-objective 4:* Identify, monitor, and evaluate policies and laws that help to reduce risk of human exposure to VBD pathogens.	*DHHS (CDC, NIH).* *NOAA.* *NASA.*
Objective 2: Determine the disease processes, progression, and clinical outcomes of VBDs: • *Sub-objective 1:* Describe the disease processes, progression, and clinical outcomes associated with priority VBDs, including symptom persistence. • *Sub-objective 2:* Describe the frequency and effect of VBD co-infections on diagnosis, treatment, and clinical outcomes. • *Sub-objective 3:* Identify differences in the clinical presentation, disease processes, progression, and clinical outcomes of VBDs associated with specific demographic factors, co-morbidities, and social determinants of health, particularly as they relate to differences across population groups.	*DHHS (CDC, NIH).* *USDA.*
Objective 3: Determine the disease burden of VBDs in the United States, including identifying differences in disease burden across population groups:	*DHHS (CDC).* *USDA (APHIS).*

[1] Data modernization is the result of the nation strengthening data reporting, management, and analytics across public health; conducting proper surveillance; supporting staff in pursuing innovation and building state-of-the-art data science skills; and delivering guidance the public can trust. *https://www.cdc.gov/surveillance/projects/dmi-initiative/.*

[2] Social determinants of health are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes. *https://www.cdc.gov/social determinants/about.html.*

[3] The built environment includes the physical makeup of where we live, learn, work, and play—our homes, schools, businesses, streets and sidewalks, open spaces, and transportation. *https://www.cdc.gov/nccdphp/dnpao/state-local-programs/built-environment-assessment/index.htm.*

STRATEGIC PRIORITY 3—BETTER UNDERSTAND THE RISK FACTORS FOR AND EFFECTS OF VBDS ON HUMANS—Continued

Objectives and sub objectives	Federal entities with accountability
• *Sub-objective 1:* Describe the epidemiology of VBDs, including social determinants of health.[2] • *Sub-objective 2:* Describe the burden of VBDs, including costs to society and health-related quality of life.	

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 1—IDENTIFY AND CHARACTERIZE NOVEL VBD PATHOGENS AND THEIR CLINICAL MANIFESTATIONS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Determine a strategy for detecting novel pathogens and variants: • *Sub-objective 1:* Develop and disseminate strategies and algorithms that seek to detect novel VBD pathogens, including the use of new technologies (*e.g.,* machine learning, genomics, emerging tech). • *Sub-objective 2:* Apply the algorithms and strategies to detect novel pathogens; publish a list of novel pathogens that pose a potential risk to human health. • *Sub-objective 3:* Describe the knowledge gaps related to newly identified pathogens that pose a risk to human health. • *Sub-objective 4:* Collaborate with agricultural and other non-health partners to detect novel VBD pathogens in vectors and animals that may pose risk to human health.	*DHHS (CDC, NIH).* *USDA.* *DOD.*
Objective 2: Conduct studies and investigations to address knowledge gaps related to novel pathogens that are potentially vector-transmitted: • *Sub-objective 1:* Investigate potential VBD transmission in people and animals with illness of unknown origin that may be attributed to an emerging vector-borne pathogen. • *Sub-objective 2:* Fill critical knowledge gaps to be prepared for and able to respond to novel VBD emergence events.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 2—DEVELOP, EVALUATE, AND IMPROVE DIAGNOSTIC TESTS FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop diagnostic tests for novel pathogens: • *Sub-objective 1:* Determine the specimen types that provide optimal diagnostic performance. • *Sub-objective 2:* Develop pathogen-detection tests, including more rapid tests, within 1 year of identifying a novel pathogen. • *Sub-objective 3:* Develop serologic tests and, when applicable, biomarker tests within 1 year of identifying a novel pathogen. • *Sub-objective 4:* Investigate new methods for pathogen detection as new technologies advance. • *Sub-objective 5:* Make new diagnostic tests available for expanded use and commercialization as public health needs arise.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.* *USDA.*
Objective 2: Develop and make improved diagnostic tests available for known pathogens: • *Sub-objective 1:* Develop pathogen-detection tests that significantly improve test accuracy, precision, efficiency, performance, and/or speed. • *Sub-objective 2:* Develop serologic tests that significantly improve test accuracy, precision, efficiency, performance, and/or speed. • *Sub-objective 3:* Investigate new methods (*e.g.,* for detecting biomarkers) for detecting existing vector-borne pathogens as new technologies advance. • *Sub-objective 4:* Make new diagnostic tests available for expanded use and commercialization as public health needs arise.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.*
Objective 3: Compare the performance of new and existing diagnostic tests for people, vectors, animals, and animal reservoirs: • *Sub-objective 1:* Develop, maintain, and disseminate panels for use in evaluations of diagnostic tests. • *Sub-objective 2:* Compare the characteristics and performance of diagnostic tests.	*DHHS (CDC, BARDA, FDA).* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 3—DEVELOP AND EVALUATE EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON VBD DIAGNOSIS IN HUMANS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: For novel pathogens, collaborate with external partners to develop guidance, recommendations, or guidelines on clinical and laboratory diagnosis: • *Sub-objective 1:* Establish a surveillance case definition for each VBD caused by a novel pathogen within 1 year of its identification. • *Sub-objective 2:* Develop and disseminate guidance, recommendations, or guidelines on appropriate test methods/procedures, to include interpretation of test results (including lab and clinical parameters).	*DHHS (CDC, NIH).* *DOD.* *USDA.*
Objective 2: Review and revise existing diagnostic guidance, recommendations, or guidelines to incorporate new knowledge: • *Sub-objective 1:* Continuously monitor emerging science that informs the diagnosis of VBDs. • *Sub-objective 2:* Revise and disseminate existing guidance, recommendations, and guidelines for vector-borne diagnosis with new knowledge.	*DHHS (CDC).* *DOD.* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 4—DEVELOP, MAINTAIN, AND DISTRIBUTE NON-COMMERCIAL DIAGNOSTIC RESOURCES TO FACILITATE VBD TESTING

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Ensure sufficient supplies of diagnostic resources for VBD pathogens to facilitate research, development, and surveillance: • *Sub-objective 1:* Identify reagents that need to be developed. • *Sub-objective 2:* Identify reagents that require production to complement commercial resources. • *Sub-objective 3:* Inventory supplies of diagnostic resources (*e.g.,* reagents, standards, and biospecimens) available for VBD pathogens of concern. • *Sub-objective 4:* Generate and disseminate sufficient diagnostic resources needed to facilitate research, development, and surveillance and diagnostic testing capacity for priority VBD pathogens.	*DHHS (CDC, NIH).* *USDA.*

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 1—DEVELOP, EVALUATE, AND IMPROVE SAFE AND EFFECTIVE VBD PREVENTION TOOLS SUCH AS VACCINES, VECTOR CONTROL STRATEGIES, AND HEALTH COMMUNICATION TOOLS AND PRODUCTS THAT ARE TAILORED FOR COMMUNITIES THAT ARE DISPROPORTIONATELY AFFECTED

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Prioritize, develop, and evaluate vaccines against priority VBD pathogens: • *Sub-objective 1:* Design and implement a decision process to prioritize VBDs for vaccine development. • *Sub-objective 2:* Identify key potential challenges to and opportunities for successful development of vaccines. • *Sub-objective 3:* Facilitate partnerships across sectors, including with communities who are disproportionately affected, for vaccine development. • *Sub-objective 4:* Develop, evaluate, and refine vaccines.	*DHHS (CDC, NIH, FDA).* *USDA.*
Objective 2: Identify, develop, prioritize, and evaluate vector control tools and approaches, including engagement with communities who are disproportionately affected as appropriate: • *Sub-objective 1:* Evaluate the factors that make vectors more or less susceptible to vector control tools. • *Sub-objective 2:* Design and implement a decision process to prioritize vector control tools for development. • *Sub-objective 3:* Identify key potential challenges to and opportunities for successful development of novel vector control tools. • *Sub-objective 4:* Facilitate partnerships across sectors for vector control tool development. • *Sub-objective 5:* Identify, develop, evaluate, and refine new and existing vector control tools and approaches.	*DHHS (CDC, NIH).* *DOD.* *USDA.*
Objective 3: Develop and evaluate public health communication tools and products to encourage public acceptance and adoption of prevention and control guidance: • *Sub-objective 1:* Conduct formative research to inform the development of public health communication tools and products. • *Sub-objective 2:* Develop appropriate outreach strategies as informed by formative research.	*DHHS (CDC).* *USDA.*

STRATEGIC PRIORITY 1—DEVELOP, EVALUATE, AND IMPROVE SAFE AND EFFECTIVE VBD PREVENTION TOOLS SUCH AS VACCINES, VECTOR CONTROL STRATEGIES, AND HEALTH COMMUNICATION TOOLS AND PRODUCTS THAT ARE TAILORED FOR COMMUNITIES THAT ARE DISPROPORTIONATELY AFFECTED—Continued

Objectives and sub-objectives	Federal entities with accountability
• *Sub-objective 3:* Evaluate public health communication tools and products to ensure fit within intended communities.	

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 2—DEVELOP AND EVALUATE DATA-DRIVEN AND ADAPTIVE PREDICTIVE MODELS AND DECISION SUPPORT TOOLS FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop predictive models and decision support tools to guide prevention and control activities:	*DHHS (CDC, NIH). USDA. NOAA (NCAR).*
• *Sub-objective 1:* Elicit and prioritize decision-maker needs and requirements for decision-support tools. • *Sub-objective 2:* Prioritize VBDs for the development of predictive models and decision support tools. • *Sub-objective 3:* Develop predictive VBD transmission models and other nowcasting and forecasting tools.	
Objective 2: Evaluate and refine predictive models and decision support tools.	*DHHS (CDC, NIH). NOAA (NCAR).*
• *Sub-objective 1:* Evaluate the accuracy and utility of predictive models and decision support tools. • *Sub-objective 2:* Refine predictive models and decision support tools based on evaluation outcomes.	

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 3—DEVELOP AND EVALUATE EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON VBD PREVENTION [4]

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop and update evidence-based recommendations and guidelines: • *Sub-objective 1:* Regularly update recommendations and guidelines based on the state of the science. • *Sub-objective 2:* Identify and prioritize VBDs for which new recommendations and guidelines are needed. • *Sub-objective 3:* Collaborate with internal and external partners to develop new recommendations and guidelines for priority VBDs, ensuring specific population needs are considered and addressed. • *Sub-objective 4:* Monitor and evaluate the implementation of recommendations and guidelines	*DHHS (CDC, NIH). USDA.*

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 4—DEVELOP AND EVALUATE TOOLS AND PROCESSES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Ensure national preparedness through the development of national, tribal, state, and territorial preparedness and emergency response plans for vector-borne disease outbreaks: • *Sub-objective 1:* Develop, maintain, and exercise preparedness and emergency response plans, including partner engagement strategies. • *Sub-objective 2:* Ensure equitable availability of medical countermeasures and vector-borne disease prevention and control tools, consistent with preparedness and emergency response plans.	*DHHS (CDC, NIH). USDA. FEMA.*

[4] To include vector control and prophylaxis.

[5] To include relevant partners across animal and public health.

STRATEGIC PRIORITY 4—DEVELOP AND EVALUATE TOOLS AND PROCESSES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES—Continued

Objectives and sub-objectives	Federal entities with accountability
Objective 2: Develop inclusive[5] public health communication plans, products, and tools for responding to vector-borne disease outbreaks that are consistent with and integrated into preparedness and emergency response plans: • *Sub-objective 1:* Develop key messages and tools to effectively communicate health information in a way that is inclusive of all communities. • *Sub-objective 2:* Identify and address challenges to implementation of response communication plans, ensuring equitable accessibility of information.	*DHHS (CDC).* *FEMA.* *USDA.*
Objective 3: Evaluate tools and processes for responding to vector-borne disease emergencies, including reducing associated health inequities: • *Sub-objective 1:* Conduct and support tabletop exercises integrating multiple sectors and community partners as appropriate. • *Sub-objective 2:* Conduct and support after action reviews and develop reports. • *Sub-objective 3:* Evaluate and improve effectiveness of public health communication products and tools.	*DHHS (CDC).* *FEMA.*

Goal 4: Develop and assess drugs and treatment strategies for VBDs

STRATEGIC PRIORITY 1—IDENTIFY, DEVELOP, AND EVALUATE SAFE AND EFFECTIVE DRUGS AND TREATMENT STRATEGIES (REGIMENS) FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop new safe and effective drugs, including immunotherapies: • *Sub-objective 1:* Identify and characterize new molecular targets for therapeutics for priority VBDs. • *Sub-objective 2:* Develop effective drugs from newly identified molecular targets including evaluating/comparing clinical efficacy.	*DHHS (NIH, FDA).* *DOD.* *USDA.*
Objective 2: Evaluate or repurpose existing therapeutic strategies for use in the treatment and management of VBDs: • *Sub-objective 1:* Optimize existing therapeutic strategies for VBDs. • *Sub-objective 2:* Optimize therapeutic strategies repurposed for VBDs. • *Sub-objective 3:* Evaluate complementary and integrative health therapies for safety and efficacy. • *Sub-objective 4:* Conduct and disseminate comparative effectiveness studies of existing VBD treatments.	*DHHS (NIH, FDA).*
Objective 3: Advance research on treatment for persistent symptoms associated with VBDs: • *Sub-objective 1:* Assess treatment strategies for extended or long-term symptoms associated with VBDs. • *Sub-objective 2:* Collaborate across fields of medicine to learn about promising therapeutic strategies for persistent symptoms following VBD infections.	*DHHS (NIH).*

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

STRATEGIC PRIORITY 2—DEVELOP EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON THE TREATMENT AND MANAGEMENT OF VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Periodically review the evidence and update *existing* federally developed recommendations and guidelines to treat and manage VBDs: • *Sub-objective 1:* Coordinate expert review of the evidence to inform revisions of federally developed recommendations and guidelines. • *Sub-objective 2:* Update and disseminate existing federally developed recommendations or guidelines on VBD treatment and management.	*DHHS (CDC, NIH).* *USDA.*
Objective 2: Develop *new* guidance for the treatment and management of VBDs when peer-reviewed recommendations or guidelines do not exist: • *Sub-objective 1:* Coordinate expert review of the evidence to inform the development of new federally developed recommendations and guidelines. • *Sub-objective 2:* Disseminate new federally developed recommendations or guidelines on VBD treatment and management.	*DHHS (CDC, NIH).* USDA.

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

STRATEGIC PRIORITY 3: EVALUATE TREATMENT AND MANAGEMENT USE PATTERNS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Describe patterns of treatment and management: • *Sub-objective 1:* Conduct and disseminate studies of drug and treatment use patterns as well as management of VBDs, including conducting surveys and analyzing administrative claims data for surveillance purposes.	*DHHS (CDC, FDA).*
Objective 2: Develop clinician and public advisories pertaining to the treatment and management of VBDs: • *Sub-objective 1:* Disseminate clinician and public advisories pertaining to the treatment and management of VBDs.	*DHHS (CDC, FDA).*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 1—DISSEMINATE EVIDENCE-BASED INFORMATION ABOUT VBD PREVENTION AND CONTROL, GUIDELINES, AND RECOMMENDATIONS TO PARTNERS AND THE PUBLIC

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Disseminate evidence-based recommendations and guidelines to key professional audiences (for example, healthcare providers, health departments, veterinarians, and professional societies): • *Sub-objective 1:* Tailor dissemination of products and tools based on audience needs. • *Sub-objective 2:* Develop and implement a dissemination plan to distribute evidence-based recommendations and guidelines.	*DHHS (CDC, FDA).* *USDA.*
Objective 2: Disseminate health communication products and tools [6] that are tailored for communities and partners: • *Sub-objective 1:* Collaborate with a diverse set of impacted populations, multi-sectoral partners, and community members to co-create dissemination plans to reach communities of focus using traditional and innovative strategies. • *Sub-objective 2:* Implement the dissemination plan to distribute VBD prevention and control information and guidance using appropriate channels, methods, and messages.	*DHHS (CDC).* *USDA.*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 2—ENSURE CURRENT AND FUTURE CAPACITY TO IMPLEMENT AND ADEQUATELY AND EQUITABLY SCALE SAFE, EFFECTIVE, AND PUBLICLY ACCEPTED VBD PREVENTION AND CONTROL PROGRAMS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Equitably support state, tribal, territories and collaborating partners in their efforts to implement VBD programs, to include surveillance, diagnosis and detection, prevention, and control: • *Sub-objective 1:* Provide support to jurisdictions, Tribes, and partners to implement effective VBD programs, including providing staffing support. • *Sub-objective 2:* Provide technical assistance to implementing jurisdictions, Tribes, and partners in their selection, planning, and implementation of programs, tools, collaborations, and innovations.	*DHHS (CDC).* *USDA.*
Objective 2: Collaborate with partners across levels, sectors, and disciplines to build and sustain implementation capacity: • *Sub-objective 1:* Assess and monitor training needs on evidence-based information, guidelines, and recommendations. • *Sub-objective 2:* Provide trainings on evidence-based information, guidelines, and recommendations. • *Sub-objective 3:* Provide funding and technical assistance to partners to build, expand, and diversify the Public Health workforce.	*DHHS (CDC).* *USDA.*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 3—MONITOR AND EVALUATE EVIDENCE-BASED PUBLIC HEALTH PROGRAMS AND TOOLS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Monitor and evaluate Public Health implementation efforts in communities: • *Sub-objective 1:* Monitor the implementation of programs and tools over time and across communities. • *Sub-objective 2:* Collaborate with implementers to evaluate acceptability, suitability, effectiveness, and sustainability of Public Health programs and tools. • *Sub-objective 3:* Broadly disseminate evaluation findings to implementers, the scientific field, and the public.	*DHHS (CDC).*
Objective 2: Adapt and optimize Public Health efforts:	*DHHS (CDC).*

[6] To be developed in G3, SP1, O3.

STRATEGIC PRIORITY 3—MONITOR AND EVALUATE EVIDENCE-BASED PUBLIC HEALTH PROGRAMS AND TOOLS—Continued

Objectives and sub-objectives	Federal entities with accountability
• *Sub-objective 1:* Regularly review and update Public Health products, tools, and guidance based on findings from program evaluations. • *Sub-objective 2:* Disseminate updated Public Health products, tools, and guidance as warranted. • *Sub-objective 3:* Synthesize the state of the field and share lessons learned, promising and best practices, technologies, and opportunities for continuous improvement.	

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 4—RESPOND TO PUBLIC HEALTH EMERGENCIES RESULTING FROM VBD THREATS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Provide direct response to public health emergencies: • *Sub-objective 1:* Provide laboratory testing for state, tribal, local, and territorial jurisdictions. • *Sub-objective 2:* Deploy staff to support local response efforts (for example, vector surveillance and vector control) when requested by jurisdictions and Tribes. • *Sub-objective 3:* Disseminate Public Health messaging to support local response efforts. • *Sub-objective 4:* Disseminate data that identifies disproportionately affected populations. • *Sub-objective 5:* Facilitate the process for emergency use of VBD tools during public health emergencies.	*DHHS (CDC, NIH).* *USDA.* *FEMA.*
Objective 2: Support jurisdictions in their response to public health emergencies, including addressing the needs of disproportionately affected populations: • *Sub-objective 1:* Support implementation of local preparedness and emergency response plans. • *Sub-objective 2:* Provide direct technical assistance to jurisdictions in the implementation of their emergency response plans. • *Sub-objective 3:* Make medical countermeasures and VBD prevention and control tools available and ensure equitable access and distribution. • *Sub-objective 4:* Ensure the collection and public access of quality data to inform public health actions.	*DHHS (CDC, NIH).*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 5—CLARIFY, FACILITATE, AND IMPROVE PROCESSES TO BRING REGULATED DIAGNOSTIC TESTS, TREATMENT STRATEGIES, VACCINES, AND VECTOR CONTROL PRODUCTS TO MARKET

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Clarify and facilitate the regulatory process for vector control and VBD products, tools, and guidelines: • *Sub-objective 1:* Develop communication strategies that clearly articulate the regulatory process. • *Sub-objective 2:* Provide direction to applicants in their submission and response to regulatory process requirements. • *Sub-objective 3:* Clarify jurisdiction of federal agencies in their regulatory responsibilities for new and innovative products.	*DHHS (FDA).* *EPA.* *USDA.*
Objective 2: Develop innovative strategies to identify and address challenges in bringing vector control and VBD products and tools to market: • *Sub-objective 1:* Conduct regulatory science to ensure that regulatory knowledge gaps are identified for new and emerging technologies. • *Sub-objective 2:* Address the scientific knowledge gaps identified through regulatory science as appropriate.	*DHHS (FDA).* *EPA.*

HHS Tick-Borne Disease Working Group Cross Walk

The purpose of this document is to crosswalk the HHS Tick-borne Diseases Working Group 2018 and 2020 congressional report recommendations with the goals and strategic priorities of the draft *National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans.*

Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs).

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of *research,* treatment, and prevention proportional to the burden of illness and need.

Strategic Priority 1: Better understand vectors, the pathogens they transmit, and the potential effects of a changing climate.

• TBDWG 2018 3.1 Fund studies and activities on tick biology and tick-borne disease ecology, including systematic tick surveillance efforts particularly in regions beyond the Northeast and Upper Midwest.

• TBDWG 2018 6.3 Improve the education and *research* on transmission (including transmission via the blood supply and pregnancy) and treatment of other tick-borne diseases and coinfections.

• TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to

study Lyme disease and other tick-borne diseases.

Strategic Priority 2: Modernize and maintain surveillance systems for vectors, reservoirs, and VBDs.

- TBDWG 2018 3.1 Fund studies and activities on tick biology and tick-borne disease ecology, including *systematic tick surveillance efforts* particularly in regions beyond the Northeast and Upper Midwest.
- TBDWG 2018 3.4 Have public health authorities formally recognize complementary, validated systematic approaches to tick-borne disease surveillance for humans, such as systematic sampling of tick-borne disease reports for investigation that reduce the burden on tick-borne disease reporting but allow for comparability of surveillance findings across states and over time.
- TBDWG 2018 7.7a Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Empower Patients with Data
- TBDWG 2018 8.2 CDC: Dedicate funding within CDC to study—with performance indicators—babesiosis *incidence, prevalence,* treatment resistance, and prevention, including maternal-fetal and transplantation/transfusion transmission risk. Consider using advanced data tools, such as patient registries, to study the potential role of Babesia in tick-borne disease patients with continuing manifestations of disease after initial treatment.
- TBDWG 2018 8.3 DoD: Commence study of tick-borne disease *incidence and prevalence* of active duty Servicemembers and their dependents. Compile data on the impact of tick-borne diseases on military readiness. Create education and preparedness programs that specifically address the unique risks faced by Servicemembers in training and on deployment and by their families.
- TBDWG 2018 8.4 VA: Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members.
- TBDWG 2020 3.1 Implement multi-agency, ecologically-based One Health efforts on tick-borne diseases promoting *research and enhanced vector surveillance* to identify and validate integrated tick management in keystone wildlife hosts, particularly white-tailed deer, and the sustainable management of their populations.
- TBDWG 2020 3.3 Provide funding to support CDC-directed expanded *tick surveillance* and promoting the development and implementation of best practices for integrated tick management capturing human tick bite events, and streamlining education, training, and coordination amongst relevant Federal, state, and local agencies.
- TBDWG 2020 4.4 Provide HHS with resources to partner with national Integrated Delivery Networks (IDNs) (for example, Geisinger, Kaiser, etc.) to conduct a pilot feasibility study to leverage Electronic Medical Records (EMRs) using Best Practice Alerts at the patient point-of-care for Alpha-gal Syndrome in endemic areas (upholding patient confidentiality).
- TBDWG 2020 4.5 Provide HHS with resources to partner with national Integrated Delivery Networks (IDNs) (for example, Geisinger, Kaiser, etc.) to conduct a pilot feasibility study to leverage Electronic Medical Records (EMRs) using Best Practice Alerts at the patient point-of-care for rickettsial diseases, ehrlichiosis, and anaplasmosis in endemic areas (upholding patient confidentiality).
- TBDWG 2020 8.2 Recommend that CDC work with Council of State and Territorial Epidemiologists (CSTE) to streamline the surveillance process and to reduce the burden on both clinicians and public health departments by permitting direct laboratory reporting of positive cases.
- TBDWG 2020 9.1 VA: Recommend that the VA continue with Recommendation 8.4 from 2018 Working Group report, ''Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members'' and additionally
  - Establish and update efforts on tracking and investigating the prevalence of Lyme and other tick-borne diseases;
- TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to study Lyme disease and other tick-borne diseases.

Strategic Priority 3: Better understand the risk factors for and effects of VBDs on humans.

- TBDWG 2018 6.1 Prioritize research into the potential pathogenic mechanisms (such as immune response, cross-reactivity, autoimmunity, bacterial persistence, coinfections, and other mechanisms) of persistent symptoms in patients who have received standard treatment regimens for tick-borne diseases, including Lyme disease.
- TBDWG 2018 6.2 Promote research on animal models of Borrelia burgdorferi infection (that is, Lyme disease) and the mechanisms of disease processes in humans with an emphasis on pathologies that are currently lacking, for example, neuroborreliosis.
- TBDWG 2018 6.5 Improve the education and *research on the pathogenesis* of alpha-gal allergy, also known as the tick-caused ''meat allergy.''
- TBDWG 2018 8.2 CDC: Dedicate funding within CDC to study—with performance indicators—babesiosis incidence, prevalence, treatment resistance, and prevention, including *maternal-fetal and transplantation/transfusion transmission risk.* Consider using advanced data tools, such as patient registries, to study the potential role of Babesia in tick-borne disease patients with continuing manifestations of disease after initial treatment.
- TBDWG 2020 4.1 Fund research aimed at characterizing the full clinical spectrum, clinical manifestations, and potential complications of human monocytic ehrlichiosis (HME) and human granulocytic anaplasmosis (HGA), including identification of risk factors for severe illness and the importance of specific comorbidities, patient characteristics (age, gender, and race), immune impairment, and genetic host factors.
- TBDWG 2020 5.1 Provide HHS with resources necessary to fund basic science research and clinical research to investigate the pathology of the human immune response following tick bites (*e.g.,* Alpha-gal Syndrome [AGS]).
- TBDWG 2020 5.2 Support the targeted funding of *research to understand the role of persistence of bacteria and bacterial products in the pathogenesis* and management of Lyme disease (*e.g.,* antibiotic regimens and other therapeutics).
- TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the diagnosis, *pathogenesis,* and management of Lyme carditis.
- TBDWG 2020 8.1 Fund prospective studies of acute febrile illnesses to assess the burden of tick-borne diseases, including rickettsial, ehrlichial, and anaplasmal pathogens.
- TBDWG 2020 8.3 Further evaluation of non-tick bite transmission of Lyme disease, for example maternal-fetal transmission.
- TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to study Lyme disease and other tick-borne diseases.
- TBDWG 2020 9.4 NIH: Recommend that the NIH create one or more study sections composed of members whose expertise is human clinical diseases and their pathogenesis and immunity not just basic science to evaluate applications focused on practical impact on human health related to tick-borne diseases.

• TBDWG 2020 9.5 NIH: Recommend that NIH receive additional funding which must be dedicated to study Lyme disease including persistent Lyme disease and other tick-borne diseases and conditions; and they encourage researchers to apply for these studies.

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.

Strategic Priority 1: Identify and characterize novel VBD pathogens and their clinical manifestations.

• TBDWG 2018 3.2 Fund systematic studies and activities to identify and characterize novel tick-borne disease agents in the United States.

• TBDWG 2020 4.3 Establish and fund research for sensitive and specific diagnostic tests for the broader range of tick-borne diseases, including tick-borne relapsing fever, Powassan virus, and other *emerging* tick-borne pathogens. Encourage development of these tests as in vitro diagnostics approved by FDA.

Strategic Priority 2: Develop, evaluate, and improve diagnostic tests for VBDs.

• TBDWG 2018 5.1 Evaluate new technology or approaches for the diagnosis of Lyme disease and other tick-borne diseases.

• TBDWG 2018 5.2 Include special populations, especially children, in Lyme disease and other tick-borne diseases diagnostic studies.

• TBDWG 2020 4.2 Establish and fund research for sensitive and specific diagnostic tests for acute rickettsial, ehrlichial, and anaplasmal diseases. Encourage development of these tests as in vitro diagnostics approved by FDA.

• TBDWG 2020 4.3 Establish and fund research for sensitive and specific diagnostic tests for the broader range of tick-borne diseases, including tick-borne relapsing fever, Powassan virus, and other emerging tick-borne pathogens. Encourage development of these tests as in vitro diagnostics approved by FDA.

• TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the *diagnosis,* pathogenesis, and management of Lyme carditis.

Strategic Priority 3: Develop and evaluate evidence-based recommendations and guidelines on VBD diagnosis in humans.

Strategic Priority 4: Develop, maintain, and distribute non-commercial diagnostic resources to facilitate VBD testing.

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, treatment, and *prevention* proportional to the burden of illness and need.

Strategic Priority 1: Develop, evaluate, and improve safe and effective VBD prevention tools such as vaccines, vector control strategies, and health communication tools and products that are tailored for communities that are disproportionately affected.

• TBDWG 2018 4.1 Fund additional studies and activities on the development and evaluation of novel and traditional tick-control methods that have shown promise in other areas of public health entomology.

• TBDWG 2018 4.2 Build trust via a transparent mechanism by which all stakeholders examine and discuss past vaccine activities and potential adverse events to inform future vaccine development in Lyme disease.

• TBDWG 2018 4.3 Support the development of safe and effective human vaccines to prevent Lyme disease with transparent mechanisms by which all stakeholders examine and discuss past vaccine activities and potential adverse events to inform future vaccine development.

• TBDWG 2018 8.3 DoD: Commence study of tick-borne disease incidence and prevalence of active duty Servicemembers and their dependents. Compile data on the impact of tick-borne diseases on military readiness. *Create education and preparedness programs* that specifically address the unique risks faced by Servicemembers in training and on deployment and by their families

• TBDWG 2018 8.5 Develop and disseminate more comprehensive clinician education that highlights diverse symptomology, expanding geography of infecting ticks, and limitations of current testing procedure. In developing the curriculum, include diverse stakeholder groups, including clinicians, research scientists, and patients who represent the spectrum of scientific and medical expertise and perspectives on tick-borne disease.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to treat and *prevent* the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

• TBDWG 2020 7.5 Generate broad awareness of Alpha-gal Syndrome through the following two mechanisms:

○ Label foods/beverages, medications and medical products, cosmetics, etc. containing mammalian-derived components for the safety of consumers with Alpha-gal Syndrome.

Strategic Priority 2: Develop and evaluate data-driven and adaptive predictive models and decision support tools for VBDs.

Strategic Priority 3: Develop and evaluate evidence-based recommendations and guidelines on VBD prevention.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to treat and *prevent* the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 4: Develop and evaluate tools and processes for responding to public health emergencies.

• TBDWG 2018 8.1 NIH: Create an NIH tick-borne disease strategic plan, with public input during creation and implementation, to address tick-borne diseases, including all stages of Lyme disease. Include in the strategic plan the coordination of research funding across NIAID, NINDS, NIAMS, and NIMH to increase knowledge of pathogenesis, improve diagnosis, and develop and test new therapeutics for tick-borne diseases. Update every five years.

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, *treatment,* and prevention proportional to the burden of illness and need.

Strategic Priority 1: Identify, develop, and evaluate safe and effective drugs and treatment strategies (regimens) for VBDs.

• TBDWG 2018 6.3 Improve the education and research on transmission (including transmission via the blood supply and pregnancy) and *treatment* of other tick-borne diseases and coinfections.

• TBDWG 2018 6.4 Conduct additional clinical trials appropriate to the target populations where gaps may exist.

• TBDWG 2020 5.2 Support the targeted funding of research to understand the role of persistence of bacteria and bacterial products in the pathogenesis and *management* of Lyme disease (*e.g.,* antibiotic regimens and other therapeutics).

• TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the diagnosis, pathogenesis, and *management* of Lyme carditis.

• TBDWG 2020 6.1 Encourage clinical trials on early and persistent Lyme disease.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to *treat* and prevent the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 2: Develop evidence-based recommendations and guidelines on the treatment and management of VBDs.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to *treat* and prevent the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 3: Evaluate drug and treatment use patterns.

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, treatment, and *prevention* proportional to the burden of illness and need.

Strategic Priority 1: Disseminate evidence-based information about VBD prevention and control, guidelines, and recommendations to partners and the public.

• TBDWG 2018 3.5 The Lyme disease surveillance criteria are not to be used alone for diagnostic purposes; public health authorities shall annually and when opportune (such as during Tick-Borne Disease Awareness Month) communicate this and inform doctors, insurers, state and local health departments, the press, and the public through official communication channels, including the CDC's Morbidity and Mortality Weekly Report (MMWR).

• TBDWG 2018 4.4 Prioritize education by informing clinicians and the general public about the regional and specific risks related to tick-borne diseases.

• TBDWG 2018 6.3 Improve the *education* and research on transmission (including transmission via the blood supply and pregnancy) and treatment of other tick-borne diseases and coinfections.

• TBDWG 2018 6.5 Improve the *education* and research on the pathogenesis of alpha-gal allergy, also known as the tick-caused ''meat allergy.''

• TBDWG 2018 7.1 Create a Federal repository for information on Lyme disease and other tick-borne diseases.

• TBDWG 2018 7.7c Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Relay Information as a Neutral Knowledge Broker

• TBDWG 2018 8.5 Develop and disseminate more comprehensive clinician education that highlights diverse symptomology, expanding geography of infecting ticks, and limitations of current testing procedure. In developing the curriculum, include diverse stakeholder groups, including clinicians, research scientists, and patients who represent the spectrum of scientific and medical expertise and perspectives on tick-borne disease.

• TBDWG 2020 3.3 Provide funding to support CDC-directed expanded tick surveillance and promoting the development and implementation of best practices for integrated tick management capturing human tick bite events, and *streamlining education, training, and coordination* amongst relevant Federal, state, and local agencies.

• TBDWG 2020 7.1 Recommend Federal government websites and educational materials and seminars for clinicians, the public, and public health departments, which discuss Lyme disease, provide information that the state of the science relating to persistent symptoms associated with Lyme disease, is limited, emerging, and unsettled; and increase public awareness that there are divergent views on diagnosis and treatment. Consider that shared medical decision-making may be appropriate in some circumstances.

• TBDWG 2020 7.2 Fund and support a directive for CDC (or other appropriate HHS OPDIV or agency) to develop (either directly or through an approved federal contract) a multi-leveled and nationwide curriculum on Lyme disease for clinicians-in-training as well as continuing medical education modules to increase the pool of qualified and practicing clinicians. Provide funding for the U.S. military to participate in this nationwide training and education on Lyme disease and other tick-borne diseases and conditions. This curriculum should be introduced and encouraged at the State level. The final curriculum shall incorporate feedback from patients, clinicians, and research scientists with expertise/experience that represents diverse scientific and clinical experiences on the full spectrum of Lyme disease and other tick-borne diseases/conditions.

• TBDWG 2020 7.3 Fund efforts across the U.S. to expand/require medical education to inform emergency, primary care, and other healthcare providers and to raise clinician and public awareness of rickettsial (including Rocky Mountain spotted fever), ehrlichial, and anaplasmal diseases.

• TBDWG 2020 7.4 Fund efforts across the U.S. to expand/require medical education to inform emergency, primary care, and other healthcare providers and to raise clinician and public awareness of babesiosis, tick-borne relapsing fever, emerging tick-borne viral infections, and other low-incidence tick-borne diseases.

• TBDWG 2020 7.5 Generate broad awareness of Alpha-gal Syndrome through the following two mechanisms:

○ Provide funding/support/resources necessary to create a National Tick-Borne Alpha-gal Syndrome Alert that is focused on awareness, prevention, and education regarding tick associated Alpha-gal Syndrome and that targets key stakeholder groups.

• TBDWG 2020 9.1 VA: Recommend that the VA continue with Recommendation 8.4 from 2018 Working Group report, ''Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members'' and additionally

○ Make educational modules available to practitioners.

• TBDWG 2020 9.3 CDC: Recommend that if the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme Disease.

Strategic Priority 2: Ensure current and future capacity to implement and adequately and equitably scale safe, effective, and publicly accepted VBD prevention and control programs.

• TBDWG 2020 3.2 Minimize the public health threat of Lyme disease and other tickborne diseases through special funding for integrated tick management, disruption of tick biological processes contributing to pathogen transmission, and the support of public/private partnerships to develop and promote area-wide tick control strategies.

• TBDWG 2020 3.3 Provide funding to support CDC-directed expanded tick surveillance and promoting the development and *implementation* of best practices for integrated tick management capturing human tick bite events, and streamlining education, training, and coordination amongst relevant Federal, state, and local agencies.

Strategic Priority 3: Monitor and evaluate evidence-based public health programs and tools.

• TBDWG 2018 7.7b Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Engage Diverse Stakeholders—Update the CSTE Surveillance Case Definition with 21st-Century Evidence

• TBDWG 2020 3.1 Implement multi-agency, ecologically-based One Health efforts on tick-borne diseases promoting research and enhanced vector surveillance to identify and *validate integrated tick management* in keystone wildlife hosts, particularly white-tailed deer, and the sustainable management of their populations.

• TBDWG 2020 8.2 Recommend that CDC work with Council of State and Territorial Epidemiologists (CSTE) to *streamline* the surveillance process and to reduce the burden on both clinicians and public health departments by permitting direct laboratory reporting of positive cases.

Strategic Priority 4: Respond to Public Health emergencies resulting from VBD threats.

Strategic Priority 5: Clarify, facilitate, and improve processes to bring regulated diagnostic tests, treatment strategies, vaccines, and vector control products to market.

Although critical to public health and wellness, the following recommendations related to healthcare utilization, access to care, reimbursement or payment for clinical services, and legal protections are outside the scope of this prevention and control strategy:

• TBDWG 2018 3.3 Support economic studies and activities to estimate the total cost of illness associated with tick-borne diseases in the United States, beginning first with Lyme disease and including both financial and societal impacts.

• TBDWG 2018 7.3 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect patients from employment discrimination.

• TBDWG 2018 7.4 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect students of all ages from discrimination.

• TBDWG 2018 7.5 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect patients from health care and disability insurance coverage and reimbursement policies that are unduly burdensome.

• TBDWG 2018 7.6 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect the rights of licensed and qualified clinicians to use individual clinical judgment, as well as recognized guidelines, to diagnose and treat patients in accordance with the needs and goals of each individual patient.

• TBDWG 2020 9.6 CMS: Recommend that CMS provides all information and data on Lyme disease and other tick-borne diseases and all applicable agency activities pertaining to these conditions which may include but should not be limited to:

○ Reimbursement costs for the diagnosis and treatment of beneficiaries with Lyme disease and other tick-borne diseases;

○ Demonstration and pilot projects with Lyme disease and other tick-borne diseases as their focus; and

○ Quality measure development and implementation related to Lyme disease and other tick-borne diseases.

[FR Doc. 2022–25241 Filed 11–18–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Health; Opportunity To Co-Sponsor OASH-Supported Grantee Workshops

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: The Grants and Acquisitions Management Division (GAM) in the Office of the Assistant Secretary for Health (OASH), in conjunction with the grant making program offices it supports, announces the opportunity for non-federal public and private sector entities to co-sponsor OASH-supported grants workshops (OASH Grants Workshops). Potential co-sponsors must have a demonstrated interest and experience in building capacity among potential grant applicants and grant recipients. Potential co-sponsors must be willing to participate substantively in the co-sponsored activity. Expressions of interest for co-sponsorships of OASH Grants Workshops are received throughout the year at the email address below. OASH intends to co-sponsor a limited number of workshops with other entities each year. Expressions of interest are being received for OASH Grants Workshops that will take place in the next fiscal year (October 2022 through September 2023) or beyond. Expressions of interest for co-sponsorships should be sent by email to *OASH_Grants@HHS.GOV* with ''Co-sponsorship for OASH-supported Grants Workshops'' in the subject field or by mail to Duane Barlow, Grants Branch Chief, OASH, Grants and Acquisitions Management Division, at 1101 Wootton Parkway, Plaza Level, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Duane Barlow, Grants Branch Chief, OASH, Grants and Acquisitions Management Division, 1101 Wootton Parkway, Plaza Level, Rockville, MD 20852; or via phone (240) 453–8822.

SUPPLEMENTARY INFORMATION: The OASH Grants and Acquisitions Management (GAM) Division oversees, administers, and supports grant-making activities of public health offices on behalf of the Secretary of the U.S. Department of Health and Human Services (HHS). The grant-making program offices that GAM supports include: the Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of Minority Health (OMH), Office of Population Affairs (OPA), Office of Research Integrity (ORI), and Office on Women's Health (OWH). Another OASH component, the Office of Regional Health Operations (ORHO), which includes ten Regional Offices covering all states and territories of the United States and three independent states in the Pacific, through its coordinating function will also be involved in the OASH Grants Workshops.

Consistent with each office's mission and applicable statutory authority, the OASH Grants Workshops aim to build capacity among potential grant applicants and grant recipients in related areas such as applying for and managing grants and cooperative agreements (collectively grants) awarded under the programs listed by Assistance Listing number below:

• 93.007 Public Awareness Campaigns on Embryo Adoption
• 93.085 Research on Research Integrity
• 93.088 Advancing System Improvements for Key Issues in Women's Health

- 93.137 Community Programs to Improve Minority Health Grant Program
- 93.217 Family Planning Services
- 93.260 Family Planning Personnel Training
- 93.297 Teenage Pregnancy Prevention Program
- 98.343 Public Health Service Evaluation Funds
- 93.344 Research, Monitoring and Outcomes Definitions for Vaccine Safety
- 93.974 Family Planning Service Delivery Improvement Research Grants

Full Assistance Listing descriptions are published and updated annually on *https://sam.gov.* Co-sponsors will work with OASH/GAM staff to jointly develop an event. Both OASH and the co-sponsor must contribute substantively to the development of the event.

OASH Grants Workshops may be convened over one to three days; conducted virtually, in-person, or in a hybrid format (virtual and in-person). Depending on the workshop format and scope, a workshop may typically accommodate between 100 and 500 attendees.

Co-sponsors can charge registration fees to recover costs associated with the events; however, co-sponsors may not set registration fees at an amount higher than necessary to recover related event expenses. Further, co-sponsors are solely responsible for collecting and handling any registration fees collected.

Eligibility for Co-Sponsorship: The co-sponsoring entity must have a demonstrated interest and experience in building capacity among potential grant applicants and grant recipients, particularly with respect to programs supported by GAM. The co-sponsoring entity must participate substantively in the co-sponsored activity, not just provide funding, logistical services, or other material support.

Each potential co-sponsorship's expression of interest shall describe:

(1) The entity's interest in building capacity among potential grant applicants and grant recipients,

(2) The entity's prior experience and current readiness to undertake the responsibilities described above,

(3) The type of event(s) that the entity is interested in co-sponsoring with GAM,

(4) Facilities and/or virtual platforms available for the event(s), and

(5) Any current constraints with respect to dates or facilities.

The type of event may be a special topic of mutual interest with one or more of the aforementioned GAM supported program offices and may be developed jointly.

The expression of interest should be a bulleted outline, no more than two pages in length, single-spaced, and 11-point font. An entity may submit an expression of interest individually or jointly with other entities describing their relative contributions.

Evaluation Criteria: After engaging in exploratory discussions with potential co-sponsors that respond to this notice, the following considerations will be used by HHS officials, as appropriate and relevant, to select the co-sponsor(s):

- Qualifications and capability to fulfill co-sponsorship responsibilities
- Suitability of the location of the proposed OASH Grants Workshops in terms of the overall geographical distribution of OASH Grants Workshops
- Potential for reaching, generating, and engaging an adequate number of attendees who may be potential grant applicants and grant recipients
- Availability and description of facilities and resources needed to support the OASH Grants Workshop
- Availability of administrative support for the logistics of hosting such OASH Grants Workshops

These duties will be outlined in a co-sponsorship agreement with GAM and the sponsoring program office(s) that will set forth the details of the co-sponsored activity, including the requirements that any fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor's related event expenses. This co-sponsorship agreement does not represent an endorsement by HHS, OASH, GAM or its supported program office(s) of an individual co-sponsor's policies, positions, or activities. Additionally, this agreement will not affect any determination concerning activities by the co-sponsors that are regulated by GAM's grant-supporting offices.

Dated: November 14, 2022.

Scott J. Moore,

Director, Grants and Acquisitions Management Division, Office of the Assistant Secretary for Health.

[FR Doc. 2022–25259 Filed 11–18–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Library of Medicine Special Emphasis Panel, March 16, 2023, 11 a.m. to 3 p.m., Virtual Meeting, which was published in the **Federal Register** on October 6, 2022, 87 FR 193 Page Number 60696.

This notice is being amended to announce that the meeting is cancelled and will not be rescheduled.

Dated: November 16, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25317 Filed 11–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–22–004 NIDDK Partnerships with Professional Societies to Enhance Scientific Workforce Diversity and Promote Scientific Leadership.

Date: December 16, 2022.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2 Democracy, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John F. Connaughton, Ph.D., Chief, Scientific Review Branch, Review Branch, DEA, Niddk National Institutes of Health, Room 7007, 6707

Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797 *connaughtonj@extra.niddk.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 16, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25318 Filed 11–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Vessel Entrance and Clearance Automation Test

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) will conduct the Vessel Entrance and Clearance Automation Test. This test will allow participants to submit certain vessel entry and clearance data and requests to CBP electronically through the Vessel Entrance and Clearance System (VECS), instead of submitting paper forms, as currently required by CBP regulations. Specifically, this test will allow participants to submit the data required on CBP Forms 26, 226, 1300, 1302, 1303, 1304, and 3171 electronically through VECS prior to arrival or departure from designated ports. This notice describes the test, sets forth the eligibility requirements for participation, and invites public comment on any aspect of the test.

DATES: The test will begin at the Port of Gulfport in Gulfport, Mississippi, no earlier than December 21, 2022 and will continue for 24 months from the date the test begins. During the 24 months, additional ports will be designated as test ports, and CBP will announce the additional ports participating in the test on its website. Comments concerning this notice and all aspects of the announced test may be submitted at any time during the test period.

ADDRESSES: Written comments concerning any aspect of the test should be submitted via email to Brian Sale, Branch Chief, Cargo and Conveyance Security, Manifest Conveyance and Security Division, Office of Field Operations, U.S. Customs and Border Protection, at *OFO-ManifestBranch@cbp.dhs.gov.* In the subject line of the email, please write ''Comments on Vessel Entrance and Clearance Automation Test.''

FOR FURTHER INFORMATION CONTACT: Brian Sale, Branch Chief, Cargo and Conveyance Security, Manifest Conveyance and Security Division, Office of Field Operations, U.S. Customs & Border Protection; *OFO-ManifestBranch@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose of the Test

A. Purpose of the Test

U.S. Customs and Border Protection (CBP) regulations generally require that the master or vessel agent [1] of a commercial vessel submit certain arrival, entrance, and clearance data to CBP when traveling to and from U.S. ports of entry. *See* part 4 of title 19 of the Code of Federal Regulations (19 CFR part 4). The vessel agent must generally submit this data to CBP on paper forms. Some of the data collected through these forms is redundant or already available to CBP through other required data submission platforms, such as data required by the applicable U.S. Coast Guard (USCG) regulations. *See* 33 CFR 160.201–216.

Executive Order 13659, ''Streamlining the Export/Import Process for America's Businesses,'' signed in February 2014, requires the U.S. Government to streamline the export/import process for America's businesses by increasing efforts to improve technologies, policies, and other controls governing the movement of goods across U.S. borders. In support of this Executive Order, as well as in response to requests from the trade industry, CBP is developing a web-based system that will allow for the partial automation and electronic filing of many of its paper-based commercial vessel arrival, entrance, and clearance data collections. The Vessel Entrance and Clearance Automation Test (''the Test'') will allow CBP to test this system. The Test will also fulfill CBP's aims to improve service delivery and customer experience, by reducing paperwork burdens and promoting greater efficiency with respect to the submission of vessel entry and clearance forms.

Specifically, the Test will allow participants to electronically submit to CBP, through the Vessel Entrance and Clearance System (VECS), when seeking to enter into or depart from a designated port, the entrance and clearance data that is currently collected on CBP Form 1300: Vessel Entrance or Clearance Statement; CBP Form 1302: Inward Cargo Declaration; CBP Form 1303: Ship's Stores Declarations; CBP Form 1304: Crew's Effects Declaration; CBP Form 3171: Application-Permit-Special-License-Unlading-Lading-Overtime Services; CBP Form 26: Report of Diversion; and CBP Form 226: Record of Vessel Foreign Repair or Equipment Purchase. The Test will also allow participants to make certain entry and clearance requests and reports. Additionally, the Test will allow vessel agents to submit required supporting documentation, such as vessel certificates, to CBP electronically. CBP will then use the data and documentation submitted through VECS to process vessel entrances and clearances electronically at designated ports.

VECS is intended to modernize the maritime commercial entry and clearance process upon the arrival and departure of a commercial vessel at U.S. ports by eliminating the need for vessel agents to fill out and submit data elements that are requested on more than one of these forms or through other required data submission methods, and instead consolidate the maritime entry and clearance process into an electronic submission to a single platform. All other CBP forms required for the entrance and clearance of a vessel (*e.g.,* CBP Form 1302A: Cargo Declaration Outward with Commercial Forms; CBP Form I–418: Passenger List-Crew List; [2] and CBP Form 5129: Crew Member's Declaration) are not part of the Test and must continue to be submitted in accordance with the procedures outlined in the CBP regulations.

The current process for entering and clearing a commercial vessel generally involves the manual preparation and presentation of paper forms (originals and copies), even though in some cases, CBP regulations allow for electronic submissions. VECS will provide a web-based interface that can be accessed by both vessel agents and CBP on a mobile

[1] For the purposes of this document, ''vessel agent'' may include a vessel master or commanding officer, authorized agent, operator, owner, consignee, or a third party contracted by the owner or operator of the vessel to prepare and submit Entrance and Clearance documentation to CBP on behalf of the vessel owner or operator.

[2] As of February 28, 2022, CBP's amended regulations require vessel operators and vessel agents to submit the data elements required on CBP Form I–418 electronically via the U.S. Coast Guard's electronic Notice of Arrival/Departure (eNOA/D) system. *See* 86 FR 73618.

tablet or a standard desktop computer. It will pre-populate a number of data fields required on the aforementioned entry and clearance forms using information provided to CBP through other CBP databases. This method will enable the vessel agent to deploy a single transmission of data and effectively eliminate the need for duplicative data transmissions to CBP. Furthermore, this Test will decrease the time it takes for CBP Officers and the trade community to process an entrance and clearance of a commercial vessel.

B. Current Vessel Arrival, Entrance, and Clearance Processes and Requirements

The regulations outlining the requirements for vessel arrival, entrance, and clearance processes are in 19 CFR part 4. They are described below.

1. Requests for Preliminary Entry, Permits, and Special Licenses

Before a commercial vessel carrying imported merchandise, baggage, and/or passengers and required to make formal entry arrives at a U.S. port of entry, the vessel agent may apply for a CBP permit or special license for unlading and lading. Alternatively, the vessel agent may make a preliminary entry before the vessel makes formal entry. *See* 19 CFR 4.8 and 4.30.

Vessel operators or agents seeking preliminary entry in advance of arrival must submit the electronic equivalent of a complete CBP Form 1302 through the CBP Automated Manifest System (AMS) under current established regulations, standards and practices and must also submit CBP Form 3171 (Application-Permit-Special License-Unlading-Lading-Overtime Services) to CBP electronically no less than 48 hours prior to the vessel's arrival. *See* 19 CFR 4.7(b)(2) and (b)(4); 19 CFR 4.8. Vessel agents typically submit CBP Form 3171 via paper, fax, or email. The submission of CBP Form 3171 also serves as notice of a vessel's intended date of arrival, and CBP uses the submitted CBP Form 3171 for vessel tracking and scheduling. If the intended date of arrival changes, the vessel agent must notify CBP of the new arrival time.

Except under certain circumstances,[3] vessels arriving directly or indirectly from any port or place outside the customs territory of the United States,[4] including the adjacent waters, or from a vessel which transits the Panama Canal, may not unlade passengers, cargo, baggage, or other articles until the port director issues a permit or special license for such unlading. 19 CFR 4.30(a). Similarly, until the port director has issued a permit or special license to the vessel operator on CBP Form 3171 or through a CBP-approved electronic data interchange system, cargo, baggage, or other articles may not be laden on a vessel destined to a port or place outside the customs territory of the United States, including the adjacent waters, if Customs supervision of such lading is required. 19 CFR 4.30(a).

Instead of applying for routine permits and special licenses to unlade/lade each time a vessel enters a U.S. port, vessel agents can request a term permit from CBP which allows them to immediately unlade/lade merchandise, baggage, and/or passengers prior to entry. With a term permit, vessel operators can immediately unlade/lade merchandise, baggage, and/or passengers for all arrivals and entrances at a particular port of entry within a specific, though extendable, time period without the submission of CBP Form 3171 at each arrival. Vessel agents can apply for a term permit to immediately unlade/lade at a particular port of entry by submitting CBP Form 3171 with a continuous bond to the CBP port director via fax, email, or in person. If granted by CBP, the term permit remains in effect until revoked by the port director or automatically cancelled by termination of the supporting continuous bond.[5] Because vessel agents with term permits do not have to submit CBP Form 3171 for each arrival and entrance, they must report their intended date of arrival to CBP for vessel tracking and scheduling. *See generally* 19 CFR 4.30.

In recent years, CBP has limited advance unlading privileges to members of the Customs Trade Partnership Against Terrorism (CTPAT) program.[6] Members of CTPAT may request the privilege of using the Advanced Qualified Unlading Approval Program (AQUA Lane), which allows them, if approved, to commence cargo operations immediately upon arrival rather than having to wait for the vessel to be boarded and cleared by CBP Officers. To obtain this benefit, the CTPAT member's agent must request the privilege at least 24 hours prior to the arrival of the vessel by submitting CBP Form 3171 to CBP.

2. Report of Arrival

Pursuant to 19 CFR 4.2, when a vessel from a foreign port or place, any foreign vessel from a port or place within the United States, or any vessel of the United States carrying foreign merchandise for which entry has not been made, arrives at a U.S. port, the vessel agent must immediately report that arrival to the nearest CBP facility or other location designated by the port director. Generally, the report of arrival may be made by any means of communication to the port director or to a CBP Officer assigned to board the vessel.

3. Entry

For vessels required to make formal entry, the vessel agent must, within 48 hours of arrival, generally submit the original vessel manifest, along with one copy, to CBP at the customhouse. *See* 19 CFR 4.3 and 4.7. The manifest consists of the following CBP forms: CBP Form 1300: Vessel Entrance or Clearance Statement (for Entrance); CBP Form 1302: Cargo Declaration; CBP Form 1303: Ship's Stores Declaration; CBP Form 1304: Crew's Effects Declaration; CBP Form I–418 (Passenger List-Crew List); and under some circumstances, CBP Form 5129, Crew Member's Declaration. *See* 19 CFR 4.7 and 4.9; 19 U.S.C. 1434.

For U.S. vessels documented for foreign or coastwise trade, as well as foreign vessels that intend to engage in foreign and coastwise trade under CBP regulations, the vessel agent must also include a foreign repairs declaration on CBP Form 226: Record of Vessel Foreign Repair or Equipment Purchase when it first arrives in the United States following a foreign voyage. *See* 19 CFR 4.14. If the agent declares that foreign repairs were done, the agent must also complete the vessel repair entry section of CBP Form 226. For foreign vessels, the vessel agent must show the vessel's document to the port director on or before the entry of the vessel. *See* 19 CFR 4.9. Along with the vessel manifest, a vessel agent making formal entry must also present any vessel certificates, such as the Certificate of Financial Responsibility (Passenger Transportation Indemnification), Load Line Certificate, and term permit to CBP. *See, e.g.,* 19 CFR 4.65–4.66c.

[3] Excepted circumstances are enumerated in 19 CFR 4.30(f), (g), and (k), as well as 19 CFR 123.8. Additionally, the exception also applies in the case of vessels exempt from entry or clearance fees under 19 U.S.C. 288.

[4] "Customs territory of the United States" includes only the States, District of Columbia, and Puerto Rico. 19 CFR 101.1.

[5] *See* 19 CFR 4.30.

[6] CTPAT is a voluntary public-private sector partnership program which recognizes that CBP can provide the highest level of cargo security only through close cooperation with the principal stakeholders of the international supply chain, including vessel operators and vessel agents. The Security and Accountability for Every Port Act of 2006 (SAFE Act) provided a statutory framework for the CTPAT program and imposed strict program oversight requirements. For more information, visit *https://www.cbp.gov/border-security/ports-entry/cargo-security/CTPAT.*

4. Manifests: Inward Foreign; Traveling; Abstract

Pursuant to 19 CFR 4.7, the master of every vessel arriving in the United States who is required to make formal entry must have a manifest on board the vessel. As discussed in the prior section, the manifest consists of CBP Forms 1300, 1302, 1303, 1304, I–418, and under some circumstances CBP Form 5129. 19 CFR 4.7(a). The original manifest, known as the ''inward foreign manifest'' and one copy must be presented to the CBP Officer who first demands it.[7] 19 CFR 4.7(b)(1).

If the vessel will proceed from the port of arrival to other U.S. ports with residue foreign cargo or passengers, the master of the vessel must provide an additional copy of the manifest for certification as a ''traveling manifest.'' 19 CFR 4.7(b)(1) and 4.85. At each subsequent U.S. port the vessel travels to with inward foreign cargo or passengers still on board, the vessel agent must present the traveling manifest. The vessel agent must also present an ''abstract manifest'' for any cargo or passengers to be discharged at that port. 19 CFR 4.85(c).

5. Clearance: Foreign and Permit To Proceed Coastwise

To depart from a U.S. port or place, vessels must generally apply for clearance from CBP.[8] 19 CFR 4.60–4.61, 4.81. When the vessel's next intended destination is a foreign port or place, vessel agents must apply for foreign clearance by submitting CBP Form 1300 (Clearance Statement), executed by the vessel master or other proper officer, to CBP at the customhouse. 19 CFR 4.61(a). The vessel agent must also file CBP Form 1302A with the appropriate CBP Officer at the U.S. port from which clearance is being sought. 19 CFR 4.63(a). CBP will grant clearance either on the paper forms or by approved electronic means. 19 CFR 4.61(a).

When a foreign vessel's next intended destination is another U.S. port or place, the vessel agent must apply for a permit to proceed coastwise, by filing two copies of CBP Form 1300 with CBP. 19 CFR 4.81(e); *see also* 19 CFR 4.85. Unless the vessel is proceeding in ballast, the vessel agent must also file three copies of the Cargo Declaration with the port director for the port from which the vessel seeks to depart. 19 CFR 4.81(e).

Additionally, before any vessel may proceed from one domestic port to another with cargo or passengers on board, the vessel agent must present CBP Form 1300, in triplicate, to the director of the port from which the vessel seeks to depart. 19 CFR 4.85(b)(1).

6. Report of Diversion

When a vessel that has been cleared by a U.S. port to depart to a foreign port and, while enroute, is diverted to a U.S. port other than the one where it was cleared, the vessel agent must immediately notify the port that granted the last clearance of the vessel's diversion. 19 CFR 4.91(b). The vessel agent must also file a report of diversion on CBP Form 26 with the port that granted the last clearance. The same process applies to vessels that have received a permit to proceed coastwise. If such a vessel is diverted, the vessel agent must immediately give notice of the diversion to the port director who granted the permit to proceed. 19 CFR 4.91(a). Again, the vessel operator must also file a report of diversion on CBP Form 26 with that port.

II. Description of the Vessel Entrance and Clearance Automation Test

A. Vessel Entrance and Clearance Data Submissions Through VECS

The Test will assess the functionality of submitting certain vessel entrance and clearance data elements to CBP electronically through VECS, a web-based program that allows for the automation and electronic submission of many paper-based commercial vessel entrance and clearance CBP data collections. The Test will allow vessel agents to submit the data requested on certain forms to CBP through VECS, instead of completing and submitting multiple paper forms.

Specifically, the Test will allow participants entering, or departing from, designated ports to submit electronically the entrance and clearance data that CBP currently collects primarily by paper on CBP Forms 1300, 1302, 1303, 1304, 3171, 26, 226. Many of these forms require data elements that are requested on more than one of the forms or through other related data submission requirements. In addition, several of the forms must currently be submitted on multiple occasions (*e.g.,* a new CBP Form 1300 must be submitted every time a subject vessel enters or departs a U.S. port of entry) and/or must be provided in duplicate or triplicate.

VECS will prepopulate certain vessel arrival, entrance, and clearance information that Test participants have previously submitted to CBP through other maritime requirements, such as USCG's electronic Notice of Arrival/Departure (eNOA/D) submission. *See* 33 CFR 160.201–216. VECS will then prompt participants to enter additional data elements required by the forms manually. The Test will streamline information collection by asking for data elements only once, even when a particular element is needed to satisfy the requirements of multiple different CBP forms. The participant must verify that the information that has been pre-populated into VECS is accurate, correct any inaccurate or incomplete data fields, supply any additional information necessary, and confirm and submit the data to CBP.

1. Requests for Preliminary Entry, Permits, and Special Licenses

Test participants intending to arrive at one of the participating ports may make a request for preliminary entry, permits, special licenses, or AQUA Lane privileges through VECS, instead of faxing or emailing CBP Form 3171 to the port. The submission of these requests will be made on the ''Arrival Report'' page of the VECS website. This submission will serve as the vessel's advance notice of arrival to the intended port and must be submitted to CBP at least 48 hours prior to arrival.

In the VECS platform, the vessel agent will be able to request services for lading, unlading, and overtime. Additionally, participants may request the following special permits: (1) Request to unlade cargo at other than the original port of destination; (2) Request to discharge malfunctioning container; (3) Request to re-lade cargo that was prematurely landed by previous importing vessel through error or emergency; (4) Request to lade empty containers or stevedoring equipment; (5) Request to lade cargo for return to original vessel for cargo not landed at its destination and overcarried through error or emergency; (6) Request to retain cargo on board, due to emergent situation (*i.e.,* port closure), for later return to the United States; (7) Request to retain cargo on board, due to denied entry of cargo at foreign port, for later return to the United States; (8) Request to retain cargo inaccessibly stowed upon arrival at destination, and carried

[7] The vessel agent must submit a CBP-approved electronic equivalent of the vessel's Cargo Declaration (CBP Form 1302), 24 hours before the cargo is laden aboard the vessel at the foreign port. 19 CFR 4.7(a)(2). The electronic cargo declaration information must be transmitted through the CBP Automated Manifest System (AMS), or any electronic data interchange system approved by CBP to replace the AMS system for this purpose. *See* 19 CFR 4.7(b)(2).

[8] Some vessels are exempt from CBP's clearance requirements. *See* 19 CFR 4.60 and 4.61 for a list of vessels required to obtain clearance from CBP; *see also* 19 CFR 4.81(a) for additional exceptions to the general requirement that vessels request and receive permission to depart from a U.S. port.

forward to another domestic port or ports, and returned to the port of destination; and (9) Request to retain or unlade cargo not landed at its destination and overcarried to another domestic port through error or emergency.

2. Report of Arrival

While participating in the Test, vessel agents will report a vessel's arrival to the nearest CBP facility or other location designated by the port director immediately via VECS. Thereafter, the vessel's arrival information will be available to CBP through the vessel agent's VECS submissions.

3. Entry

For vessels required to make a formal entry, participants in the Test must, within 48 hours of arrival at a designated port, submit to CBP, via VECS, the data elements required on CBP Form 1300, CBP Form 1302, CBP Form 1303, and CBP Form 1304. Test participants will first log into their Vessel Agency Portal Accounts in ACE, click the ''Launch VECS'' button, and then submit this information via the ''Entrance'' page of the VECS website. By submitting this data to CBP through VECS, participants in the Test will not need to bring the manifest to CBP at the customhouse.

For vessels subject to the requirements of 19 CFR 4.14 (addressing equipment purchases for, and repairs to, U.S. vessels), the vessel agent must also submit a declaration regarding foreign repairs through VECS, consistent with the declaration portion of CBP Form 226. If an agent declares in VECS that a U.S. vessel had undergone foreign repairs, VECS will send a notification to the Vessel Repair Unit and the vessel agent must then follow standard entry procedures.

For foreign vessels, a vessel agent may submit entry data to CBP via VECS, but the vessel agent must also bring the vessel's documents to the port director on or before the entry of the vessel at its port of first arrival for CBP validation.[9] The vessel agent may upload a valid vessel certificate into VECS using the Document Imaging System (DIS) and subsequently present the vessel's document to CBP. A CBP Officer will examine the document and verify that the copy uploaded to VECS is accurate. The verified electronic copy will be valid for entry at subsequent participating ports for one year or until the Test ends, whichever is sooner.

A vessel agent may also upload other supporting documentation into VECS through DIS for future electronic validation. If CBP needs to review any documentation in person, it may require vessel operators to travel to or from the customhouse to provide such documentation.

A CBP Officer at a designated port of arrival will use a vessel agent's VECS submission to review and process the vessel's arrival or entrance electronically. If there are no issues with the arrival or entrance data submissions, the CBP Officer will then certify the vessel's entry application electronically,[10] verify fees or taxes collected by CBP, and grant arrival or formal entry to the vessel, all through the VECS interface.

4. Manifests: Inward Foreign; Traveling; Abstract

As previously discussed, a manifest consists of CBP Forms 1300, 1302, 1303, 1304, I–418, and under some circumstances 5129. 19 CFR 4.7(a). Through VECS, numerous data elements requested on CBP Forms 1300, 1302, 1303, and 1304 will be auto-populated into the ''Manifest'' screen, using data submitted by the vessel operator to the USCG through the eNOA/D system. *See* 33 CFR 160.201–216. Through an information-sharing agreement between the two agencies, USCG sends to CBP this data soon after the vessel operator or vessel agent submits the same data to eNOA/D system. As part of this Test, participants must verify that the information that has been auto-populated into VECS is accurate, correct any inaccurate or incomplete data fields, supply any additional information necessary, and confirm and submit the data to CBP.

While the Test will be evaluating CBP's capacity to automate CBP Forms 1300, 1302, 1303, 1304, 3171, 26 and 226 through VECS, the Test will not include the automated or electronic collection of information on CBP Forms I–418 or 5129. CBP currently requires vessel operators or vessel agents to submit the data required on CBP Form I–418 electronically through the eNOA/D system. *See* 19 CFR 4.7(a). CBP intends for the CBP Form I–418 data that is electronically submitted through the eNOA/D system and then sent to CBP to instead be transmitted directly to VECS at a future date. CBP Form 5129 is generally optional for manifest purposes. The information collected on CBP Form 5129 is largely duplicative of the information collected on CBP Form 1304.

5. Clearance: Foreign Clearance and Permit to Proceed Coastwise

As discussed above, when a vessel seeks to depart from a U.S. port or place, the vessel agent must request clearance from CBP. 19 CFR 4.60. Whether seeking clearance to a foreign port or a permit to proceed coastwise the vessel agent must submit the request for departure on a CBP Form 1300 (Clearance Statement).

Test participants may request clearance from designated ports by submitting the necessary information on the ''Clearance'' page of the VECS website. Most of the data elements requested will be auto-populated because of the vessel's earlier entry submission. However, some data elements will still need to be entered manually during the Test. Participants must verify that the information that has been auto-populated into VECS is accurate, correct any inaccurate or incomplete data fields, supply any additional information necessary, and confirm and submit the data to CBP.

The requirement to file three copies of the Cargo Declaration with the port director at the U.S. port where the vessel is seeking to depart from will be waived for vessels requesting a permit to proceed coastwise that are not proceeding in ballast. *See* 19 CFR 4.81(e). If a vessel requests foreign clearance, the vessel agent must affirm that CBP Form 1302A or its electronic equivalent has been filed with the appropriate CBP Officer at the port from which clearance is being sought. Through the Test, after a CBP Officer has reviewed and approved the vessel agent's request for clearance and associated forms, the CBP Officer must notify the vessel agent through VECS that the vessel has been cleared to depart.

While Test participants will not be required to submit a paper CBP Form 1300, it is important to highlight that foreign governments may not accept the electronic foreign clearance notification that CBP will send to participants through VECS. Accordingly, Test participants seeking foreign clearance from one of the designated ports may

[9] These documents are: (1) Certificate Name; (2) Safety Construction Certificate; (3) Safety Equipment Certificate; (4) Radio Certificate; (5) Dangerous Goods Compliance; (6) Ship Security; (7) Safety Management Certificate; (8) Load Line Certificate; (9) Registry/Certificate of Nationality; (10) Tonnage Certificate; (11) Certificate of Financial Responsibility; (12) Continuous Synopsis Record; (13) Certificate of Financial Responsibility (Passenger Transportation Indemnification); (14) Certificate of Documentation; and (15) Bareboat Charter/Bridge Letter.

[10] Vessel operators will have the ability to print and save PDF copies of vessel manifest forms and will have access to the form data submitted through their VECS accounts. Vessel operators traveling coastwise to other U.S. ports of entry and who are required to make formal entry must have a traveling manifest for their future coastwise arrivals.

also submit a paper CBP Form 1300. Alternatively, during the Test, CBP will also accept submissions of CBP Form 1300 via fax or as an email attachment from participants. For fax or email submissions, CBP will respond in the same manner.

6. Report of Diversion

Throughout the Test, if a vessel that has been cleared for departure from a participating port through VECS is diverted while enroute to a U.S. port other than that from which it was cleared, the vessel agent must, as soon as reasonably possible, log into VECS and submit information regarding the diversion on the ''Report of Diversion'' page. Upon arrival, CBP will notify the vessel agent through VECS, and the vessel will be authorized to proceed to the new destination.

7. Supplemental Documents

Through VECS, participants will have the ability to upload vessel documents into the CBP Document Imaging System (DIS). After a vessel agent uploads a document into the DIS, the vessel agent must present the original document to CBP. A CBP Officer will then confirm that the original document matches the one uploaded to DIS. Once a vessel document is uploaded into DIS and verified by CBP, CBP Officers at participating ports will be able to use the electronic copies of vessel documents at the time of entrance and clearance. Afterwards, CBP will no longer need the original documents to be presented again at a participating port during the course of the Test, until the Test is completed or the document is no longer valid or associated with the vessel (for example, in the case of an expired vessel document/registry or a vessel name change). Supplemental document submission through VECS/DIS is voluntary during the Test, but participants are strongly encouraged to participate in this aspect of the Test in order to take full advantage of the automation opportunities provided by VECS.

The following documents are eligible for submission to CBP through VECS/DIS during the Test: (1) Certificate Name; (2) Safety Construction Certificate; (3) Safety Equipment Certificate; (4) Radio Certificate; (5) Dangerous Goods Compliance; (6) Ship Security; (7) Safety Management Certificate; (8) Load Line Certificate; (9) Registry/Certificate of Nationality; (10) Tonnage Certificate; (11) Certificate of Financial Responsibility; (12) Continuous Synopsis Record; (13) Certificate of Financial Responsibility (Passenger Transportation Indemnification); (14) Certificate of Documentation; and (15) Bareboat Charter/Bridge Letter.

B. Eligibility for Participation

Any commercial vessel agent or other entity responsible for the filing of vessel entry and clearance forms at designated ports of entry may participate in the Test, as long as it meets the requirements outlined below. The ports designated for participation in this Test are listed in section II.G.

All participants must have a Vessel Agency Portal Account in ACE, along with the technical capability to electronically submit data to CBP, as well as receive responses from CBP. The Vessel Agency Portal Account in ACE will serve as access for Test participants to the VECS platform. For more information and for instructions on how to request an ACE Vessel Agency Portal Account, please visit *http://www.cbp.gov/trade/automated/getting-started/using-ace-secure-data-portal*. Additionally, Test participants will be required to provide a Type 3 Bond for each VECS filing with CBP. They also must have a valid U.S. address that is not a Post Office Box.

Test participants must agree to participate in any teleconferences or meetings established by CBP, when necessary. CBP may hold these teleconferences or meetings, as needed, for Test participants to ensure that any challenges or operational or technical issues regarding the Test are properly communicated and addressed. Lastly, each Test participant will be held accountable for the accuracy of the information submitted to CBP through VECS, as the participant would be for submitting the same information to CBP through the regular vessel entry and clearance process. *See* 19 CFR 4.3a.

C. Application Process and Acceptance

Commercial vessel agents and other entities interested in participating in the Test should first request and create an ACE Vessel Agency Account via *http://www.cbp.gov/trade/automated/getting-started/using-ace-secure-data-portal*. Once an ACE Vessel Agency Account is created, CBP will contact the vessel operator or vessel agent to provide training on VECS and instructions on how to properly submit the required data. Training for VECS is expected to take one to two hours. Once the training has been completed, a CBP Officer at the designated Test port will inform the Manifest and Conveyance Security Branch of the Office of Field Operations in CBP Headquarters to allow access to VECS for the Test participant. The vessel operator or vessel agent can then begin to submit all relevant data electronically. Vessel operators or vessel agents that complete the training will also receive training materials from CBP on VECS so that they, in turn, can train other employees of their respective vessel agency.

CBP will continue to provide technical and operational assistance to Test participants throughout the Test.

D. Waiver of Certain Regulatory Requirements

For purposes of the Test, the requirement to file paper CBP Forms 3171, 1300, 1302, 1303, 1304, 26, and 226 as provided for in 19 CFR part 4, will be waived for Test participants seeking entry into or clearance out of one of the designated ports when they submit the applicable data elements from these forms into VECS, as described above. All other CBP forms required for the entrance and clearance of a vessel (*e.g.,* CBP Form 1302A: Cargo Declaration Outward with Commercial Forms; CBP Form I–418: Passenger List-Crew List; and CBP Form 5129: Crew Member's Declaration) must continue to be submitted in accordance with the procedures outlined in the CBP regulations. 19 CFR 4.7, 4.7a, and 4.7b.

As discussed in section II.A.5, while participants in this Test will not be required to submit a paper CBP Form 1300 to CBP during the Test, CBP notes that foreign governments may not accept the electronic foreign clearance notification that CBP will send out to participants through VECS. Accordingly, participants seeking foreign clearance from one of the designated ports during this Test may also submit a paper CBP Form 1300. Alternatively, during the Test, CBP will also accept submissions of CBP Form 1300 by fax or as an email attachment from Test participants. For fax or email submissions, CBP will respond in the same manner.

Participation in the Test does not affect a participant's obligations to comply with any other applicable statutory and regulatory requirements. Participants will therefore still be subject to the relevant penalties for non-compliance. Additionally, submission of data under the Test does not exempt the participant from any CBP or other U.S. Government agency program requirements. Further, participation in the Test does not exempt participants from any statutory sanctions if a violation of U.S. laws is discovered within a shipment or container presented for entrance or clearance.

E. Costs to Test Participants

Test participants are responsible for all costs incurred as a result of their participation in the Test. The costs of participation will vary, depending on participants' current operations. Prospective Test participants will incur application time burdens, along with participation costs. These could include costs to: create and maintain a VECS profile; possess a type 3 bond; maintain a valid U.S. address; and adapt to and use the Test process. Such costs may be offset by a significant reduction in the expenses associated with printing, processing, and presenting paper forms and supporting documents to CBP. Participants are encouraged to keep track of the costs incurred by their participation in the Test.

F. Benefits to Test Participants

While the benefits of the Test will vary by participant, several advantages of participating will include: the reduction in costs associated with the elimination of paper form printing, processing, and presentation; added time savings from eliminating the need to provide duplicative data on multiple forms; and greater transparency, flexibility, and communication with CBP during the vessel entrance and clearance process. The Test will also offer participants opportunities to help CBP establish, evaluate, and refine its electronic vessel entrance and clearance system and facilitate the future of implementing mandatory electronic vessel entrance and clearance information submission requirements. Participants are encouraged to keep track of the benefits experienced by their participation in the Test.

G. Designated Ports; Duration, Scope, and Evaluation of the Vessel Entrance and Clearance Forms Automation Test

1. Designated Ports

The Test will initially operate at the Port of Gulfport in Gulfport, Mississippi. CBP later intends to roll out the Test at the following designated ports: Mobile, AL; Los Angeles-Long Beach, CA; Port Hueneme, CA; Jacksonville, FL; Port Everglades, FL; Savannah, GA; Baton Rouge, LA; Gramercy, LA; Lake Charles, LA; and New Orleans, LA. CBP will notify participants of the Test expansion at the above-designated ports, as well as the designation of additional ports for Test expansion after publication of this document, via the Vessel Entrance and Clearance System page on CBP's website, available at *www.cbp.gov/trade/automated/vessel-entrance-and-clearance-system-vecs.*

2. Duration, Scope, and Evaluation of the Test

The Test will begin no earlier than December 21, 2022 and will continue for 24 months from the date the Test begins.

Throughout the Test, CBP will evaluate the results and determine if the Test should be expanded to additional ports beyond those designated above, be extended for an additional period of time, or be expanded to include additional maritime forms. CBP will take into consideration any comments or feedback that is received from Test participants. Any expansion or extension of the Test will be announced in the **Federal Register**.

CBP will begin rulemaking to require the submission of most vessel entry and clearance data to CBP electronically through VECS for all mandated vessels seeking entry into or clearance from U.S. ports after sufficient Test analysis and evaluation is conducted.

H. Misconduct Under the Test

If a Test participant fails to abide by the rules, procedures, or terms and conditions of this and all other applicable **Federal Register** notices, fails to exercise appropriate level of care in the execution of Test participant obligations, or otherwise fails to comply with all applicable laws and regulations, the participant may be suspended from participation in this Test and may also be subject to civil or criminal penalties, liquidated damages, and other applicable enforcement action. Additionally, CBP may suspend a Test participant if it determines that an unacceptable compliance risk exists.

If CBP determines that a suspension is warranted, CBP will notify the participant of this decision, set forth the facts or conduct warranting suspension, and provide the date when the suspension is effective. In the case of willful misconduct or where public health interests or safety are concerned, the suspension may be effective immediately. This decision may be appealed in writing to the Executive Assistant Commissioner, Office of Field Operations, within 15 days of notification. The appeal should address the facts or conduct charges contained in the notice and state how the participant has or will achieve compliance. CBP will notify the participant within 30 days of receipt of an appeal whether the appeal is granted or denied. If a Test participant has already been suspended, CBP will notify the participant if and when his or her participation in the Test will be reinstated.

III. Authority

This Test is being conducted in accordance with 19 CFR 101.9(a) of the CBP regulations, which authorizes the Commissioner to impose requirements different from those specified in the CBP regulations for the purposes of conducting a test program or procedure designed to evaluate the effectiveness of new technology or operational procedures regarding the processing of passengers, vessels, or merchandise.

IV. Privacy

CBP will ensure that all Privacy Act requirements and applicable policies are adhered to during the implementation of this Test.

V. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

This Test does not impose any new information collection requirements; it simply changes the modality through which currently collected information is submitted to CBP. The Vessel Entrance and Clearance Statement (CBP Form 1300) (VECS) has been approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under OMB control number 1651–0019. In addition, the following collections of information have been submitted to OMB for review and approval in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507): 1651–0025 Report of Diversion (CBP Form 26), 1651–0027 Record of Vessel Foreign Repair or Equipment (CBP Form 226), 1651–0001 Cargo Manifest/Declaration, Stow Plan, Container Status Messages and Importer Security Filing (CBP Form 1302), 1651–0018 Ships Stores Declaration (CBP Form 1303), 1651–0020 Crew Effects Declaration (CBP Form 1304), 1651–0005 Application-Permit-Special License Unlading/Lading, Overtime Services (CBP Form 3171).

Pete Flores,

Executive Assistant Commissioner, Office of Field Operations.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2022–0015]

Revision of a Currently Approved Information Collection for the State, Local Tribal and Private Sector (SLTPS) Clearance Program

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; revision of information collection request: 1670–0013.

SUMMARY: CISA is issuing a 60-day notice and request for comments to revise Information Collection Request (ICR) 1670–0013. CISA will submit the ICR to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are due January 20, 2023.

ADDRESSES: You may submit comments, identified by docket number CISA–2022–0015 through the Federal eRulemaking Portal available at *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All comments received via *https://www.regulations.gov* will be posted to the public docket at *https://www.regulations.gov,* including any personal information provided.

Do not submit comments that include trade secrets, confidential commercial or financial information, Protected Critical Infrastructure Information (PCII), or Sensitive Security Information (SSI) directly to the public regulatory docket. Contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below with questions about comments containing such protected information. CISA will not place comments containing such protected information in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. Additionally, CISA will hold them in a separate file to which the public does not have access and place a note in the public docket that CISA has received such protected materials from the commenter. If CISA receives a request to examine or copy this information, CISA will treat it as any other request under the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department's FOIA regulation found in part 5 of Title 6 of the Code of Federal Regulations (CFR).

FOR FURTHER INFORMATION CONTACT: Quintin Whitaker, 202–805–4959 *PSCP@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Partnerships between the U.S. Government and the state, local tribal and private sector at times necessitate the sharing of classified information. The State, Local, Tribal and Private Sector (SLTPS) Clearance Request Form facilitates this sharing by sponsoring security clearances for certain members of each sector based on either their membership on a Sector Coordinating Council (SCC)/association or their infrastructure protection job-related duties and their need-to-know. The SLTPS is designed to sponsor security clearances for state, local, tribal and private sector officials involved in the infrastructure protection mission. These partners are subject matter experts within specific industries and have specialized knowledge not available within the Department of Homeland Security (DHS) and other Federal Departments or Agencies. Private citizens do not receive monetary compensation for their time. CISA created this program to sponsor clearances for these individuals who are not employed by or contracted with another Federal agency (the traditional means of obtaining a clearance) and must have clearances.

The Cyber Information Sharing and Collaboration Agreement (CISCA) and Classified Critical Infrastructure Protection Program (CCIPP) nominees will also use the form in the same manner as the SLTPS. The form updates will include adding State and Local, CISCA and CCIPP to the drop-down capabilities. Type of submission will have a dropdown capability added. Subsectors will be added to some of the Sectors. A generic approving signature title will be added.

CISA collects necessary information through 1670–0013 to facilitate security clearances needed for sharing classified information with the vetted SLTPS Stakeholders. The U.S. Government is authorized to ask for this information under sections 201 and 229 of the Homeland Security Act (Pub. L. 107–296, 6 U.S.C. 121, 150), and Executive Orders 12968, 13526, 13549, 13636, and 13691 which authorize the collection of this information.

In order to begin this process of adjudicating a nominee to participate in the clearance program, federal nominators will complete the DHS Form 9014, State, Local, Tribal and Private Sector Clearance Request Form, excluding their date of birth, place of birth and social security number. The federal nominator will sign the form and have it approved by a senior-level official from the corresponding Federal Department or Agency. Before being submitted to the CISA Office of the Chief Security Officer (OCSO) SLTPS Administrator via the CISA Action Task Tracker (CATT), the nominee would have been deemed to have a CISA mission and meet the requirements and criteria as outlined in Executive Order (E.O.) 13549, the Department of Homeland Security, Classified National Security Information Program for SLTPS Implementing Directive and E.O. 13691, sec. 4(c), and 32 CFR part 117, sec. 117.22 of the National Industrial Security Program Operating Manual (NISPOM). The SLTPS Administrator will extract the application from the electronic tracking system and will capture first and last name, clearance level being requested, sector or subsector they are involved in, company, job title, city and state the company is located, work and personal email and work phone number. This information is entered into a SharePoint system in order to track the clearance process and to provide a real-time status of a nominee [and Stakeholders] to federal nominators and DHS employees who have a need to know. The OCSO Security Specialist is informed that the nominee is ready to start the clearance process and the Personally Identifiable Information (PII) is requested and input into the Electronic Questionnaires for Investigations Processing (e-QIP) system, the Office of Personnel Management's (OPM) secure portal for investigation processing. Once the data is entered into e-QIP, the nominee is provided a password and can access the system and complete the online security questionnaire.

This information is only available to Security Specialists within OCSO working on the program and is maintained in the Integrated Security Management System (ISMS), which is ''owned'' by the OCSO. The two-part PII request process helps minimize the collection of sensitive PII for only those nominees who meet the threshold and are sponsored by CISA.

Number of Respondents

The current estimate of annual respondents is 660, however, based on recent program data, CISA is revising the estimate to 550.

Estimated Time per Response

CISA is choosing to retain the estimate of 10 minutes (0.1667 hours) per response in the current information collection.

Annual Burden Hours

In the current information collection, the estimated annual burden is 110 hours. To estimate the annual burden hours for this collection, the CISA multiplied the number of annual respondents by the estimated time burden of 0.1667 hours (10 minutes), for an estimated annual burden of 91.67 hours (*i.e.,* 0.1667 hours multiplied by 550 annual respondents).

Total Annual Burden

To estimate the total annual burden, CISA multiplied the annual burden of 24,879 hours by the average loaded hourly wage rate computer and information systems managers of $110.66 [1] per hour. Therefore, the total annual burden cost for the collection is $10,144 (91.67 hours × $110.66). For the three-year period for which this collection will be approved, the total cost burden would be $6,603,456 ($2,201,152 annual cost multiplied by 3 years).

This is a revised information collection.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Analysis

Agency: Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

Title of Collection: State, Local, Tribal and Private Sector (SLTPS) Clearance Request Program.

OMB Number: 1670–0013.

Instrument: DHS Form 9014: State, Local, Tribal and Private Sector (SLTPS) Clearance Request Form.

Frequency: ''Other''.

Affected Public: Business or other for-profit.

Number of Respondents: 550 respondents.

Estimated Time per Respondent: 0.1667 hours (10 minutes).

Total Burden Hours: 91.67 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost: $10,144.

Authority: 6 U.S.C. 121, 150.

Robert Costello,

Chief Information Officer, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2022–25273 Filed 11–18–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–61]

30-Day Notice of Proposed Information Collection: Economic Development Initiative Community Project Funding Grants, OMB Control No.: 2506–0217

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 21, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.* HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 26, 2022 at 87 FR 52590.

A. Overview of Information Collection

Title of Information Collection: Economic Development Initiative Community Project Funding Grants.

OMB Approval Number: 2506–0217.

Type of Request: Revision of a currently approved collection.

Form Number: Application for Federal Assistance (SF–424); Assurances for Non-Construction Programs (SF–424B); Assurances for Construction Programs (SF–424D); Disclosure of Lobbying Activities (SF–LLL); Disclosure/Update Report (Form HUD–2880); Direct Deposit Sign-Up (SF–1199A); Federal Financial Report (SF–425); Tangible Personal Property Report (SF 428); Tangible Personal Property Report (The Final/Award Closeout form on Acquired Equipment (SF 428 B); Tangible Personal Property Report (Disposition Request) (SF 428 C); Real Property Status Report (SF–429); Real Property Status Report—(General Reporting) (SF–429 A); Real Property Status Report—(Request to Acquire, Improve, or Furnish) (SF–429 B); Real Property Status Report—(Disposition or Encumbrance Request) (SF–429 C); Application narrative; Detailed Budget Worksheet, (HUD) 424 CBW; eLOCCS Access Authorization Form (HUD 27054); Change of Address Request (HUD 27056); and Grant Reporting (DRGR).

Description of the need for the information and proposed use:

[1] The above Average Hourly Wage Rate is the May 2021 Bureau of Labor Statistics average wage for Computer and Information Systems Managers (11–3021) of $78.33 times the wage rate benefit multiplier of 1.4127 (to account for fringe benefits) equaling $110.66. The benefits multiplier is estimated by dividing total compensation of $37.24 by salaries and wages of $26.36, based on Employer Cost for Employee Compensation, September 2021, released December 16, 2021 (*https://www.bls.gov/news.release/archives/ecec_12162021.pdf*).

Information collection	Number of respondents	Frequency of response	Responses per annual	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Application for Federal Assistance (SF–424)	0	0	0	0	0	0	0
Assurances for Non-Construction Programs (SF–424B)	0	0	0	0	0	0	0
Assurances for Construction Programs (SF–424D)	0	0	0	0	0	0	0
Disclosure of Lobbying Activities (SF–LLL)	0	0	0	0	0	0	0
Disclosure/Update Report (Form HUD–2880)	1,000	1	1,000	2	2,000	$32.73	$65,460.00
Direct Deposit Sign-Up (SF–1199A)	0	0	0	0	0	0	0
Federal Financial Report (SF–425)	0	0	0	0	0	0	0
Tangible Personal Property Report (SF 428)	0	0	0	0	0	0	0
Tangible Personal Property Report (The Final/Award Closeout form on Acquired Equipment (SF 428 B)	0	0	0	0	0	0	0
Tangible Personal Property Report (Disposition Request) (SF 428 C)	0	0	0	0	0	0	0
Real Property Status Report (SF–429)	0	0	0	0	0	0	0
Real Property Status Report—(General Reporting) (SF–429 A)	0	0	0	0	0	0	0
Real Property Status Report—(Request to Acquire, Improve, or Furnish) (SF–429 B)	0	0	0	0	0	0	0
Real Property Status Report—(Disposition or Encumbrance Request) (SF–429 C)	0	0	0	0	0	0	0
Application narrative	0	0	0	0	0	0	0
Detailed Budget Worksheet, (HUD) 424 CBW	1,000	1	1,000	2	2,000	32.73	65,460
ELOCCS Access Authorization Form (HUD 27054)	0	0	0	0	0	0	0
Change of Address Request (HUD 27056)	1,000	1	1,000	.5	500	32.73	16,365.00
Grant Reporting (DRGR)	1,000	2	2,000	3	6,000	32.73	196,380.00
Total	1,000	5	5,000	7.5	37,500	32.73	1,227,375.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) If the information will be processed and used in a timely manner;

(3) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(4) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(5) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Data Officer.

[FR Doc. 2022–25260 Filed 11–18–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–60]

30-Day Notice of Proposed Information Collection: Standards for Success Reporting, OMB Control No: 2501–0034

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 21, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.* HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 20, 2022 at 87 FR 43283.

A. Overview of Information Collection

Title of Information Collection: Standards for Success Reporting.

OMB Approval Number: 2501–0034.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: This request is for the continued clearance of data collection and reporting requirements to enable the Department of Housing and Urban Development (HUD) Office of the Chief Financial Officer (OCFO) to better assess the effectiveness of discretionary-funded programs included in this information collection request (ICR). The discretionary-funded programs included in this ICR are the Multifamily Housing Service Coordinator Grant Program, the Multifamily Housing Budget-based Service Coordinator Program, and the Resident Opportunity and Self Sufficiency Service Coordinator Grant Program (ROSS).

This proposed collection, titled Standards for Success, has three key tenets which improves data collection and reporting for participating programs. First is the standardization of data collection and reporting requirements across programs which increases data comparability and utility. Second is the ability to report on measurable outcomes and aligning them with higher-level agency objectives. And third is the collection of record-level data, instead of aggregate data. Collecting de-identified data at the level of the service recipient allows for more meaningful analysis, improved management, and the ability to demonstrate the progress and achievements of the funding recipients and the programs. Standards for Success accepts data submission by direct data input through the HUD-funded GrantSolutions online data collection and reporting tool (OLDC) and by data file upload, accommodating file formats in Microsoft Excel or Extensible Markup Language (XML).

Currently across HUD, there are several reporting models in place for its discretionary programs. The reporting models provide information on a wide variety of outputs and outcomes and are based on unique data definitions and outcome measures in program-specific performance and progress reports. In Federal Fiscal Year 2013, nine program offices at HUD used six systems and 15 reporting tools to collect over 700 data elements in support of varied metrics to assess the performance of their funding recipients. The proposed data collection and reporting requirements described in this notice are designed to provide HUD programs a tested alternative to their existing disparate reporting methodologies, forms, systems, and requirements.

The lack of standardized data collection and reporting requirements imposes an increased burden on funding recipients with multiple HUD funding streams. The need for a comprehensive standardized reporting approach is underscored by reviews conducted by external oversight agencies, including the HUD Office of Inspector General (OIG) and the Government Accountability Office (GAO). These oversight agencies have questioned the soundness and comparability of data reported by HUD prior to Standards for Success. To address these issues, HUD is using its statutory and regulatory authority to improve and strengthen performance reporting for its discretionary programs, ultimately working towards a single comprehensive reporting approach.

The Secretary's statutory and regulatory authority to administer housing and urban development programs include provisions allowing for the requirement of performance reporting from funding recipients. This legal authority is codified at 42 U.S.C. 3535(r). The individual privacy of service recipients is of the highest priority. The reporting repository established at HUD to receive data submission from funding recipients will not include any personally identifiable information (PII).

Eligible entities receiving funding by HUD are expected to implement the proposed recordkeeping and reporting requirements with available HUD funds. It is important to note that affected HUD funding recipients only submit a subset of the universe of data elements presented. The participating HUD program offices determine the specific data collection and reporting requirements, which considers the type and level of service provided by the respective HUD program.

The reporting requirements in this proposed information collection better organize the data than participating programs collected in the past, standardize outcomes and performance measures, and allow program offices at HUD to select which data elements are relevant for their respective programs. Documents detailing the data elements are available for review by request from Anna P. Guido (*Anna.P.Guido@hud.gov*). All information reported to HUD will be submitted electronically. Funding recipients may use existing management information systems provided those systems collect all the required data elements and can be exported for submission to HUD. Funding recipients that sub-award funds to other organizations will need to collect the required information from their sub-recipients.

Information collected and reported will be used by funding recipients and HUD for the following purposes:

- To provide data for program evaluation;
- To provide program and performance information to recipients, general public, Congress, and other stakeholders;
- To continuously improve the quality, effectiveness, and efficiency of discretionary-funded programs;
- To provide management information for use by HUD in program administration and oversight, including the scoring of applications and the monitoring of funding-recipient participation, services, and outcomes; and
- To better measure and analyze performance information to identify successful practices to be replicated and prevent or correct problematic practices and improve outcomes in compliance with the Government Performance and Results Act (GPRA) and the GPRA Modernization Act.

The data collection and reporting requirements may expand to other HUD programs. Program implementation will be determined by the program. HUD will provide technical assistance to funding recipients throughout the implementation.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Annual Cost
HUD Participant Record-Level Report (HUD–PRL)	5,723	104	595,192	0.33	196,413.36	$20.88	$4,101,110.96

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) If the information will be processed and used in a timely manner;

(3) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(4) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(5) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Data Officer.

[FR Doc. 2022–25261 Filed 11–18–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2022–0153; FXIA16710900000–223–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by December 21, 2022.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2022–0153.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2022–0153.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2022–0153; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Endangered Species

Applicant: Smithsonian National Zoo and Conservation Biology Institute, Washington, DC; Permit No. PER0054384

The applicant requests a permit to import biological samples derived from wild black rhinoceros (*Diceros bicornis*) taken in Kruger National Park, South Africa, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Smithsonian National Zoo and Conservation Biology Institute, Washington, DC; Permit No. PER0054387

The applicant requests a permit to import biological samples derived from wild mountain tapirs (*Tapirus pinchaque*) taken in Ecuador for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Cornell University Animal Health Diagnostic Center and NYS Veterinary Diagnostic Laboratory, Ithaca, NY; Permit No. PER0042576

The applicant requests a permit to import biological samples derived from captive-bred African wild dogs (*Lycaon pictus*) from the United Kingdom, for the purpose of scientific research. This notification is for a single import. This notification covers activities to be conducted by the applicant over a 1-year period.

Applicant: USGS Western Ecological Research Center, San Diego, CA; Permit No. PER0054702

The applicant requests authorization to import blood samples derived from wild light-footed clapper rail (*Rallus longirostris levipes*) from Ensenada, Mexico, for the purpose of enhancing the propagation or survival of the species through scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: U.S. Geological Survey, National Wildlife Health Center, Madison, WI; Permit No. PER0040855

The applicant requests authorization to import biological samples for all wildlife species, both of wild-origin and captive-held or captive-bred, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Safari Wild Animal Park, Como, MS; Permit No. PER0036455

The applicant requests a permit to purchase in interstate commerce 15 captive-born juvenile Galapagos tortoises (*Chelonoidis niger*) from Jerry Fife, Laveen, AZ, for the purpose of enhancing the propagation or survival of the species. This notification is for a single interstate commerce activity.

Applicant: Russell B. Kimbrell, Mountain Home, TX; Permit No. PER0025148

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for Arabian oryx (*Oryx leucoryx*) to enhance the propagation and survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Audubon Nature Institute, New Orleans, LA; Permit No. PER0054404

The applicant requests to amend its captive-bred wildlife registration under 50 CFR 17.21(g) to add the following species, in order to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Blue throated macaw	*Ara Glaucogularis.*
Bali starling	*Leucopsar Rothschildi.*

Applicant: Safari Game Search Foundation, Winston, OR; Permit No. PER0036502

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Cheetah	*Acinonyx jubatus.*
Maned wolf	*Chrysocyon brachyurus.*
White-naped crane	*Grus vipio.*
Ring-tailed lemur	*Lemur catta.*
Red-ruffed lemur	*Varecia rubra.*
African elephant	*Loxodonta africana.*
White-cheeked gibbon.	*Nomascus leucogenys.*
Lion	*Panthera leo.*
Cotton-topped tamarin.	*Saguinus Oedipus.*
Sumatran tiger	*Panthera tigris sumatrae.*
Southern white rhinoceros.	*Ceratotherium simum simum.*

Applicant: Bernice Pauahi Bishop Museum, Honolulu, HI; Permit No. PER0054866

The applicant requests authorization to export and re-import nonliving museum specimens of endangered species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Trophy Applicants

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

Applicant: William Byron Taylor, Jr., Henderson, TX; Permit No. PER0055329

Applicant: Benjamin Caleb Wright, Montgomery, TX; Permit No. PER0056018

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *https://regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2022–25320 Filed 11–18–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[2231A2100DD/AAKC001030/A0A501010.999900; OMB Control Number 1076–0174]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Energy and Mineral Development Program Grants

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before December 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; or by email to *comments@bia.gov.* Please reference Office of Management and Budget (OMB) Control Number 1076–0174 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Winter Jojola-Talburt, Deputy Chief, Division of Energy and Mineral Development, by telephone: (720) 207–8063; or by email: *ieedgrants@bia.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 22, 2022 (87 FR 43889). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Energy Policy Act of 2005 authorizes the Secretary of the Interior to provide grants to Indian Tribes for energy development and appropriates funds for such grants on a year-to-year basis. See 25 U.S.C. 3502 (a)(2)(B). When funding is available, the Division of Energy and Mineral Development (DEMD) may solicit applications for energy development projects from Indian Tribes whose lands are held in trust or restricted fee by the federal government under the Energy and Mineral Development Program (EMDP). Indian Tribes that would like to apply for an EMDP grant must submit an application that includes certain information, and once funding is received, recipients must submit reports on how they are using the funding.

Proposed Revisions

BIA proposes to revise the information collection by modifying the progress report submission frequency from quarterly to semi-annual.

Title of Collection: Energy and Mineral Development Program Grants.

OMB Control Number: 1076–0174.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Federally recognized Indian Tribes with Indian land.

Total Estimated Number of Annual Respondents: 113.

Total Estimated Number of Annual Responses: 143.

Estimated Completion Time per Response: Varies from 3 to 100 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 8,480 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annual for applications; semi-annual for progress reports.

Total Estimated Annual Nonhour Burden Cost: $0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Steven Mullen,

Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2022–25299 Filed 11–18–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–34868; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before November 5, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 6, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public

Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before November 5, 2022. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers

KEY: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

COLORADO

Denver County

South High School, 1700 East Louisiana Ave., Denver, SG100008460

DISTRICT OF COLUMBIA

District of Columbia

Uptown Theatre, 3426 Connecticut Ave. NW, Washington, SG100008461

GEORGIA

Fulton County

Conklin, Daniel E., House, 205 Blackland Rd., Atlanta, SG100008463

LOUISIANA

Pointe Coupee Parish

New Roads Commercial Historic District, 453 East Main to 348 West Main, 107–121 Court, 124–151 New Roads, 142 St. Mary, and 112–159 Richey Sts.; Morrison Pkwy., New Roads, SG100008456

MICHIGAN

Wayne County

Higginbotham, William E., Elementary School, (Public Schools of Detroit MPS), 8730 Chippewa St., Detroit, MP100008470

MONTANA

Carbon County

Yellowstone Bighorn Research Association Camp, 118 Howell Gulch Rd., Red Lodge vicinity, SG100008457

NORTH CAROLINA

Buncombe County

Shiloh African Methodist Episcopal Zion Church, 95 Shiloh Rd., Asheville, SG100008469

Caswell County

Thompson, Nicholas and Lucretia, House, 7846 US 158 East, Leasburg, SG100008468

Forsyth County

Downtown Winston-Salem Historic District, 3rd, 4th, 5th, 6th, Spring, Spruce, Marshall, Cherry, Town Run, Trade, Liberty, and Church Sts., Winston-Salem, SG100008467

Gaston County

Stanley Mills, 357, 361 North Main, 100 West Parkwood and 111 West Church Sts., Stanley, SG100008466

Rowan County

City Motor Company, 419 South Main St., Salisbury, SG100008465

Wayne County

Goldsboro Woman's Club, 116 North William St., Goldsboro, SG100008464

NORTH DAKOTA

McLean County

Schlafmann Barn, (Common Farm and Ranch Barns in North Dakota MPS), 696 l6th Ave. NW, Turtle Lake, MP100008472

OHIO

Hamilton County

Arlington School, 607 Carthage Ave., Arlington Heights, SG100008459

OKLAHOMA

Woods County

Alva Municipal Swimming Pool and Bathhouse, 1402 Flynn St., Alva, SG100008455

WASHINGTON

Clark County

Northrop Primary School, (The Architecture of Donald J. Stewart in Washington and Oregon, 1933–1967 MPS), 611 Grand Blvd., Vancouver, MP100008454

A request for removal has been made for the following resource:

WASHINGTON

Snohomish County

Weyerhaeuser Office Building, 1710 West Marine View Dr., Everett, OT86001079

Authority: Section 60.13 of 36 CFR part 60.

Dated: November 9, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2022–25257 Filed 11–18–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1279]

Flocked Swabs, Products Containing Flocked Swabs, and Methods of Using Same; Notice of Request for Submissions on the Public Interest

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on October 28, 2022, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. On November 14, 2022, the ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3115. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United

States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1)

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a general exclusion order (''GEO'') directed to certain flocked swabs and products containing same, or, if no GEO is issued, a limited exclusion order directed to certain flocked swabs and products containing same imported, sold for importation, and/or sold after importation by respondents Wuxi NEST Biotechnology Co., Ltd., NEST Scientific Inc., and NEST Scientific USA (collectively, ''NEST''); Jiangsu Changfeng Medical Industry Co.; BioTeke Corporation (Wuxi) Co., Ltd.; Miraclean Technology Co.; and Huachenyang (Shenzhen) Technology Co., Ltd. and HCY USA, LLC (collectively, ''Respondents''); and a cease and desist order directed to the NEST Respondents. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on November 14, 2022. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on December 14, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1279'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25248 Filed 11–18–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1232 (REMAND)]

Certain Chocolate Milk Powder and Packaging Thereof; Notice of a Commission Determination To Issue a General Exclusion Order; Termination of Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a general exclusion order (''GEO'') prohibiting the unlicensed importation of chocolate milk powder and packaging thereof that infringe U.S. Trademark Registration No. 4,206,026 (''the '026 mark'') (collectively, the ''covered products''). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket system (''EDIS'') at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 1, 2020, based on a complaint filed on behalf of Meenaxi

Enterprise Inc. (''Meenaxi'') of Edison, New Jersey. 85 FR 77237–8 (Dec. 1, 2020). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain chocolate milk powder and packaging thereof by reason of infringement of the '026 mark. The Commission's notice of investigation named as respondents Bharat Bazar Inc. of Union City, California; Madras Group Inc. d/b/a Madras Groceries of Sunnyvale, California; Coconut Hill Inc. d/b/a Coconut Hill of Sunnyvale, California; Organic Food d/b/a Namaste Plaza Indian Super Market (''Organic Food'') of Fremont, California; India Cash & Carry of Sunnyvale California; New India Bazar Inc. d/b/a New India Bazar of San Jose, California; Aapka Big Bazar of Jersey City, New Jersey; Siya Cash & Carry Inc. d/b/a Siya Cash & Carry of Jersey City, New Jersey; JFK Indian Grocery LLC d/b/a D-Mart Super Market of Jersey City, New Jersey; Trinethra Indian Super Markets of Newark, California; Apna Bazar Cash & Carry Inc. d/b/a Apna Bazar Cash & Carry of Edison, New Jersey; Subzi Mandi Cash & Carry Inc. d/b/a Subzi Mandi Cash & Carry of Piscataway, New Jersey; Subhlaxmi Grocers of Piscataway, New Jersey; Patidar Cash & Carry Inc. d/b/a Patidar Cash & Carry of South Plainfield, New Jersey; Keemat Grocers of Sugarland, Texas; KGF World Food Warehouse Inc. d/b/a World Food Mart of Houston, Texas; Telfair Spices of Sugarland Texas; Indian Groceries and Spices Inc. d/b/a iShopIndia.com of Milwaukee, Wisconsin; Rani Foods LP d/b/a Rani's World Foods of Houston, Texas; Tathastu Trading LLC of South Plainfield, New Jersey; and Choice Trading LLC of Guttenberg, New Jersey. *Id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation.

On February 10, 2021, the former chief administrative law judge (''CALJ'') issued an initial determination (''ID'') (Order No. 6) finding all respondents in default. Order No. 6 (Feb. 10, 2021), *unreviewed by* Comm'n Notice (Mar. 2, 2021).

On May 24, 2021, Meenaxi moved for a summary determination of violation by all of the respondents, each of whom had previously been found in default. On June 16, 2021, OUII responded in support of the motion. On December 1, 2021, the former CALJ granted the motion as an ID (Order No. 15). No petitions for review of the ID were filed. The ID, however, noted discrepancies with respect to respondent Organic Food, calling into question whether that respondent was ever properly served with the complaint and notice of investigation and with the CALJ's order to show cause why the respondents should not be found in default, Order No. 5 (Jan. 13, 2021). *See* Order No. 15 at 1 n.1. The Commission determined *sua sponte* to review Order No. 15, and ordered reconsideration of Order No. 6 as to Organic Food and/or any other respondents who may not have been properly served with documents in the underlying investigation. Notice at 3 (Jan 18, 2022). The Commission remanded the investigation to an ALJ for further proceedings. *Id.*

On remand, the CALJ issued Order No. 18, granting Meenaxi's unopposed motion for leave to amend the complaint and notice of investigation to (i) substitute Organic Food with proposed respondent Organic Ingredients Inc. d/b/a Namaste Plaza Indian Super Market (''Organic Ingredients'') of San Diego, California; (ii) correct the address of respondent New India Bazar Inc. d/b/a New India Bazar (''New India'') of San Jose, California; (iii) correct the address of respondent Bharat Bazar Inc. (''Bharat Bazar'') of Union City, California; and (iv) supplement the complaint with Exhibits 9–a, 9–b, and 9–c, concerning Organic Food and/or Organic Ingredients. Order No. 18 at 1–5 (Mar. 11, 2022), *unreviewed by* Comm'n Notice, 87 FR 22940 (Apr. 18, 2020). Meenaxi demonstrated that Bharat Bazar had been actually served with all of the documents in the investigation (prior to remand) despite incorrectly spelling Bharat Bazar's address as being on ''Niled Road'' instead of ''Niles Road.'' Order No. 18 at 4.

The CALJ conducted remand proceedings as to Organic Ingredients and New India, first ordering them to respond to the amended complaint and notice of investigation, and then ordering them to respond to an order to show cause why they should not be found in default. *See* Order No. 19 (Mar. 11, 2022); Order No. 21 at 3 (May 3, 2022). On May 19, 2022, the CALJ issued an ID finding Organic Ingredients and New India in default. Order No. 23 (May 19, 2022), *unreviewed by* Comm'n Notice (June 14, 2022).

On June 15, 2022, Meenaxi filed a second motion for summary determination of violation of section 337 as to the defaulting respondents, and requested the issuance of a GEO. On July 6, 2022, OUII responded in support of Meenaxi's motion.

On August 3, 2022, the CALJ issued a remand ID (''RID'') (Order No. 27) granting Meenaxi's motion. Order No. 27 (Aug. 3, 2022), *unreviewed by* Comm'n Notice (Sept. 19, 2022). The RID adopted substantially all of the findings of Order No. 15. The CALJ concurrently issued a recommended determination (''RD'') on the issues of remedy and bonding. The RD recommended the issuance of a GEO and setting the bond during the period of Presidential review in the amount of one hundred percent (100%) of the entered value of the covered products.

Accordingly, the Commission requested written submissions on the issues of remedy, the public interest, and bonding and the RD's recommendation as to issuance of a GEO and bonding. 87 FR 58130–1 (Sept. 23, 2022). On October 3 and 12, 2022, respectively, OUII and Meenaxi submitted briefing responsive to the Commission's request. No other submissions were received.

Having reviewed the record in the investigation, including the written submissions from Meenaxi and OUII, the Commission has made its determination on the issues of remedy, the public interest, and bonding. As all statutory requirements of this subsection are met here, the Commission has determined that the appropriate remedy is a GEO directed to the covered products pursuant to section 337(g)(2), 19 U.S.C. 1337(g)(2). The Commission has further determined that the public interest factors enumerated in Section 337(d) (19 U.S.C. 1337(d)) do not preclude issuance of the GEO. Accordingly, the Commission has determined to issue a GEO prohibiting the unlicensed entry of chocolate milk powder and components thereof that infringe the '026 mark.

Finally, the Commission has determined that a bond in the amount of one hundred percent (100%) of the entered value of the covered products is required during the period of Presidential review (19 U.S.C. 1337(j)). The Commission's order was delivered to the President and to the United States Trade Representative on the day of its issuance.

The Commission voted to approve this determination on November 15, 2022.

The authority for the Commission's determinations is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210.

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25250 Filed 11–18–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1315 (Review)]

Ferrovanadium From South Korea

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on ferrovanadium from South Korea would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on April 1, 2022 (87 FR 19129) and determined on July 5, 2022 that it would conduct an expedited review (87 FR 63090, October 18, 2022).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on November 15, 2022. The views of the Commission are contained in USITC Publication 5384 (November 2022), entitled *Ferrovanadium from South Korea: Investigation No. 731–TA–1315 (Review).*

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25249 Filed 11–18–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–563 and 731–TA–1331–1333 (Review)]

Finished Carbon Steel Flanges From India, Italy, and Spain

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing duty order on finished carbon steel flanges from India and the antidumping duty orders on finished carbon steel flanges from India, Italy, and Spain would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on May 2, 2022 (87 FR 25662) and determined on August 5, 2022 that it would conduct expedited reviews (87 FR 63798, October 20, 2022).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on November 15, 2022. The views of the Commission are contained in USITC Publication 5385 (November 2022), entitled *Finished Carbon Steel Flanges from India, Italy, and Spain: Investigation Nos. 701–TA–563 and 731–TA–1331–1333 (Review).*

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–25247 Filed 11–18–22; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

Notice of Task Force on Research on Violence Against American Indian and Alaska Native Women Meeting

AGENCY: Office on Violence Against Women, United States Department of Justice.

ACTION: Notice of meeting.

SUMMARY: The Office on Violence Against Women (OVW), U.S. Department of Justice has scheduled a meeting of the Task Force on Research on Violence Against American Indian and Alaska Native Women (hereinafter ''the Task Force'').

DATES: The meeting will take place on December 13, 2022, from 1 p.m. to 5 p.m. (Eastern Standard Time).

ADDRESSES: This meeting will be convened virtually.

FOR FURTHER INFORMATION CONTACT: Visit the OVW website at *https://www.justice.gov/ovw/section-904-task-force* or contact Sherriann Moore, Deputy Director of Tribal Affairs, Office on Violence Against Women, United States Department of Justice, at (202) 616–0039 or *ovw.tribalaffairs@usdoj.gov*.

SUPPLEMENTARY INFORMATION: Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. Title IX of the Violence Against Women Act of 2005 (VAWA 2005), as amended, required the Attorney General to establish a task force to assist the National Institute of Justice (NIJ) in developing and implementing a program of research on violence against American Indian and Alaska Native women, including domestic violence, dating violence, sexual assault, stalking, sex trafficking, and murder. The program will evaluate the effectiveness of the federal, state, tribal, and local response to violence against Indian women and propose recommendations to improve the government response. The Attorney General, acting through the Director of the Office on Violence Against Women, established the Task Force on March 31, 2008, and the charter has been renewed every two years since then.

More information on the Task Force may be found at *https://www.justice.gov/ovw/section-904-task-force* and about the NIJ program of research at: *https://nij.ojp.gov/topics/articles/violence-against-american-indian-and-alaska-native-women-program-research*.

This meeting will include the introduction of Task Force members, an update on NIJ's research program, and facilitated Task Force discussion on research findings and recommendations. In addition, the Task Force is also welcoming public oral comment at this meeting and has reserved 30 minutes for this. The meeting will take place on December 13, 2022, from 1 p.m. to 5 p.m. Time will be reserved for public comment from 4:15 p.m. to 4:45 p.m. See the section below for information on reserving time for public comment.

Access: The meeting will be available online via a video conferencing platform. Members of the public who wish to participate must register in advance of the meeting online, no later than December 7, 2022. Details about registration can be found on the OVW website: *https://www.justice.gov/ovw/section-904-task-force*. Should issues arise with online or email registration, the public should contact Sherriann C. Moore, Deputy Director of Tribal Affairs, Office on Violence Against Women, at (202) 616–0039 or *ovw.tribalaffairs@usdoj.gov*.

Written Comments: Interested parties are invited to submit written comments by December 7, 2022, to Sherriann C.

Moore, Deputy Director of Tribal Affairs, Office on Violence Against Women, at (202) 616–0039 or *ovw.tribalaffairs@usdoj.gov*.

Public Comment: Persons interested in participating during the public comment period of the meeting are requested to reserve time on the agenda by contacting Sherriann C. Moore, Deputy Director of Tribal Affairs, Office on Violence Against Women, at (202) 616–0039 or *ovw.tribalaffairs@usdoj.gov*. Requests must include the participant's name, the organization represented, if appropriate, and a brief description of the subject of the comments. Each participant will be permitted approximately 3 to 5 minutes to present comments, depending on the number of individuals reserving time on the agenda. Participants are also encouraged to submit written copies of their comments at the meeting. Comments that are submitted to Sherriann C. Moore, Deputy Director of Tribal Affairs, Office on Violence Against Women, at (202) 616–0039 or *ovw.tribalaffairs@usdoj.gov* before December 7, 2022, will be circulated to Task Force members prior to the meeting.

Given the expected number of individuals interested in presenting comments at the meeting, reservations should be made as soon as possible.

Allison Randall,

Acting Director, Office on Violence Against Women.

[FR Doc. 2022–25280 Filed 11–18–22; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

Supply and Service Program; Proposed Approval of Information Collection Requirements; Comment Request

ACTION: Notice.

SUMMARY: The U.S. Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA). The program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Federal Contract Compliance Programs (OFCCP) is soliciting comments concerning its proposal to obtain approval from the Office of Management and Budget (OMB) to renew the information collection that implements OFCCP's supply and service program jurisdiction.

A copy of the proposed information collection request can be obtained by contacting the office listed below in the **FOR FURTHER INFORMATION CONTACT** section of this notice or by accessing it at *www.regulations.gov.*

DATES: Written comments must be submitted to the office listed in the addresses section below on or before January 20, 2023.

ADDRESSES: You may submit comments by any of the following methods:

Electronic comments: The federal eRulemaking portal at *www.regulations.gov.* Follow the instructions found on that website for submitting comments.

Mail, Hand Delivery, Courier: Addressed to Tina T. Williams, Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue NW, Room C–3325, Washington, DC 20210.

Instructions: Please submit one copy of your comments by only one method. For faster submission, we encourage commenters to transmit their comment electronically via the *www.regulations.gov* website. Comments that are mailed to the address provided above must be postmarked before the close of the comment period. All submissions must include OFCCP's name for identification. Comments submitted in response to the notice, including any personal information provided, become a matter of public record and will be posted on *www.regulations.gov.* Comments will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Tina T. Williams, Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue NW, Washington, DC 20210. Telephone: (202) 693–0103 (voice) (this is not a toll-free number). Copies of this notice may be obtained in alternative formats (large print, braille, audio recording) upon request by calling the number listed above.

SUPPLEMENTARY INFORMATION:

I. Background: OFCCP administers and enforces the three equal employment opportunity authorities listed below.

- Executive Order 11246, as amended (E.O. 11246)
- Section 503 of the Rehabilitation Act of 1973, as amended (Section 503)
- Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (VEVRAA)

These authorities prohibit employment discrimination by covered federal contractors and subcontractors and require that they take affirmative action to provide equal employment opportunity regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or status as a protected veteran. Additionally, federal contractors and subcontractors are prohibited from discriminating against applicants and employees for inquiring about, discussing, or disclosing information about their pay or, in certain circumstances, the pay of their co-workers.

E.O. 11246 applies to federal contractors and subcontractors and to federally assisted construction contractors holding a government contract in excess of $10,000, or government contracts that have, or can reasonably be expected to have, an aggregate total value exceeding $10,000 in a 12-month period. E.O. 11246 also applies to government bills of lading, depositories of federal funds in any amount, and financial institutions that are issuing and paying agents for U.S. savings bonds.

Section 503 prohibits employment discrimination against applicants and employees because of physical or mental disability and requires contractors and subcontractors to take affirmative action to employ and advance in employment qualified individuals with disabilities. Section 503 applies to federal contractors and subcontractors with contracts in excess of $15,000.[1] VEVRAA requires contractors to take affirmative action to employ, and advance in employment, qualified protected veterans. VEVRAA applies to federal contractors and subcontractors with contracts of $150,000 or more.[2]

[1] Effective October 1, 2010, the coverage threshold under Section 503 increased from $10,000 to $15,000, in accordance with the inflationary adjustment requirements in 41 U.S.C. 1908. *See Federal Acquisition Regulation; Inflation Adjustment of Acquisition-Related Thresholds,* 75 FR 53129 (Aug. 30, 2010).

[2] Effective October 1, 2015, the coverage threshold under VEVRAA increased from $100,000

Continued

This proposed information collection request outlines the legal authority, procedures, burden, and cost associated with developing and maintaining affirmative action programs and responding to the compliance review Scheduling Letter.

II. Review Focus: OFCCP is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the compliance assistance functions of the agency that support the agency's compliance mission, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected;
- Provide feedback on the agency's proposal to require post-secondary institutions and contractors with campus-like settings to submit all AAPs and Itemized Listing information for the entire campus in the city where OFCCP schedules the compliance evaluation;
- Provide feedback on the agency's proposed definitions of ''competitive promotion'' and ''non-competitive promotion'' and any other necessary guidance;
- Provide feedback on the potential use of OFCCP's Contractor Portal as a method for contractors to utilize when uploading and submitting their Itemized Listing data in response to a Scheduling Letter; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions: OFCCP seeks approval of this information collection in order to carry out and enhance its responsibilities to enforce the nondiscrimination and affirmative action provisions of the three legal authorities it administers.

Type of Review: Regular.

Agency: Office of Federal Contract Compliance Programs.

Title: Supply and Service Program.

OMB Number: 1250–0003.

Agency Number: None.

Affected Public: Business or other for-profit entities.

Total Respondents: 91,913 contractor establishments complying with recordkeeping and third-party disclosure obligations; 1,258 contractor establishments complying with reporting obligations.

Total Annual Responses: 91,913 contractor establishments complying with recordkeeping and third-party disclosure obligations; 1,258 contractor establishments complying with reporting obligations.

Average Time per Response: 97.6 hours for complying with recordkeeping and third-party disclosure obligations; 39 hours for complying with reporting obligations.

Estimated Total Burden Hours: 9,022,416 hours.

Frequency: Annually for recordkeeping; upon selection for reporting.

Total Monetized Burden Cost: $677,583,442.

Total Burden Cost (costs to federal government): $2,115,855.

Total Burden Cost (operating/maintenance): $33,658.

Tina T. Williams,

Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs.

[FR Doc. 2022–25311 Filed 11–18–22; 8:45 am]

BILLING CODE 4510–CM–P

to $150,000, in accordance with the inflationary adjustment requirements in 41 U.S.C. 1908. *See Federal Acquisition Regulation; Inflation Adjustment of Acquisition-Related Thresholds,* 80 FR 38293 (July 2, 2015).

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on External Engagement hereby gives notice of a change in a previously scheduled meeting for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 87 FR 52419, August 25, 2022.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Monday, November 28, 2022, from 5:00–5:30 p.m. EDT.

CHANGES IN THE MEETING: The meeting will occur on Monday, November 28, but at 1:00–1:30 p.m. EST. The matter to be considered remains the same.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000.

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–25366 Filed 11–17–22; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 21, 28, December 5, 12, 19, 26, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Tyesha.Bush@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of November 21, 2022

There are no meetings scheduled for the week of November 21, 2022.

Week of November 28, 2022—Tentative

There are no meetings scheduled for the week of November 28, 2022.

Week of December 5, 2022—Tentative

Tuesday, December 6, 2022

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting). (Contact: Celimar Valentin-Rodriguez: 301–415–7124)

Additional Information: The meeting will be held in the Commissioners'

Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Thursday, December 8, 2022

9:00 a.m. Overview of Advanced Reactor Fuel Activities (Public Meeting). (Contact: Stephanie Devlin-Gill, 301–415–5301)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of December 12, 2022—Tentative

Wednesday, December 14, 2022

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting). (Contact: Larniece McKoy Moore: 301–415–1942)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of December 19, 2022—Tentative

There are no meetings scheduled for the week of December 19, 2022.

Week of December 26, 2022—Tentative

There are no meetings scheduled for the week of December 26, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: November 16, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–25332 Filed 11–17–22; 11:15 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

International Product Change—Global Reseller Expedited Package Contracts

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission for classification changes to the Global Reseller Expedited Package Contracts subsection in the Competitive Product List in the Mail Classification Schedule.

DATES: *Effective date:* November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, 202–268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 CFR 3040.180, on November 10, 2022, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service for Classification Changes Concerning Global Reseller Expedited Package Contracts* to remove references to Priority Mail International Regional Rate Boxes from the Global Reseller Expedited Package Contracts subsection in the Mail Classification Schedule. Documents are available at *www.prc.gov,* Docket No. MC2023–46.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–25297 Filed 11–18–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—Removal of Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rates Boxes Contracts

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to remove Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rate Boxes (PMI RRB) Contracts from the Competitive Product List in the Mail Classification Schedule.

DATES: *Applicable date:* November 10, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, 202–268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 39 CFR 3040.130 *et seq.,* on November 10, 2022, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Remove Priority Mail International Regional Rate Boxes—Non-Published Rates and Priority Mail International Regional Rate Boxes (PMI RRB) Contracts from the Competitive Product List* in the Mail Classification Schedule. Documents are available at *www.prc.gov,* Docket No. MC2023–45.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–25293 Filed 11–18–22; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96313; File No. SR–CboeBZX–2022–056]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 and a Related Definition in Rule 16.1

November 15, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2022, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX Options'') proposes to amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 and a related definition in Rule 16.1. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05. Specifically, the Exchange proposes to amend the Short Term Option Series Program to: (1) limit the number of Short Term Option Expiration Dates for options on SPDR S&P 500 ETF Trust (SPY), the INVESCO QQQ TrustSM, Series 1 (QQQ), and iShares Russell 2000 ETF (IWM) from five to two expirations for Monday and Wednesday expirations; and (2) expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the same proposed limitation of two expirations.

The Exchange also proposes to amend the definition of Short Term Option Series in Rule 16.1.

Curtail Short Term Option Expiration Dates

Currently, after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays on which monthly options series or Quarterly Options Series expire (''Short Term Option Expiration Dates''). The Exchange may have no more than a total of five Short Term Option Expiration Dates not including any Monday or Wednesday SPY, QQQ, and IWM Expirations. Further, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on a Friday, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

Today, with respect to Wednesday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Tuesday or Wednesday that is a business day series of options on SPY, QQQ, and IWM to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire (''Wednesday SPY Expirations,'' ''Wednesday QQQ Expirations,'' and ''Wednesday IWM Expirations''). With respect to Monday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Friday or Monday that is a business day series of options on the SPY, QQQ, or IWM to expire on any Monday of the month that is a business day and is not a Monday in which Quarterly Options Series expire (''Monday SPY Expirations,'' ''Monday QQQ Expirations,'' and ''Monday IWM Expirations''), provided that Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration. The Exchange may list up to five consecutive Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and five consecutive Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations at one time; the Exchange may have no more than a total of five each of Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and a total of five each of Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations. Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations will be subject to the provisions of Rule 19.6, Interpretation and Policy .05.

Proposal

At this time, the Exchange proposes to curtail the number of Short Term Option Expiration Dates from five to two [5] for SPY, QQQ and IWM for Monday and Wednesday Expirations, as well as the proposed Tuesday and Thursday Expirations in SPY and QQQ (''Short Term Option Daily Expirations''). The Exchange proposes to create a new category of Short Term Option Expirations Dates called ''Short Term Option Daily Expirations,'' which will only permit two Short Term Option Expiration Dates for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. The Exchange proposes to include a table, labelled ''Table 1'', within Rule 19.6, Interpretation and Policy .05(h), which specifies each symbol that qualifies as a Short Term Option Daily Expiration. The table would note the number of expirations for each symbol as well as expiration days. The Exchange proposes to include Monday and Wednesday expirations for SPY, QQQ, and IWM and Tuesday and Thursday expirations for SPY and QQQ and list the number of expirations as ''2'' for these symbols. The Exchange's proposal to permit Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program is explained below in more detail. In the event Short Term Option Daily Expirations expire on the same day in the same class as a monthly options series or a Quarterly Options Series, the Exchange would skip that week's listing and instead list the following week; the two weeks of Short Term Option Expiration Dates would therefore not be consecutive. Specifically, the Exchange proposes to state within Rule 19.6, Interpretation and Policy .05(h):

> In addition to the above, the Exchange may open for trading series of options on the symbols provided in Table 1 below that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly Options Series expire (''Short Term Option Daily Expirations''). The Exchange may have no more than a total of two Short Term Option Daily Expirations for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. Short Term Option Daily Expirations would be subject to this Interpretation and Policy .05

SPY, QQQ, and IWM Friday expirations and other option symbols expiring on a Friday that are not noted in Table 1 will continue to have a total of five Short Term Option Expiration Dates provided those Friday expirations are not Fridays on which monthly options series or Quarterly Options Series expire (''Friday Short Term Option Expiration Dates''). These expirations would be referred to as ''Short Term Option Weekly

[5] The Exchange proposes to list the two front months for Short Term Option Daily Expirations.

Expirations'' to distinguish them from the proposed expirations that would be subject to Short Term Option Daily Expirations. The Exchange proposes to add rule text to Rule 19.6, Interpretation and Policy .05(h) which states that Monday Short Term Option Expiration Dates, Tuesday Short Term Option Expiration Dates, Wednesday Short Term Option Expiration Dates, and Thursday Short Term Option Expiration Dates, together with Friday Short Term Option Expiration Dates, are collectively ''Short Term Option Expiration Dates.''[6]

Tuesday and Thursday Expirations

At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two consecutive Tuesday and Thursday ''Tuesday Short Term Option Daily Expirations'' and ''Thursday Short Term Option Daily Expirations'' each for SPY and QQQ at one time. Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 19.6, Interpretation and Policy .05.

A Short Term Option Series means a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday, or Friday that is a business day and that expires on the Monday, Wednesday, or Friday of the following business week that is a business day, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

The Exchange proposes to amend this definition in Rule 16.1 to accommodate the listing of options series that expire on Tuesdays and Thursdays. Specifically, the Exchange proposes to add Tuesday and Thursdays to the permitted expiration days, which currently include Monday, Wednesday, and Friday, that it may open for trading.

The Exchange also proposes corresponding changes within Rule 19.6, Interpretation and Policy .05, which sets forth the requirements for SPY and QQQ options that are listed pursuant to the Short Term Option Series Program as Short Term Option Daily Expirations, to accommodate the listing of options series that expire on Tuesdays and Thursdays. Similar to Monday and Wednesday SPY, QQQ, and IWM Short Term Option Daily Expirations within Rule 19.6, Interpretation and Policy .05, the Exchange proposes that it may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').

Likewise, the Exchange proposes that it may open for trading on any Wednesday or Thursday that is a business day series of options on symbols provided in Table 1 that expire at the close of business on each of the next two Thursdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Thursday Short Term Option Expiration Date'').

In the event that options on SPY and QQQ expire on a Tuesday or Thursday and that Tuesday or Thursday is the same day that a monthly option series or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. Today, Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a Quarterly Options Series. Currently, there is no rule text provision that states that Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a monthly option series. Practically speaking, Monday and Wednesday Expirations in SPY, QQQ, and IWM would not expire on the same day as a monthly expiration.

The interval between strike prices for the proposed Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will be the same as those for the current Short Term Option Series for Monday, Wednesday, and Friday expirations applicable to the Short Term Option Series Program.[7] Specifically, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will have a $0.50 strike interval minimum.[8] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to proposed Rule 19.6, Interpretation and Policy .05, with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series will expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[9] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[10] This thirty (30) series restriction would apply to Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY and QQQ options expiring on Tuesdays and Thursdays with a limit of two Tuesday Short Term Daily Expirations and two Thursday Short Term Daily Expirations.

Finally, the Exchange is amending Rule 19.6, Interpretation and Policy .05(b) to conform the rule text to the usage of the term ''Short Term Option Daily Expirations.'' Today, with the exception of Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. With respect to monthly option series, Short Term Option Daily Expirations will be permitted to expire in the same week in which monthly option series in the same class expire. Not listing Short Term Option Daily Expirations for one

[6] Defining the term ''Short Term Option Expiration Dates'' will make clear that this term includes expiration dates for each day Short Term Options are listed.

[7] *See* Rule 19.6, Interpretation and Policy .05(e)

[8] *See id.*

[9] *See* Rule 19.6, Interpretation and Policy .05(a).

[10] *See id.*

week every month because there was a monthly on that same class on the Friday of that week would create investor confusion. Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[11] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly Options Series expire. The Exchange believes that it is reasonable to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below tables sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2020 and 2022 in the options industry.[12] The weekly strikes decreased from 24% to 19% in these two years. The Exchange notes that during this timeframe, all options exchanges mitigated weekly strike intervals.

NUMBER OF STRIKES—2020

Expiration	Percent of total series
Monthly	59
Weekly	24
LEAP	16
Quarterly	1

NUMBER OF STRIKES—2022

Expiration	Percent of total series
Monthly	64
Weekly	19
LEAP	17
Quarterly	0

By limiting the number of Short Term Option Daily Expirations for SPY, QQQ, and IWM to two expirations for Monday and Wednesday expirations, and expanding the Short Term Option Series Program to permit Tuesday and Thursday expirations for SPY and QQQ, the Exchange anticipates that it would overall reduce the number of weekly expiration dates. With respect to SPY, the reduction from five to two expirations will reduce 11.80% of strikes on SPY with Monday and Wednesday expirations. With respect to QQQ, the reduction from five to two expirations will reduce 12.86% of strikes on QQQ with Monday and Wednesday expirations. With respect to IWM, the reduction from five to two expirations will reduce 11.86% of strikes on IWM with Monday and Wednesday expirations. Additionally, expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in SPY and QQQ will account for the addition of 7.86% of strikes in SPY and the addition of 8.57% of strikes in QQQ. Therefore, the total net reduction would be 3.94% for SPY and 4.29% for QQQ.[13] The overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange and should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[14] Also, the Exchange's proposal curtails the number of expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools because all days of the week would be available to permit Trading Permit Holders to tailor their investment and hedging needs more effectively in SPY and QQQ.

TOTAL VOLUME—2022

[Through August 18]

Expiration	Percent of total series
Monthly	39
Weekly	48
LEAP	12
Quarterly	1

Weeklies comprise 48% of the total volume of options listings.[15] The Exchange believes that inner weeklies represent high volume as compared to outer weeklies and would be more attractive to market participants. Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the introduction of SPY and QQQ Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

Implementation

The Exchange proposes to implement this rule change on November 14, 2022. The Exchange will issue an Exchange Notice to notify Trading Permit Holders of the implementation date. Notwithstanding this implementation, Monday and Wednesday Expirations in SPY, QQQ, and IWM that were listed prior to the date of implementation will continue to be listed on the Exchange until those options expire pursuant to

[11] While the Exchange proposes to add rule text within Rule 19.6, Interpretation and Policy .05 with respect to Monday Expirations, Tuesday Expirations, and Wednesdays Expirations stating that those expirations would not expire on business days that are business days on which monthly options series expire, practically speaking this would not occur.

[12] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 16 options markets up to August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18).

[13] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 16 options markets as of August 18, 2022. *See id.*

[14] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[15] This table sets forth industry volume. Weeklies comprise 48% of volume while only being 19% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 16 options markets as of August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18)

current Short Term Option Series rules within Rule 19.6, Interpretation and Policy .05.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [18] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposal is consistent with the Act as the overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange. This reduction would remove impediments to and perfect the mechanism of a free and open market by encouraging Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[19] Also, the Exchange's proposal curtails the number of Monday, Tuesday, Wednesday, and Thursday expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ, and IWM Monday and Wednesday Expirations (proposed to be SPY, QQQ and IWM Monday and Wednesday Short Term Daily Expirations), the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations is consistent with the Act as it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations (proposed to be SPY and QQQ Tuesday and Thursday Short Term Daily Expirations) will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in SPY and QQQ options, thus allowing them to better manage their risk exposure.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should create greater trading and hedging opportunities and flexibility and will provide customers with the ability to tailor their investment objectives more effectively. The Exchange currently lists Monday and Wednesday SPY, QQQ, and IWM Expirations (proposed to be SPY, QQQ, and IWM Monday and Wednesday Short Term Daily Expirations).[20]

Today, with the exception of Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange believes that permitting Short Term Option Daily Expirations to expire in the same week that standard monthly options expire on Fridays is consistent with Act. Not listing Short Term Option Daily Expirations for one week every month because there was a monthly on that same class on the Friday of that week would create investor confusion.

Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire. Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. The Exchange believes that it is consistent with the Act to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire similar to Monday and Wednesday SPY, QQQ, and IWM Expirations.

There are no material differences in the treatment of Wednesday SPY and QQQ expirations for Short Term Option Series as compared to the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations. Given the similarities between Wednesday SPY, QQQ and IWM Expirations and the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, the Exchange believes that applying the provisions in Rule 19.6, Interpretation and Policy .05 that currently apply to Wednesday SPY, QQQ and IWM Expirations to Tuesday and Thursday SPY and QQQ Short Term Daily Expirations is justified.

The Exchange further represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations.

Finally, the Exchange notes the proposed rule change is substantively

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *Id.*

[19] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[20] *See* Rule 19.6, Interpretation and Policy .05.

the same as a rule change proposed by ISE, which the Commission recently approved.[21]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal will provide an overall reduction in the number of Short Term Option Expirations to be listed on the Exchange. The Exchange believes this reduction will not impose an undue burden on competition, rather, it should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[22] Also, the Exchange's proposal curtails the number of weekly expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of weekly expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the Exchange believes the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange does not believe the proposal will impose any burden on intermarket competition, as nothing prevents the other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday SPY and QQQ expirations is not a novel proposal, as Wednesday SPY, QQQ and IWM Expirations are currently listed on the Exchange.[23] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[24] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[25] and Rule 19b–4(f)(6) thereunder.[26] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[27] and subparagraph (f)(6) of Rule 19b–4 thereunder.[28] The Commission notes that it recently approved Nasdaq ISE's substantially similar proposal.[29] The Exchange has stated that waiver of the 30-day operative delay will allow the Exchange to implement the proposal at the same time as competitor exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[30]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR-CboeBZX–2022–056 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2022–056. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal

[21] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[22] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[23] *See* Rule 19.6, Interpretation and Policy .05.

[24] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[25] 15 U.S.C. 78s(b)(3)(A)(iii).

[26] 17 CFR 240.19b–4(f)(6).

[27] 15 U.S.C. 78s(b)(3)(A)(iii).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[29] *See* Securities Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[30] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2022–056 and should be submitted on or before December 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25232 Filed 11–18–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96315; File No. SR–CBOE–2022–059]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Option Series Program in Rule 4.5(d)

November 15, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the Short Term Option Series Program in Rule 4.5(d). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Rule 4.5(d). Specifically, the Exchange proposes to amend the Short Term Option Series Program to: (1) limit the number of Short Term Option Expiration Dates for options on SPDR S&P 500 ETF Trust (SPY), the INVESCO QQQ TrustSM, Series 1 (QQQ), and iShares Russell 2000 ETF (IWM) from five to two expirations for Monday and Wednesday expirations; and (2) expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the same proposed limitation of two expirations.

Curtail Short Term Option Expiration Dates

Currently, after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays on which monthly options series or Quarterly Options Series expire (''Short Term Option Expiration Dates''). The Exchange may have no more than a total of five Short Term Option Expiration Dates not including any Monday or Wednesday SPY, QQQ, and IWM Expirations. Further, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on a Friday, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

Today, with respect to Wednesday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Tuesday or Wednesday that is a business day series of options on SPY, QQQ, and IWM to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire (''Wednesday SPY Expirations,'' ''Wednesday QQQ Expirations,'' and ''Wednesday IWM Expirations''). With respect to Monday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Friday or Monday that is a business day series of options on the SPY, QQQ, or IWM to expire on any Monday of the month that is a business day and is not a Monday in which Quarterly Options Series expire (''Monday SPY Expirations,'' ''Monday QQQ Expirations,'' and ''Monday IWM Expirations''), provided that Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration. The Exchange may list up to five consecutive Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and five consecutive Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations at one time; the Exchange may have no more than a total of five each of Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and a total of five each of Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations. Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations will be subject to the provisions of Rule 4.5(d).

Proposal

At this time, the Exchange proposes to curtail the number of Short Term Option Expiration Dates from five to two[5] for SPY, QQQ and IWM for Monday and Wednesday Expirations, as well as the proposed Tuesday and

[31] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange proposes to list the two front months for Short Term Option Daily Expirations.

Thursday Expirations in SPY and QQQ (''Short Term Option Daily Expirations''). The Exchange proposes to create a new category of Short Term Option Expirations Dates called ''Short Term Option Daily Expirations,'' which will only permit two Short Term Option Expiration Dates for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. The Exchange proposes to include a table, labelled ''Table 1'', within Rule 4.5(d), which specifies each symbol that qualifies as a Short Term Option Daily Expiration. The table would note the number of expirations for each symbol as well as expiration days. The Exchange proposes to include Monday and Wednesday expirations for SPY, QQQ, and IWM and Tuesday and Thursday expirations for SPY and QQQ and list the number of expirations as ''2'' for these symbols. The Exchange's proposal to permit Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program is explained below in more detail. In the event Short Term Option Daily Expirations expire on the same day in the same class as a monthly options series or a Quarterly Options Series, the Exchange would skip that week's listing and instead list the following week; the two weeks of Short Term Option Expiration Dates would therefore not be consecutive. Specifically, the Exchange proposes to state within Rule 4.5(d):

> In addition to the above, the Exchange may open for trading series of options on the symbols provided in Table 1 below that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly Options Series expire (''Short Term Option Daily Expirations''). The Exchange may have no more than a total of two Short Term Option Daily Expirations for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. Short Term Option Daily Expirations would be subject to this paragraph (d).

SPY, QQQ, and IWM Friday expirations and other option symbols expiring on a Friday that are not noted in Table 1 will continue to have a total of five Short Term Option Expiration Dates provided those Friday expirations are not Fridays on which monthly options series or Quarterly Options Series expire (''Friday Short Term Option Expiration Dates''). These expirations would be referred to as ''Short Term Option Weekly Expirations'' to distinguish them from the proposed expirations that would be subject to Short Term Option Daily Expirations. The Exchange proposes to add rule text to Rule 4.5(d), which states that Monday Short Term Option Expiration Dates, Tuesday Short Term Option Expiration Dates, Wednesday Short Term Option Expiration Dates, and Thursday Short Term Option Expiration Dates, together with Friday Short Term Option Expiration Dates, are collectively ''Short Term Option Expiration Dates.'' [6]

Tuesday and Thursday Expirations

At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two consecutive Tuesday and Thursday ''Tuesday Short Term Option Daily Expirations'' and ''Thursday Short Term Option Daily Expirations'' each for SPY and QQQ at one time. Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 4.5(d).

Currently, series listed pursuant to the Short Term Option Series program are series in an option class that is approved for listing and trading on the Exchange in which the series opened for trading on any Monday, Tuesday, Wednesday, Thursday, or Friday (as applicable) that is a business day and that expires on the Monday, Wednesday, or Friday of the following business week that is a business day, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday, or Friday is not a business day, the series may be opened (or will expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday, or Friday. For a series listed pursuant to Rule 4.5(d) for Monday expiration, if a Monday is not a business day, the series will expire on the first business day immediately following that Monday.[7]

The Exchange proposes changes within Rule 4.5(d), which sets forth the requirements for SPY and QQQ options that are listed pursuant to the Short Term Option Series Program as Short Term Option Daily Expirations, to accommodate the listing of options series that expire on Tuesdays and Thursdays. Similar to Monday and Wednesday SPY, QQQ, and IWM Short Term Option Daily Expirations within Rule 4.5(d), the Exchange proposes that it may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').

Likewise, the Exchange proposes that it may open for trading on any Wednesday or Thursday that is a business day series of options on symbols provided in Table 1 that expire at the close of business on each of the next two Thursdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Thursday Short Term Option Expiration Date'').

In the event that options on SPY and QQQ expire on a Tuesday or Thursday and that Tuesday or Thursday is the same day that a monthly option series or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. Today, Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a Quarterly Options Series. Currently, there is no rule text provision that states that Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a monthly option series. Practically speaking, Monday and Wednesday Expirations in SPY, QQQ, and IWM would not expire on the same day as a monthly expiration.

The interval between strike prices for the proposed Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will be the same as those for the current Short Term Option Series for Monday, Wednesday, and Friday expirations applicable to the Short Term Option Series Program.[8] Specifically, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will have a $0.50 strike interval minimum.[9] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to proposed Rule 4.5(d), with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series will expire on the first business day immediately prior to that

[6] Defining the term ''Short Term Option Expiration Dates'' will make clear that this term includes expiration dates for each day Short Term Options are listed.

[7] *See* current Rule 4.5(d).

[8] *See* Rule 4.5(d)(5).

[9] *See id.*

Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[10] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[11] This thirty (30) series restriction would apply to Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY and QQQ options expiring on Tuesdays and Thursdays with a limit of two Tuesday Short Term Daily Expirations and two Thursday Short Term Daily Expirations.

Finally, the Exchange is amending Rule 4.5(d)(2) to conform the rule text to the usage of the term ''Short Term Option Daily Expirations.'' Today, with the exception of Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. With respect to monthly option series, Short Term Option Daily Expirations will be permitted to expire in the same week in which monthly option series in the same class expire. Not listing Short Term Option Daily Expirations for one week every month because there was a monthly on that same class on the Friday of that week would create investor confusion. Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[12] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly Options Series expire. The Exchange believes that it is reasonable to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below tables sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2020 and 2022 in the options industry.[13] The weekly strikes decreased from 24% to 19% in these two years. The Exchange notes that during this timeframe, all options exchanges mitigated weekly strike intervals.

NUMBER OF STRIKES—2020

Expiration	Percent of total series
Monthly	59
Weekly	24
LEAP	16
Quarterly	1

NUMBER OF STRIKES—2022

Expiration	Percent of total series
Monthly	64
Weekly	19
LEAP	17
Quarterly	0

By limiting the number of Short Term Option Daily Expirations for SPY, QQQ, and IWM to two expirations for Monday and Wednesday expirations, and expanding the Short Term Option Series Program to permit Tuesday and Thursday expirations for SPY and QQQ, the Exchange anticipates that it would overall reduce the number of weekly expiration dates. With respect to SPY, the reduction from five to two expirations will reduce 11.80% of strikes on SPY with Monday and Wednesday expirations. With respect to QQQ, the reduction from five to two expirations will reduce 12.86% of strikes on QQQ with Monday and Wednesday expirations. With respect to IWM, the reduction from five to two expirations will reduce 11.86% of strikes on IWM with Monday and Wednesday expirations. Additionally, expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in SPY and QQQ will account for the addition of 7.86% of strikes in SPY and the addition of 8.57% of strikes in QQQ. Therefore, the total net reduction would be 3.94% for SPY and 4.29% for QQQ.[14] The overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange and should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[15] Also, the Exchange's proposal curtails the number of expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools because all days of the week would be available to permit Trading Permit Holders to tailor their investment and hedging needs more effectively in SPY and QQQ.

[10] *See* Rule 4.5(d)(1).

[11] *See id.*

[12] While the Exchange proposes to add rule text within Rule 4.5(d) with respect to Monday Expirations, Tuesday Expirations, and Wednesdays Expirations stating that those expirations would not expire on business days that are business days on which monthly options series expire, practically speaking this would not occur.

[13] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 16 options markets up to August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18).

[14] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 16 options markets as of August 18, 2022. *See id.*

[15] Market-Makers (including Lead Market-Makers, Designated Primary Market-Makers, and Preferred Market-Makers) are required to quote a specified time in their assigned options series. *See* Rules 5.52, 5.54, 5.55, and 5.56.

TOTAL VOLUME—2022

[Through August 18]

Expiration	Percent of total series
Monthly	39
Weekly	48
LEAP	12
Quarterly	1

Weeklies comprise 48% of the total volume of options listings.[16] The Exchange believes that inner weeklies represent high volume as compared to outer weeklies and would be more attractive to market participants. Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the introduction of SPY and QQQ Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

Implementation

The Exchange proposes to implement this rule change on November 14, 2022. The Exchange will issue an Exchange Notice to notify Trading Permit Holders of the implementation date. Notwithstanding this implementation, Monday and Wednesday Expirations in SPY, QQQ, and IWM that were listed prior to the date of implementation will continue to be listed on the Exchange until those options expire pursuant to current Short Term Option Series rules within Rule 4.5(d).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[17] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[18] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[19] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposal is consistent with the Act as the overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange. This reduction would remove impediments to and perfect the mechanism of a free and open market by encouraging Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[20] Also, the Exchange's proposal curtails the number of Monday, Tuesday, Wednesday, and Thursday expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ, and IWM Monday and Wednesday Expirations (proposed to be SPY, QQQ and IWM Monday and Wednesday Short Term Daily Expirations), the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations is consistent with the Act as it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations (proposed to be SPY and QQQ Tuesday and Thursday Short Term Daily Expirations) will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in SPY and QQQ options, thus allowing them to better manage their risk exposure.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should create greater trading and hedging opportunities and flexibility and will provide customers with the ability to tailor their investment objectives more effectively. The Exchange currently lists Monday and Wednesday SPY, QQQ, and IWM Expirations (proposed to be SPY, QQQ, and IWM Monday and Wednesday Short Term Daily Expirations).[21]

Today, with the exception of Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange believes that permitting Short Term Option Daily Expirations to expire in the same week that standard monthly options expire on Fridays is consistent with Act. Not listing Short Term Option Daily Expirations for one week every month because there was a monthly on that same class on the Friday of that week would create investor confusion.

Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly

[16] This table sets forth industry volume. Weeklies comprise 48% of volume while only being 19% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 16 options markets as of August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18)

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] *Id.*

[20] Market-Makers (including Lead Market-Makers, Designated Primary Market-Makers, and Preferred Market-Makers) are required to quote a specified time in their assigned options series. *See* Rules 5.52, 5.54, 5.55, and 5.56.

[21] *See* Rule 4.5(d).

options series or Quarterly Options Series expire. Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. The Exchange believes that it is consistent with the Act to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire similar to Monday and Wednesday SPY, QQQ, and IWM Expirations.

There are no material differences in the treatment of Wednesday SPY and QQQ expirations for Short Term Option Series as compared to the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations. Given the similarities between Wednesday SPY, QQQ and IWM Expirations and the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, the Exchange believes that applying the provisions in Rule 4.5(d) that currently apply to Wednesday SPY, QQQ and IWM Expirations to Tuesday and Thursday SPY and QQQ Short Term Daily Expirations is justified.

The Exchange further represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations.

Finally, the Exchange notes the proposed rule change is substantively the same as a rule change proposed by ISE, which the Commission recently approved.[22]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal will provide an overall reduction in the number of Short Term Option Expirations to be listed on the Exchange. The Exchange believes this reduction will not impose an undue burden on competition, rather, it should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[23] Also, the Exchange's proposal curtails the number of weekly expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of weekly expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the Exchange believes the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange does not believe the proposal will impose any burden on intermarket competition, as nothing prevents the other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday SPY and QQQ expirations is not a novel proposal, as Wednesday SPY, QQQ and IWM Expirations are currently listed on the Exchange.[24] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[25] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[28] and subparagraph (f)(6) of Rule 19b–4 thereunder.[29] The Commission notes that it recently approved Nasdaq ISE's substantially similar proposal.[30] The Exchange has stated that waiver of the 30-day operative delay will allow the Exchange to implement the proposal at the same time as competitor exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the

[22] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[23] Market-Makers (including Lead Market-Makers, Designated Primary Market-Makers, and Preferred Market-Makers) are required to quote a specified time in their assigned options series. *See* Rules 5.52, 5.54, 5.55, and 5.56.

[24] *See* Rule 4.5(d).

[25] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[30] *See* Securities Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[31] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2022–059 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2022–059. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2022–059 and should be submitted on or before December 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25231 Filed 11–18–22; 8:45 am]

BILLING CODE 8011–01–P

[32] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–396, OMB Control No. 3235–0452]

Proposed Collection; Comment Request; Extension: Notice of Exempt Preliminary Roll-Up Communication

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Exchange Act Rule 14a–6(n) (17 CFR 240.14a–6(n)) requires any person that engages in a proxy solicitation subject to Exchange Act Rule 14a–2(b)(4) [(17 CFR 240.14a–2(b)(4))] to file a Notice of Exempt Preliminary Roll-Up Communication (''Notice'') [(17 CFR 240.14a–104)] with the Commission. The Notice provides information regarding ownership interest and any potential conflicts of interest to be included in statements submitted by or on behalf of a person engaging in the solicitation. The Notice takes approximately 0.25 hours per response and is filed by approximately 4 respondents for a total of one annual burden hour (0.25 hours per response × 4 response).

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by January 20, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25225 Filed 11–18–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96320; File No. SR–CboeEDGX–2022–051]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 and a Related Definition in Rule 16.1

November 15, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2022, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') proposes to amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 and a related definition in Rule 16.1. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05. Specifically, the Exchange proposes to amend the Short Term Option Series Program to: (1) limit the number of Short Term Option Expiration Dates for options on SPDR S&P 500 ETF Trust (SPY), the INVESCO QQQ TrustSM, Series 1 (QQQ), and iShares Russell 2000 ETF (IWM) from five to two expirations for Monday and Wednesday expirations; and (2) expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the same proposed limitation of two expirations.

The Exchange also proposes to amend the definition of Short Term Option Series in Rule 16.1.

Curtail Short Term Option Expiration Dates

Currently, after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays on which monthly options series or Quarterly Options Series expire (''Short Term Option Expiration Dates''). The Exchange may have no more than a total of five Short Term Option Expiration Dates not including any Monday or Wednesday SPY, QQQ, and IWM Expirations. Further, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on a Friday, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

Today, with respect to Wednesday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Tuesday or Wednesday that is a business day series of options on SPY, QQQ, and IWM to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire (''Wednesday SPY Expirations,'' ''Wednesday QQQ Expirations,'' and ''Wednesday IWM Expirations''). With respect to Monday SPY, QQQ, and IWM Expirations, the Exchange may open for trading on any Friday or Monday that is a business day series of options on the SPY, QQQ, or IWM to expire on any Monday of the month that is a business day and is not a Monday in which Quarterly Options Series expire (''Monday SPY Expirations,'' ''Monday QQQ Expirations,'' and ''Monday IWM Expirations''), provided that Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration. The Exchange may list up to five consecutive Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and five consecutive Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations at one time; the Exchange may have no more than a total of five each of Wednesday SPY Expirations, Wednesday QQQ Expirations, and Wednesday IWM Expirations and a total of five each of Monday SPY Expirations, Monday QQQ Expirations, and Monday IWM Expirations. Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations will be subject to the provisions of Rule 19.6, Interpretation and Policy .05.

Proposal

At this time, the Exchange proposes to curtail the number of Short Term Option Expiration Dates from five to two[5] for SPY, QQQ and IWM for Monday and Wednesday Expirations, as well as the proposed Tuesday and Thursday Expirations in SPY and QQQ (''Short Term Option Daily Expirations''). The Exchange proposes to create a new category of Short Term Option Expirations Dates called ''Short Term Option Daily Expirations,'' which will only permit two Short Term Option Expiration Dates for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. The Exchange proposes to include a table, labelled ''Table 1'', within Rule 19.6, Interpretation and Policy .05(h), which specifies each symbol that qualifies as a Short Term Option Daily Expiration. The table would note the number of expirations for each symbol as well as expiration days. The Exchange proposes to include Monday and Wednesday expirations for SPY, QQQ, and IWM and Tuesday and Thursday expirations for SPY and QQQ and list the number of expirations as ''2'' for these symbols. The Exchange's proposal to permit Tuesday and Thursday expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program is explained below in more detail. In the event Short Term Option Daily Expirations expire on the same day in the same class as a monthly options series or a Quarterly Options Series, the Exchange would skip that week's listing and instead list the following week; the two weeks of Short Term Option Expiration Dates would therefore not be consecutive. Specifically, the Exchange proposes to state within Rule 19.6, Interpretation and Policy .05(h):

> In addition to the above, the Exchange may open for trading series of options on the symbols provided in Table 1 below that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly

[5] The Exchange proposes to list the two front months for Short Term Option Daily Expirations.

Options Series expire (''Short Term Option Daily Expirations''). The Exchange may have no more than a total of two Short Term Option Daily Expirations for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time. Short Term Option Daily Expirations would be subject to this Interpretation and Policy .05

SPY, QQQ, and IWM Friday expirations and other option symbols expiring on a Friday that are not noted in Table 1 will continue to have a total of five Short Term Option Expiration Dates provided those Friday expirations are not Fridays on which monthly options series or Quarterly Options Series expire (''Friday Short Term Option Expiration Dates''). These expirations would be referred to as ''Short Term Option Weekly Expirations'' to distinguish them from the proposed expirations that would be subject to Short Term Option Daily Expirations. The Exchange proposes to add rule text to Rule 19.6, Interpretation and Policy .05(h) which states that Monday Short Term Option Expiration Dates, Tuesday Short Term Option Expiration Dates, Wednesday Short Term Option Expiration Dates, and Thursday Short Term Option Expiration Dates, together with Friday Short Term Option Expiration Dates, are collectively ''Short Term Option Expiration Dates.''[6]

Tuesday and Thursday Expirations

At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two consecutive Tuesday and Thursday ''Tuesday Short Term Option Daily Expirations'' and ''Thursday Short Term Option Daily Expirations'' each for SPY and QQQ at one time. Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 19.6, Interpretation and Policy .05.

A Short Term Option Series means a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday, or Friday that is a business day and that expires on the Monday, Wednesday, or Friday of the following business week that is a business day, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

The Exchange proposes to amend this definition in Rule 16.1 to accommodate the listing of options series that expire on Tuesdays and Thursdays. Specifically, the Exchange proposes to add Tuesday and Thursdays to the permitted expiration days, which currently include Monday, Wednesday, and Friday, that it may open for trading.

The Exchange also proposes corresponding changes within Rule 19.6, Interpretation and Policy .05, which sets forth the requirements for SPY and QQQ options that are listed pursuant to the Short Term Option Series Program as Short Term Option Daily Expirations, to accommodate the listing of options series that expire on Tuesdays and Thursdays. Similar to Monday and Wednesday SPY, QQQ, and IWM Short Term Option Daily Expirations within Rule 19.6, Interpretation and Policy .05, the Exchange proposes that it may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').

Likewise, the Exchange proposes that it may open for trading on any Wednesday or Thursday that is a business day series of options on symbols provided in Table 1 that expire at the close of business on each of the next two Thursdays that are business days and are not business days in which monthly options series or Quarterly Options Series expire (''Thursday Short Term Option Expiration Date'').

In the event that options on SPY and QQQ expire on a Tuesday or Thursday and that Tuesday or Thursday is the same day that a monthly option series or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. Today, Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a Quarterly Options Series. Currently, there is no rule text provision that states that Monday and Wednesday Expirations in SPY, QQQ, and IWM skip the weekly listing in the event the weekly listing expires on the same day in the same class as a monthly option series. Practically speaking, Monday and Wednesday Expirations in SPY, QQQ, and IWM would not expire on the same day as a monthly expiration.

The interval between strike prices for the proposed Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will be the same as those for the current Short Term Option Series for Monday, Wednesday, and Friday expirations applicable to the Short Term Option Series Program.[7] Specifically, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations will have a $0.50 strike interval minimum.[8] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to proposed Rule 19.6, Interpretation and Policy .05, with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series will expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[9] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[10] This thirty (30) series restriction would apply to Tuesday and Thursday SPY and QQQ Short Term Option Daily Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY and QQQ options expiring on Tuesdays and Thursdays with a limit of two Tuesday Short Term Daily Expirations and two Thursday Short Term Daily Expirations.

Finally, the Exchange is amending Rule 19.6, Interpretation and Policy .05(b) to conform the rule text to the usage of the term ''Short Term Option Daily Expirations.'' Today, with the exception of Monday and Wednesday

[6] Defining the term ''Short Term Option Expiration Dates'' will make clear that this term includes expiration dates for each day Short Term Options are listed.

[7] *See* Rule 19.6, Interpretation and Policy .05(e).

[8] *See id.*

[9] *See* Rule 19.6, Interpretation and Policy .05(a).

[10] *See id.*

SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. With respect to monthly option series, Short Term Option Daily Expirations will be permitted to expire in the same week in which monthly option series in the same class expire. Not listing Short Term Option Daily Expirations for one week every month because there was a monthly on that same class on the Friday of that week would create investor confusion. Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[11] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days on which monthly options series or Quarterly Options Series expire. The Exchange believes that it is reasonable to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Monday and Wednesday for SPY, QQQ and IWM.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below tables sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2020 and 2022 in the options industry.[12] The weekly strikes decreased from 24% to 19% in these two years. The Exchange notes that during this timeframe, all options exchanges mitigated weekly strike intervals.

Expiration	Percent of total series
Number of Strikes—2020	
Monthly	59
Weekly	24
LEAP	16
Quarterly	1
Number of Strikes—2022	
Monthly	64
Weekly	19
LEAP	17
Quarterly	0

By limiting the number of Short Term Option Daily Expirations for SPY, QQQ, and IWM to two expirations for Monday and Wednesday expirations, and expanding the Short Term Option Series Program to permit Tuesday and Thursday expirations for SPY and QQQ, the Exchange anticipates that it would overall reduce the number of weekly expiration dates. With respect to SPY, the reduction from five to two expirations will reduce 11.80% of strikes on SPY with Monday and Wednesday expirations. With respect to QQQ, the reduction from five to two expirations will reduce 12.86% of strikes on QQQ with Monday and Wednesday expirations. With respect to IWM, the reduction from five to two expirations will reduce 11.86% of strikes on IWM with Monday and Wednesday expirations. Additionally, expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in SPY and QQQ will account for the addition of 7.86% of strikes in SPY and the addition of 8.57% of strikes in QQQ. Therefore, the total net reduction would be 3.94% for SPY and 4.29% for QQQ.[13] The overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange and should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[14] Also, the Exchange's proposal curtails the number of expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools because all days of the week would be available to permit Trading Permit Holders to tailor their investment and hedging needs more effectively in SPY and QQQ.

TOTAL VOLUME—2022

[through August 18]

Expiration	Percent of total series
Monthly	39
Weekly	48
LEAP	12
Quarterly	1

Weeklies comprise 48% of the total volume of options listings.[15] The Exchange believes that inner weeklies represent high volume as compared to outer weeklies and would be more attractive to market participants. Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the introduction of SPY and QQQ Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

[11] While the Exchange proposes to add rule text within Rule 19.6, Interpretation and Policy .05 with respect to Monday Expirations, Tuesday Expirations, and Wednesdays Expirations stating that those expirations would not expire on business days that are business days on which monthly options series expire, practically speaking this would not occur.

[12] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 16 options markets up to August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18).

[13] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 16 options markets as of August 18, 2022. *See id.*

[14] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[15] This table sets forth industry volume. Weeklies comprise 48% of volume while only being 19% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 16 options markets as of August 18, 2022. *See* Securities Exchange Act Release No. 95841 (September 20, 2022), 87 FR 58399 (September 26, 2022) (SR–ISE–2022–18).

Implementation

The Exchange proposes to implement this rule change on November 14, 2022. The Exchange will issue an Exchange Notice to notify Trading Permit Holders of the implementation date. Notwithstanding this implementation, Monday and Wednesday Expirations in SPY, QQQ, and IWM that were listed prior to the date of implementation will continue to be listed on the Exchange until those options expire pursuant to current Short Term Option Series rules within Rule 19.6, Interpretation and Policy .05.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [18] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposal is consistent with the Act as the overall reduction offered by this proposal reduces the number of Short Term Option Expirations to be listed on the Exchange. This reduction would remove impediments to and perfect the mechanism of a free and open market by encouraging Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[19] Also, the Exchange's proposal curtails the number of Monday, Tuesday, Wednesday, and Thursday expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ, and IWM Monday and Wednesday Expirations (proposed to be SPY, QQQ and IWM Monday and Wednesday Short Term Daily Expirations), the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations is consistent with the Act as it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday expirations (proposed to be SPY and QQQ Tuesday and Thursday Short Term Daily Expirations) will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on SPY and QQQ listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in SPY and QQQ options, thus allowing them to better manage their risk exposure.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday SPY and QQQ Short Term Daily Expirations should create greater trading and hedging opportunities and flexibility and will provide customers with the ability to tailor their investment objectives more effectively. The Exchange currently lists Monday and Wednesday SPY, QQQ, and IWM Expirations (proposed to be SPY, QQQ, and IWM Monday and Wednesday Short Term Daily Expirations).[20]

Today, with the exception of Monday and Wednesday SPY Expirations, Monday and Wednesday QQQ Expirations, and Monday and Wednesday IWM Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire. With this proposal, Tuesday and Thursday SPY Expirations and Tuesday and Thursday QQQ Expirations would be treated similarly to existing Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange believes that permitting Short Term Option Daily Expirations to expire in the same week that standard monthly options expire on Fridays is consistent with Act. Not listing Short Term Option Daily Expirations for one week every month because there was a monthly on that same class on the Friday of that week would create investor confusion.

Further, as with Monday and Wednesday SPY, QQQ, and IWM Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire. Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. The Exchange believes that it is consistent with the Act to not permit two expirations on the same day in which a monthly options series or a Quarterly Options Series would expire similar to Monday and Wednesday SPY, QQQ, and IWM Expirations.

There are no material differences in the treatment of Wednesday SPY and QQQ expirations for Short Term Option Series as compared to the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations. Given the similarities between Wednesday SPY, QQQ and IWM Expirations and the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, the Exchange believes that applying the provisions in Rule 19.6, Interpretation and Policy .05 that currently apply to Wednesday SPY, QQQ and IWM Expirations to Tuesday and Thursday SPY and QQQ Short Term Daily Expirations is justified.

The Exchange further represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday SPY and QQQ Short Term Daily Expirations, in the same way that it monitors trading in the current Short

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *Id.*

[19] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[20] *See* Rule 19.6, Interpretation and Policy .05.

Term Option Series and trading in Monday and Wednesday SPY, QQQ, and IWM Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations.

Finally, the Exchange notes the proposed rule change is substantively the same as a rule change proposed by ISE, which the Commission recently approved.[21]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal will provide an overall reduction in the number of Short Term Option Expirations to be listed on the Exchange. The Exchange believes this reduction will not impose an undue burden on competition, rather, it should encourage Market-Makers to continue to deploy capital more efficiently and improve displayed market quality.[22] Also, the Exchange's proposal curtails the number of weekly expirations in SPY, QQQ, and IWM without reducing the classes of options available for trading on the Exchange. The Exchange believes that despite the proposed curtailment of weekly expirations, Trading Permit Holders will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in SPY, QQQ, and IWM.

Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the Exchange believes the introduction of SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that SPY and QQQ Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase SPY and QQQ options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange does not believe the proposal will impose any burden on intermarket competition, as nothing prevents the other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday SPY and QQQ expirations is not a novel proposal, as Wednesday SPY, QQQ and IWM Expirations are currently listed on the Exchange.[23] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[24] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[25] and Rule 19b–4(f)(6) thereunder.[26] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[27] and subparagraph (f)(6) of Rule 19b–4 thereunder.[28] The Commission notes that it recently approved Nasdaq ISE's substantially similar proposal.[29] The Exchange has stated that waiver of the 30-day operative delay will allow the Exchange to implement the proposal at the same time as competitor exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[30]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2022–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2022–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[21] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[22] Market-Makers are required to quote a specified time in their assigned options series. *See* Rule 22.6.

[23] *See* Rule 19.6, Interpretation and Policy .05.

[24] *See* Securities and Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[25] 15 U.S.C. 78s(b)(3)(A)(iii).

[26] 17 CFR 240.19b–4(f)(6).

[27] 15 U.S.C. 78s(b)(3)(A)(iii).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[29] *See* Securities Exchange Act Release No. 96281 (November 9, 2022) (SR–ISE–2022–18).

[30] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2022–051 and should be submitted on or before December 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25234 Filed 11–18–22; 8:45 am]

BILLING CODE 8011–01–P

[31] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96312; File No. SR–CboeBZX–2022–031]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

November 15, 2022.

On May 13, 2022, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the ARK 21Shares Bitcoin ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on June 1, 2022.[3]

On July 12, 2022, pursuant to section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On August 29, 2022, the Commission instituted proceedings under section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on June 1, 2022.[9] The 180th day after publication of the proposed rule change is November 28, 2022. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to section 19(b)(2) of the Act,[10] designates January 27, 2023, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–CboeBZX–2022–031).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25233 Filed 11–18–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94982 (May 25, 2022), 87 FR 33250.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 95257, 87 FR 42530 (July 15, 2022). The Commission designated August 30, 2022, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 95622, 87 FR 54270 (Sep. 2, 2022).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3 and accompanying text.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

DEPARTMENT OF STATE

[Public Notice: 11900]

60-Day Notice of Proposed Information Collection: Application for A, G, or NATO Visa

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to January 20, 2023.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2022–0043'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: PRA_BurdenComments@state.gov.*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Tonya Whigham who may be reached at *PRA_BurdenComments@state.gov* or at 202–485–7586.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Application for A, G, or NATO Visa.
- *OMB Control Number:* 1405–0100.
- *Type of Request:* Renewal of a Currently Approved Collection.
- *Originating Office:* CA/VO.

• *Form Number:* DS–1648.

• *Respondents:* Foreign Government Officials.

• *Estimated Number of Respondents:* 30,000.

• *Estimated Number of Responses:* 30,000.

• *Average Time per Response:* 15 Minutes.

• *Total Estimated Burden Time:* 7,500 hours.

• *Frequency:* On Occasion, when applying for an A, G, or NATO Visa.

• *Obligation to Respond:* Required to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Department of State uses Form DS–1648 to elicit information from applicants who are applying for an A, G, or NATO visa in the United States, excluding applicants for an A–3, G–5 or NATO–7 visa. Sections 101(a)(15)(A) and (G) of the Immigration and Nationality Act (INA), and Department regulations at 22 CFR 41.25, 41.26, and 41.27, describe the criteria for these nonimmigrant visa classifications.

Methodology

The DS–1648 will be submitted electronically to the Department. The applicant will be instructed to print a confirmation page containing a bar coded record locator, which will be scanned at the time of processing.

Robert L. Batchelder,

Acting Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2022–25252 Filed 11–18–22; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 11922]

30-Day Notice of Proposed Information Collection: Eligibility Questionnaire for HAVANA Act Payments

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to December 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Susan Ware Harris, Senior Advisor, Health Incidents Response Task Force, who may be reached on 202–679–0127, or at *HIRTFStaffers@state.gov.*

SUPPLEMENTARY INFORMATION:

• *Title of Information Collection:* Eligibility Questionnaire for HAVANA Act Payments.

• *OMB Control Number:* 1405–0250.

• *Type of Request:* Extension of a Currently Approved Collection.

• *Originating Office:* S/HIRTF, Health Incidents Response Task Force.

• *Form Number:* DS–4316.

• *Respondents:* Department of State employees, former employees, and their dependents, and the qualified physicians whom they have consulted.

• *Estimated Number of Respondents:* 100.

• *Estimated Number of Responses:* 100.

• *Average Time per Response:* 30 minutes.

• *Total Estimated Burden Time:* 50 hours.

• *Frequency:* Once.

• *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

On October 8, 2021, President Biden signed the ''Helping American Victims Affected by Neurological Attacks'' (HAVANA) Act of 2021 (Pub. L. 117–46). In this statute, Congress authorized federal agencies to make payments to affected current employees, former employees, and their dependents for qualifying injuries to the brain. The DS–4316 provides the required medical substantiation for claims filed pursuant to the HAVANA Act and the Department's recent rule, which was effective August 15, 2022.

Methodology

An individual wishing to make a claim under the HAVANA Act IFR will fill out the ''Patient Demographics'' portion of the DS–4316, and provide it to a U.S. board-certified physician (currently certified by the American Board of Psychiatry and Neurology (ABPN) or the American Board of Physical Medicine and Rehabilitation (ABPMR)), who will complete the form after examining the individual and reviewing their records and will fax or email the completed form to the Department.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2022–25253 Filed 11–18–22; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–1565]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Mitsubishi MU–2B Series Airplane Training Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection of information is necessary to document participation in, completion of, and compliance with the pilot training program for the MU–2B series airplane.

DATES: Written comments should be submitted by January 20, 2023.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Christopher Morris, AFS–850, 800 Independence Ave. SW, Washington, DC 20591.

By email: chris.morris@faa.gov.

FOR FURTHER INFORMATION CONTACT: Paul Penner by email at: *paul.penner@faa.gov;* phone: 818–267–3343.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0725.

Title: Mitsubishi MU–2B Series Airplane Special Training Requirements.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal.

Background: In response to the increasing number of accidents and incidents involving the Mitsubishi MU–2B series airplane, the Federal Aviation Administration (FAA) began a safety evaluation of the MU–2B in July of 2005. As a result of this safety evaluation, on February 6, 2008 the FAA issued Special Federal Aviation Regulation No. 108—Mitsubishi MU–2B Series Special Training, Experience, and Operating Requirements. This Special Federal Aviation Regulation (SFAR) established a standardized pilot training program. The collection of information is necessary to document participation in, completion of, and compliance with the pilot training program for the MU–2B under subpart N of part 91, issued on September 7, 2016, which superseded SFAR No. 108.

Respondents: Approximately 15 part 91 training providers, and approximately 250 active MU–2 pilots.

Frequency: Every year (pilots); every two years (training providers).

Estimated Average Burden per Response: Pilots: Logbook endorsement and training course final phase check = 10 minutes. Training providers: Submission of training program = 4 hours.

Estimated Total Annual Burden: Pilots: 21 hours. Training providers: 30 hours. Total: 51 hours.

Issued in Washington, DC, on November 16, 2022.

D.C. Morris,

Project Manager, Flight Standards Service, General Aviation and Commercial Division.

[FR Doc. 2022–25278 Filed 11–18–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Fiscal Service

Notice of Rate To Be Used for Federal Debt Collection, and Discount and Rebate Evaluation

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Notice of rate to be used for Federal debt collection, and discount and rebate evaluation.

SUMMARY: The Secretary of the Treasury is responsible for computing and publishing the percentage rate that is used in assessing interest charges for outstanding debts owed to the Government (The Debt Collection Act of 1982, as amended). This rate is also used by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, this rate is used in determining when agencies should pay purchase card invoices when the card issuer offers a rebate. Notice is hereby given that the applicable rate for calendar year 2023 is 1.00 percent.

DATES: January 1, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Department of the Treasury, Bureau of the Fiscal Service, Disbursing and Debt Management, E-Commerce Division (LC–RM 349B), 3201 Pennsy Drive, Building E, Landover, MD 20785 (Telephone: 202–874–9428).

SUPPLEMENTARY INFORMATION: The rate reflects the Current Value of Funds to the Treasury for use in connection with Federal Cash Management systems and is based on investment rates set for purposes of Public Law 95–147, 91 Stat. 1227 (October 28, 1977). The annual Interest Rate Factors used in determining the Current Value of Funds Rate are based on weekly average Fed funds, less 25 basis points for the 12-month period ending every September 30. The Treasury Office of Debt Management began providing the annual Interest Rate Factors in the October 2021 monthly reporting cycle. The Current Value of Funds Rate is rounded to the nearest whole percentage for applicability effective each January 1. Quarterly revisions are made if the annual average, on a moving basis, changes by 2 percentage points.

Authority: 31 U.S.C. Section 3717.

Linda Claire Chero,

Assistant Commissioner, Disbursing and Debt Management, and Chief Disbursing Officer.

[FR Doc. 2022–25077 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea M. Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On October 26, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals:

1. KARIMI, Farzin (Arabic: فرزین کریمی) (a.k.a. MAZLGHANCHAY, Farzin Karimi (Arabic: فرزین کریمی مزلقانچای); a.k.a. MAZLQANCHAY, Farzin Karimi), Iran; DOB 07 Dec 1992; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0440273961 (Iran) (individual) [HRIT-IR] (Linked To: RAVIN ACADEMY).

   Designated pursuant to section 1(a)(ii)(D) of Executive Order 13606 of April 22, 2012, "Blocking the Property and Suspending Entry Into the United States of Certain Persons With Respect to Grave Human Rights Abuses by the Governments of Iran and Syria via Information Technology" (E.O. 13606), 77 FR 24571, 3 CFR 2012 Comp., p. 24, for having acted or purported to act for or on behalf of, directly or indirectly, RAVIN ACADEMY.

2. MOSTAFAVI, Seyed Mojtaba (Arabic: سید مجتبی مصطفوی) (a.k.a. MORTAZAVI, Mojtaba; a.k.a. MOSTAF, Mojtaba), Tehran, Iran; DOB 02 Apr 1987; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0080467741 (Iran) (individual) [HRIT-IR] (Linked To: RAVIN ACADEMY).

   Designated pursuant to section 1(a)(ii)(D) of E.O. 13606 for having acted or purported to act for or on behalf of, directly or indirectly, RAVIN ACADEMY.

3. KHIABANI, Hossein Modarres (Arabic: حسین مدرس خیابانی), Sistan and Baluchistan, Iran; DOB Mar 1968 to Mar 1969; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Governor of Sistan and Baluchistan province (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of Executive Order 13553 of September 28, 2010, "Blocking Property of Certain Persons With Respect To Serious Human Rights Abuses by the Government of Iran and Taking Certain Other Actions" (E.O. 13553), 75 FR 60567, 3 CFR 2010 Comp., p. 253, for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

4. SHAFAHI, Ahmad (Arabic: احمد شفاهی) (a.k.a. SHAFA'I, Ahmad (Arabic: احمد شفائی)), Sistan and Baluchistan, Iran; DOB 21 May 1968; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Commander of Salman Corps in Sistan and Baluchistan province (individual) [IRGC] [IFSR] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS.

5. AL-GHAIB, Seyyed Heshmatollah Hayat (Arabic: سیدحشمت الله حیا□ الغیب) (a.k.a. AL-GHAIB, Heshmatollah Hayat; a.k.a. AL-GHAIB, Seyyed Heshmat Hayat (Arabic: سید حشمت حیا□ الغیب); a.k.a. AL-GHAYB, Sayyid Heshmat Hayat), Tehran, Iran; DOB 21 Mar 1965; POB Yazd, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 5289820841 (Iran); Director-General of Tehran Province Prisons (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

6. FARZADI, Hedayat (Arabic: هدایت فرزادی) (a.k.a. FARZADI, Hedayatollah (Arabic: هدایت‌الله فرزادی)), Tehran, Iran; DOB 25 Jul 1971; POB Sahneh, Bisotun, Kermanshah Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 4969829268 (Iran); Warden of Evin Prison (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

7. FATHI, Murad (Arabic: مورد فتحی), Kurdistan, Iran; DOB 20 May 1971; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 2971486151 (Iran); Director-General of Kurdistan Province Prisons (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

8. KHOSRAVI, Mohammad Hossein (Arabic: محمد حسین خسروی), Sistan and Baluchistan, Iran; DOB 23 Sep 1974; POB Birjand, South Khorasan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0653027761 (Iran); Director-General of Sistan and Baluchistan Province Prisons (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible

for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

9. PASANDIDEH, Heidar (Arabic: حيدر پسنديده) (a.k.a. PASANDIDEH, Haydar; a.k.a. PASANDIDEH, Heidar Mehdigholi (Arabic: حيدر مهديقلى پسنديده); a.k.a. PASANDIDEH, Heider), Sanandaj, Iran; DOB 16 Jul 1976; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 2754291598 (Iran); Warden of Sanandaj Central Prison (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

10. PIRI, Morteza (Arabic: مرتضى پيرى), Zahedan, Iran; DOB 05 Jul 1977; POB Zabol, Sistan and Baluchistan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 4072307122 (Iran); Warden of Zahedan Central Prison (individual) [IRAN-HR].

    Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

11. KAZEMI, Mohammad (Arabic: محمد كاظمى), Tehran, Iran; DOB 11 Jul 1961; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Brigadier General (individual) [IRGC] [IFSR] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

    Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS.

12. NILFORUSHAN, Abbas (Arabic: عباس نيلفروشان) (a.k.a. NILFOROUSHAN DARDASHTI, Abbas; a.k.a. NILFOROUSHAN, Abbas; a.k.a. NILFRUSHAN DARDASHTI, Abbas Mortaza), Tehran, Iran; DOB 23 Aug 1966; POB Isfahan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport P46631463 (Iran) expires 26 Sep 2023; Deputy Commander for Operations (individual) [IRGC] [IFSR] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

    Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS.

Entities:

1. SAMANE GOSTAR SAHAB PARDAZ PRIVATE LIMITED COMPANY (Arabic: شركت سامانه گستر سحاب پرداز شركت سهامى خاص) (a.k.a. SAHAB PARDAZ CO.), No. 22, Khorramshahr Street, Tehran, Iran; No. 28, Arab Ali St., Korramshahr St., Tehran, Iran; North Shohvardi Street, Korramshahr Street, Number 24, Floor 1, Tehran, Iran; Website https://www.sahab.ir; Additional Sanctions Information - Subject to Secondary Sanctions; Registration Country Iran; National ID No. 14004241708 (Iran); Registration Number 457647 (Iran) [IRAN-TRA].

   Designated pursuant to 7(a)(v) of Executive Order 13846 of August 6, 2018, "Reimposing Certain Sanctions With Respect to Iran," 83 FR 38939, 3 CFR, 2018 Comp., p. 854, for having engaged in censorship or other activities with respect to Iran on or after June 12, 2009, that prohibit, limit or penalize the exercise of freedom of expression or assembly by citizens of Iran, or that limit access to print or broadcast media, including the facilitation or support of intentional frequency manipulation by the government of Iran that would jam or restrict an international signal.

2. RAVIN ACADEMY (Arabic: آكادمى راوين) (a.k.a. AAVAYE HOOSHMAND RAVIN INSTITUTE (Arabic: مؤسسه آواى هوشمند راوين); a.k.a. RAVIN SMART VOICE INSTITUTE), No. 36, Naghdi Alley, North Sohrevardi, Tehran, Iran; No. 105, Shahid Motahari St., Suleiman Kharter St., Tehran, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; National ID No. 14008970823 (Iran) [HRIT-IR].

   Designated pursuant to section 1(a)(ii)(C) of E.O. 13606 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY.

Dated: October 26, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25303 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea M. Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On September 22, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals:

1. ABNOUSH, Salar (Arabic: سالار آبنوش) (a.k.a. ABNOOSH, Salar), Iran; DOB 02 May 1962; POB Hamedan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of Executive Order 13553 of September 28, 2010, "Blocking Property of Certain Persons With Respect to Serious Human Rights Abuses by the Government of Iran and Taking Certain Other Actions" (E.O. 13553), 75 FR 60567, October 1, 2010, for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

2. AMANOLLAHI, Manouchehr (Arabic: منوچهر امن اللهي) (a.k.a. AMANOLLAHI BAHARVAND, Manouchehr), Iran; DOB Mar 1965 to Mar 1966; POB Khorramabad, Iran; citizen Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Brigadier General (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

3. HEIDARI, Kiyumars (Arabic: كيومرث حيدرى) (a.k.a. HEYDARI, Kioumars), Iran; DOB 1964; POB Kermanshah, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

4. KHATIB, Esmail (Arabic: اسماعيل خطيب) (a.k.a. KHATIB, Seyed Esmaeil (Arabic: سيد اسماعيل خطيب)), Iran; DOB 1960 to 1961; POB Ghayenat, South Khorasan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IFSR] [IRAN-HR] [CYBER2] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY.

5. MIRZAEI, Haj Ahmad (Arabic: حاج احمد میرزایی) (a.k.a. MIRZAEI, Ahmed; a.k.a. MIRZAEI, Hajahmad; a.k.a. MIRZAYI, Hajj Ahmad), Tehran, Iran; DOB 09 Feb 1957; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 4268935215 (Iran); Colonel (individual) [IRAN-HR] (Linked To: LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN).

   Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN.

6. REZAEI, Qasem (Arabic: قاسم رضایی) (a.k.a. REZAEI, Ghasem; a.k.a. REZAEI, Qassem; a.k.a. REZAI, Qasem; a.k.a. REZAYEE, Qassem; a.k.a. REZAYI REZA, Ghasem), Iran; DOB 27 Sep 1961; POB Abhar City, Zanjan Province, Iran; citizen Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport D10005996 (Iran); National ID No. 4410232436 (Iran) (individual) [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

7. ROSTAMI CHESHMEH GACHI, Mohammad (Arabic: محمد رستمی چشمه گچی) (a.k.a. ROSTAMI, Mohammad (Arabic: محمد رستمی)), Kermanshah, Iran; DOB 1976 to 1977; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 111936 (Iran); Identification Number 13821 (Iran); General (individual) [IRAN-HR] (Linked To: LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN).

   Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN.

Entity:

1. IRAN'S MORALITY POLICE (a.k.a. MORAL SECURITY POLICE (Arabic: پلیس امنیت اخلاقی), Vozara Street, corner of 25th Street, District 6, Tehran, Iran; Additional Sanctions

Information - Subject to Secondary Sanctions; Target Type Government Entity [IRAN-HR] (Linked To: LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN).

Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN.

Dated: September 22, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25305 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On November 15, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals

1. DJUMA, Abbas (a.k.a. DZHUMA, Abbas (Cyrillic: ДЖУМА, Аббас); a.k.a. DZHUMA, Abbas Mokhammadovich (Cyrillic: ДЖУМА, Аббас Мохаммадович)), Moscow, Russia; DOB 10 Jul 1993; POB Moscow, Russia; nationality Russia; Gender Male; Passport 724609161 (Russia) expires 23 May 2023 (individual) [RUSSIA-EO14024] (Linked To: PRIVATE MILITARY COMPANY 'WAGNER').

   Designated pursuant to section 1(a)(vi)(B) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect to Specified Harmful Foreign Activities of the Government of the Russian Federation," 86 FR 20249 (E.O. 14024) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods and services to or in support of, PRIVATE MILITARY COMPANY 'WAGNER', a person whose property and interests in property are blocked pursuant to E.O. 14024.

2. SRABIONOV, Tigran Khristoforovich, Moscow, Russia; DOB 17 Apr 1986; Gender Male (individual) [RUSSIA-EO14024] (Linked To: PRIVATE MILITARY COMPANY 'WAGNER').

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, PRIVATE MILITARY COMPANY 'WAGNER', a person whose property and interests in property are blocked pursuant to E.O. 14024.

Entities:

1. SHAHED AVIATION INDUSTRIES RESEARCH CENTER (a.k.a. SHAHED AVIATION; a.k.a. SHAHED AVIATION INDUSTRIES; a.k.a. SHAHED AVIATION INDUSTRIES COMPLEX; a.k.a. SHAHED AVIATION INDUSTRIES RESEARCH (Arabic: تحقیقات صنایع هوایی شاهد); a.k.a. SHAHED AVIATION INDUSTRIES RESEARCH CENTRE; a.k.a. "SAIC"; a.k.a. "SAIRC"), Shahid Lavi Street, Sajad Street, Isfahan, Iran; Website http://www.shahedaviation.com; Additional Sanctions Information - Subject to Secondary Sanctions [NPWMD] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS AIR FORCE).

   Designated pursuant to section 1(a)(iii) of Executive Order 13382 of June 28, 2005, "Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters," 70 FR 38567 (E.O. 13382) for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS AIR FORCE.

2. I JET GLOBAL DMCC (a.k.a. TRADE MED MIDDLE EAST; a.k.a. TRADE MID MIDDLE EAST; a.k.a. "IJET"), Unit No: 3504, 1 Lake Plaza, Plot No: JLT-PH2-T2A, Jumeirah Lakes Towers, Dubai, United Arab Emirates; Plaza del Olivar, 1 4, Palma de Mallorca, Baleares H24 07002, Spain; 116/8, St. George's Road, St. Julians STJ3203, Malta; Damascus, Syria; Organization Established Date 13 Oct 2014; Organization Type: Service activities incidental to air transportation; Registration Number DMCC19501 (United Arab Emirates) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

3. SUCCESS AVIATION SERVICES FZC, 608, The Apricot Tower, Dubai Silicon Oasis, Dubai, United Arab Emirates; Building L1, Sharjah International Airport, Sharjah, United Arab Emirates; Organization Established Date 17 Nov 2015; Organization Type: Service activities incidental to air transportation; Registration Number 16039 (United Arab Emirates) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

Dated: November 15, 2022.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25306 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On November 16, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. JEBELLI, Peyman (Arabic: پیمان جبلی) (a.k.a. JEBELLI, Payman; a.k.a. JEBLI, Peyman), Tehran, Iran; DOB 25 Jan 1967; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport D10010071 (Iran) expires 25 Jun 2027; Director, Islamic Republic of Iran Broadcasting (individual) [IRAN-EO13846] (Linked To: ISLAMIC REPUBLIC OF IRAN BROADCASTING).

   Designated pursuant to section 7(a)(vii) of Executive Order 13846 of August 6, 2018, "Reimposing Certain Sanctions With Respect to Iran" ("E.O. 13846") 83 FR 38939, 3 CFR, 2019 Comp., p. 854, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to Executive Order 13628 of October 9, 2012, "Authorizing the Implementation of Certain Sanctions Set Forth in the Iran Threat Reduction and Syria Human Rights Act of 2012 and Additional Sanctions With Respect to Iran" ("E.O. 13628"), which was revoked and superseded by E.O. 13846.

2. NOROOZI, Ahmad (Arabic: احمد نوروزی) (a.k.a. NOROUZI, Ahmad), Tehran, Iran; DOB 05 May 1987; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport G10521994 (Iran) expires 25 Jan 2027; Vice President, Islamic Republic of Iran Broadcasting World Service (individual) [IRAN-EO13846] (Linked To: ISLAMIC REPUBLIC OF IRAN BROADCASTING).

   Designated pursuant to section 7(a)(vii) of E.O. 13846 for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to E.O. 13628, which was revoked and superseded by E.O. 13846.

3. BARMAHANI, Mohsen (Arabic: محسن برمهانی) (a.k.a. BORMAHANI, Mohsen), Tehran, Iran; DOB 24 May 1979; POB Neishabur, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport A54062245 (Iran) expires 12 Jul 2026; National ID No. 1063893488 (Iran); Deputy Director, Islamic Republic of Iran Broadcasting (individual) [IRAN-EO13846] (Linked To: ISLAMIC REPUBLIC OF IRAN BROADCASTING).

   Designated pursuant to section 7(a)(vii) of E.O. 13846 for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to E.O. 13628, which was revoked and superseded by E.O. 13846.

4. POURANVARI, Yoosef (Arabic: یوسف پورانواری) (a.k.a. POURANVARI, Yousef), Tehran, Iran; DOB 26 May 1983; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0492699836 (Iran) (individual) [IRAN-EO13846] (Linked To: ISLAMIC REPUBLIC OF IRAN BROADCASTING).

   Designated pursuant to section 7(a)(vii) of E.O. 13846 for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to E.O. 13628, which was revoked and superseded by E.O. 13846.

5. REZVANI, Ali (Arabic: علی رضوانی), Tehran, Iran; DOB 19 Dec 1984; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-EO13846] (Linked To: ISLAMIC REPUBLIC OF IRAN BROADCASTING).

   Designated pursuant to section 7(a)(vii) of E.O. 13846 for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to E.O. 13628, which was revoked and superseded by E.O. 13846.

6. ZABIHPOUR, Ameneh Sadat (Arabic: آمنه سادات ذبیح پور) (a.k.a. ZABIH POUR, Ameneh Sadat; a.k.a. ZABIHPOUR AHMADI, Ameneh Sadat (Arabic: آمنه سادات ذبیح پور احمدی)), Tehran, Iran; DOB 07 Aug 1984; POB Babol, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; Passport 09324611 (Iran) expires 05 Jul 2017 (individual) [IRAN- EO13846] (Linked To: ISLAMIC REPUBLIC).OF IRAN BROADCASTING

   Designated pursuant to section 7(a)(vii) of E.O. 13846 for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REPUBLIC OF IRAN BROADCASTING, a person whose property and interests in property are blocked pursuant to E.O. 13628, which was revoked and superseded by E.O. 13846.

Dated: November 16, 2022.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25301 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On September 8, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individual:

1. HEIDARI, Rahmatollah (Arabic: رحمت اله حیدری), Iran; DOB 22 Sep 1985; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 2392019630 (Iran) (individual) [NPWMD] [IFSR] (Linked To: BAHARESTAN KISH COMPANY).

   Designated pursuant to section 1(a)(iv) of Executive Order 13382 of June 28, 2005, "Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters," 70 FR 38567 (E.O. 13382) for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, BAHARESTAN KISH COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13382.

Entities:

1. BAHARESTAN KISH COMPANY (Arabic: شرکت بهارستان کیش), Sheikh Fazlollah Highway, Teimuri Blvd, before Sharif University Metro Station, Yas Building, Number 116, Fifth Floor, Unit 17, Tehran, Iran; Sheikh Fazlollah Highway, Teimuri Blvd, before Sharif University Metro Station, Yas Building, Number 116, Fifth Floor, Unit 18, Tehran, Iran; Sheikh Fazlollah Highway, Teimuri Blvd, before Sharif University Metro Station, Yas Building, Number 166, Fifth Floor, Unit 19, Tehran, Iran; Sa'adat Abad, Farhang Boulevard, East 18th Street, No. 47, Tehran 1997857976, Iran; Exhibition Industrial Town, Number 2, EX35, First Floor, Unit 2, Kish Island 7941659854, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; National ID No. 10861531217 (Iran); Tax ID No. 411146547979 (Iran); Registration Number 1480 (Iran) [NPWMD] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. DESIGN AND MANUFACTURING OF AERO-ENGINE COMPANY (Arabic:شركت طراحى و ساخت موتورهاي هوايي) (a.k.a. DESIGN AND MANUFACTURE OF AIRCRAFT ENGINES; a.k.a. IRANIAN TURBINE MANUFACTURING INDUSTRIES; a.k.a. TURBINE ENGINE MANUFACTURING CO.; f.k.a. TURBINE ENGINE MANUFACTURING PLANT; a.k.a. "DAMA"; a.k.a. "SAMT"; f.k.a. "TEM"), Shishesh Mina Street, Karaj Special Road, Tehran, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; National ID No. 14005160213 (Iran); Registration Number 22142 (Iran); alt. Registration Number 477457 (Iran) [NPWMD] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. PARAVAR PARS COMPANY (Arabic: شركت پرآورپارس) (a.k.a. PARAVAR PARS AEROSPACE RESEARCH AND ENGINEERING SERVICES; a.k.a. PARAVAR PARS AEROSPACE RESEARCH INSTITUTE; a.k.a. PARAVAR PARS ENGINEERING AND SERVICES AEROSPACE RESEARCH COMPANY), 13 km of Shahid Babaei Highway, after Imam Hossein University, Next to Telo Road, Tehran, Iran; Website www.paravar-pars.com; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 1992; National ID No. 10101373495 (Iran); Registration Number 93240 (Iran) [NPWMD] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS AIR FORCE).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS AIR FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. SAFIRAN AIRPORT SERVICES (a.k.a. SAFIRANAS; a.k.a. SAFRAN AIRPORT SERVICES), No 36 Esfandyar Boulevard, Valie-Asr Avenue, Tehran 19686 53953, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Type: Service activities incidental to air transportation [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(vii) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect to Specified Harmful Foreign Activities of the Government of the Russian Federation," 86 FR 20249 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

Dated: September 8, 2022.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25302 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List) based on OFAC's determination that one or more

applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea M. Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On October 6, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals:

1. MAJID, Vahid Mohammad Naser (a.k.a. MAJID, Vahid (Arabic: وحيد مجيد)), Tehran, Iran; DOB 15 Aug 1964; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 3874409929 (Iran); Second Brigadier General (individual) [IRAN-TRA] (Linked To: IRANIAN CYBER POLICE).

   Designated pursuant to section 1(a)(iii)(A) of Executive Order 13846 of August 6, 2018, "Reimposing Certain Sanctions With Respect to Iran" (E.O. 13846), 83 FR 38939, 3 CFR, 2019 Comp., p. 854, for, on or after November 5, 2018, having materially assisted, sponsored, or provided financial, material, or other technological support for, or goods or services to or in support of, the IRANIAN CYBER POLICE*, an Iranian person whose property and interests in property are blocked pursuant to E.O. 13628..

2. ZAREPOUR, Eisa (Arabic: عیسی زارعپور) (a.k.a. ZAREPOUR, Isa; a.k.a. ZAREPOUR, Issa), Iran; DOB 21 Apr 1980; POB Eslamabad-e Gharb, Kermanshah, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport E96027104 (Iran) expires 29 Sep 2020; alt. Passport U39823438 (Iran) expires 13 Nov 2021; alt. Passport E20082749 (Iran) expires 21 Jan 2016; National ID No. 3341246576 (Iran) (individual) [IRAN-TRA].

   Designated pursuant to section 7(a)(v) of E.O. 13846 for having engaged in censorship or other activities with respect to Iran on or after June 12, 2009, that prohibit limit, or penalize the exercise of freedom of expression or assembly by citizens of Iran, or that limit access to print or broadcast media, including the facilitation or support of intentional frequency manipulation by the Government of Iran or an entity owned or controlled by the Government of Iran that would jam or restrict an international signal.

3. JAVANI, Yadollah (Arabic: یدالله جوانی), Iran; DOB 1962; POB Isfahan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Deputy Political Commander (individual) [IRGC] [IFSR] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

   Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 of September 28, 2010, "Blocking Property of Certain Persons With Respect to Serious Human Rights Abuses by the Government of Iran and Taking Certain Other Actions" (E.O. 13553), 75 FR 60567, 3 CFR, 2011 Comp., p. 253, for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

4. SAJEDINIA, Hossein (Arabic: حسین ساجدی نیا) (a.k.a. SAJEDI-NIA, Hossein), Iran; DOB 21 Mar 1962 to 20 Apr 1962; POB Isfahan, Isfahan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Deputy Operations

Commander (individual) [IRAN-HR] (Linked To: LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN).

Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13553.

5. VAHIDI, Ahmad (Arabic: احمد وحیدی) (a.k.a. CHERAGHI, Ahmad Shah), c/o MODAFL, Tehran, Iran; DOB 27 Jun 1958; POB Shiraz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Brigadier General (individual) [NPWMD] [IFSR] [IRAN-HR].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 for being an official of the Government of Iran or a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

6. NEJAT, Hossein (Arabic: حسین نجات) (a.k.a. ZIBAEE NEJAD, Mohammad Hossein (Arabic: محمدحسین زیبایی‌نژاد)), Tehran, Iran; DOB Mar 1955 to Mar 1956; POB Shiraz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; IRGC Brigadier General (individual) [IRGC] [IFSR] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

   Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

7. RAHIMI, Hossein (Arabic: حسین رحیمی), Tehran, Iran; DOB Mar 1963 to Mar 1964; POB Markazi Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Police chief of Tehran (individual) [IRAN-HR] (Linked To: LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN).

   Designated pursuant to section 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the LAW ENFORCEMENT FORCES OF THE ISLAMIC REPUBLIC OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13553.

Dated: October 6, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–25304 Filed 11–18–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 98–46 and 97–44

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burdeninvites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The

IRS is soliciting comments concerning LIFO Conformity Requirements.

DATES: Written comments should be received on or before January 20, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Number 1545–1559–LIFO Conformity Requirements'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Martha R. Brinson, at (202)317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: LIFO Conformity Requirements.

OMB Number: 1545–1559.

Revenue Procedure Numbers: 98–46 and 97–44.

Abstract: Revenue Procedure 97–44 permits automobile dealers that comply with the terms of the revenue procedure to continue using the LIFO inventory method despite previous violations of the LIFO conformity requirements of Internal Revenue Code section 472(c) or (e)(2). Revenue Procedure 98–46 modified Revenue Procedure 97–44 by allowing medium-and heavy-duty truck dealers to take advantage of the favorable relief provided in Revenue Procedure 97–44.

Current Actions: There are no changes in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 20 mins.

Estimated Total Annual Burden Hours: 100,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 9, 2022.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2022–25298 Filed 11–18–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0820]

Agency Information Collection Activity: Adaptive Sport Grant Application

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 20, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov;* or Joshua McCoy, National Veterans Sports Programs and Special Events (12RPS5), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email: *Joshua.McCoy1@va.gov.* Please refer to ''Application for Adaptive Sports Grant, OMB Control No. 2900–0820'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0820'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C 521A.

Title: Application for Adaptive Sports Grant.

OMB Control Number: 2900–0820.

Type of Review: Extension of a currently approved collection.

Abstract:

Legal authority for this data collection is found under 38 U.S.C. 521A that authorizes and mandates the collection of data during the grant application, implementation to include quarterly and annual reporting, and closeout phases of the adaptive sports grant. Mandated collection of data allows measurement and evaluation of the adaptive sports grant program, the goal of which is providing adaptive sport opportunities for disabled veterans and members of the Armed Forces.

The information will be used by VA to evaluate multiple criteria to confirm grantee eligibility, to score grantee proposals according to application criteria, and to ensure program efficacy and appropriate use of grant funds. The application information will indicate

whether and to what extent a grant program is likely to be successful in meeting the program's intent for providing adaptive sports opportunities for disabled veterans and members of the Armed Forces.

Affected Public: Private sector non-profit.

Estimated Annual Burden: 83 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annual.

Estimated Number of Respondents: 250.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–25313 Filed 11–18–22; 8:45 am]

BILLING CODE 8320–01–P

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1

Requirements for Additional Traceability Records for Certain Foods

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 20, 2023. For the applicable compliance dates, see section VI ''Effective and Compliance Dates'' in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose and Coverage of the Rule

This final rule, which is part of FDA's implementation of FSMA (Pub. L. 111–353), establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the Agency has determined these additional requirements are appropriate and necessary to protect the public health in accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

B. Summary of the Major Provisions of the Final Rule

The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food tracing. The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through

processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

The final rule requires persons who manufacture, process, pack, or hold an FTL food to establish and maintain a traceability plan that, among other things, describes their procedures for maintenance of records under the new requirements, identification of FTL foods handled, and assignment of traceability lot codes to FTL foods. Entities that grow or raise an FTL food (other than eggs) will also need to keep (as part of their traceability plan) a farm map showing the area in which the food is grown or raised, including geographic coordinates for the growing/raising area. Harvesters and coolers of raw agricultural commodities (RACs) (not obtained from a fishing vessel) that are on the FTL must keep records of their activities and provide information on them to the initial packers of these RACs. These initial packers, along with the first land-based receivers of FTL foods obtained from a fishing vessel, as well as entities that transform an FTL food (by manufacturing/processing a food or by changing the food or its packaging or labeling), must assign a traceability lot code to the food to help ensure accurate identification of the food as it moves through the supply chain, as well as maintain other records relating to their activities. Shippers and receivers of FTL foods must keep records of these actions, and shippers must provide the traceability lot code and other information identifying the food to the recipients of the food, including information relating to the traceability lot code source (*i.e.,* the entity that assigned the traceability lot code to the food). To avoid disclosing confidential information about their suppliers, instead of directly identifying the traceability lot code source of an FTL food, the shipper may instead choose to provide a traceability lot code source ''reference,'' such as an FDA Food Facility Registration number or a web address (which could be configured to require authentication for access), that provides an alternative means for FDA to identify and contact the traceability lot code source for the food. Taken together, these core subpart S requirements establish a structure for maintaining and providing traceability information that will enable FDA to more rapidly and effectively identify the source of contamination when investigating a foodborne illness outbreak than is possible under existing traceability recordkeeping requirements.

The final rule exempts certain small producers (including small produce farms, shell egg producers, and other producers of RACs) and, at the other end of the supply chain, certain small retail food establishments (RFEs) and restaurants. The rule also provides several other exemptions, including, but not limited to, those for the following: farms when food is sold or donated directly to consumers; food produced and packaged on a farm whose packaging maintains product integrity and prevents subsequent contamination; foods that receive certain types of processing, including produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, shell eggs that receive a certain treatment, foods that are subjected to a kill step, and foods changed such that they are no longer on the FTL; produce rarely consumed raw; certain raw bivalve molluscan shellfish; persons who manufacture, process, pack, or hold FTL foods during or after the time when the food is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA); commingled RACs (not including fruits and vegetables subject to the produce safety regulation); RFEs and restaurants purchasing directly from a farm; certain ad hoc purchases by RFEs and restaurants from other such entities; farm to school and farm to institution programs; fishing vessels; transporters; nonprofit food establishments; and food for research or evaluation. (See section V.E of this document for more information on exemptions provided in the final rule.)

In addition to the exemptions codified in the final rule, the rule establishes procedures under which persons may request modified requirements or an exemption from the new traceability recordkeeping requirements for a specific food or a type of entity on the grounds that application of the requirements to that food or type of entity is not necessary to protect the public health. The rule also establishes procedures for requesting a waiver of one or more of the requirements for an individual entity or a type of entity on the grounds that having to meet the requirements would result in an economic hardship due to the unique circumstances of that entity or type of entity.

The rule specifies that persons subject to subpart S may have another entity establish and maintain required records on their behalf, although the person remains responsible for ensuring the records can be provided onsite to FDA within 24 hours of our request for official review. In addition, when necessary to help prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to public health, firms must provide an electronic sortable spreadsheet containing information FDA requests on CTEs involving particular FTL foods for the date ranges or traceability lot codes specified in our request. Certain smaller entities are exempt from the requirement to provide this information in an electronic sortable spreadsheet, though they must still provide the information in other electronic or paper form. To help speed our access to information in such exigent circumstances, we may request the information remotely (*e.g.,* by phone) instead of onsite at the entity's place of business.

In response to many comments expressing concern about the ability of some entities to come into compliance within 2 years after the rule's effective date (as proposed), the final rule extends the compliance date for all persons subject to the rule to 3 years after the effective date. In this interim period, we intend to provide outreach and training, as well as guidance and other materials, to help all sectors of the food industry come into compliance with the new traceability recordkeeping requirements applicable to them under the new regulation.

C. Legal Authority

FSMA directs FDA to publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under the FD&C Act and existing regulations, for facilities that manufacture, process, pack, or hold foods FDA designates. FSMA also directs FDA to designate the foods for which such additional recordkeeping requirements are appropriate and necessary to protect the public health.

D. Costs and Benefits

This final rule will impose compliance costs on covered entities by increasing the number of records that are required for covered foods. Entities that manufacture, process, pack, or hold covered foods will incur costs to establish and maintain a traceability plan and traceability records and one-time costs of reading and understanding the rule. Some firms may also incur initial and recurring capital investment and training costs for systems that will enable them to keep, maintain, and make available to other supply chain entities (and to us upon our request)

their traceability records. We estimate that the present value of costs of the rule over 20 years ranges from about $0.7 billion to $24.6 billion, with a primary estimate of about $6 billion in 2020 dollars at a 7 percent discount rate, and from $0.8 billion to $33.7 billion, with a primary estimate of $8.2 billion at a 3 percent discount rate. At a 7 percent discount rate, annualized costs range from about $63 million to $2.3 billion, with a primary estimate of $570 million per year. At a 3 percent discount rate, annualized costs range from about $53 million to $2.3 billion, with a primary estimate of $551 million per year.

By allowing faster identification of contaminated foods and increasing rates of successful tracing completions, the rule will result in public health benefits if foodborne illnesses directly related to those outbreaks are averted. This might also lead to more efficient use of FDA and industry resources needed for outbreak investigations by potentially resulting in more precise recalls and avoidance of overly broad market withdrawals and advisories for covered foods. We estimate public health benefits using several case studies of outbreak tracebacks for four pathogens associated with illnesses caused by covered foods. We calculate these benefits based on an estimated 83 percent reduction of traceback time resulting from the requirements of this rule. These benefits have a tendency toward underestimation of the total public health benefits because these four pathogens do not represent the total burden of all illnesses associated with foods on the FTL. However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both illnesses and benefits associated with listed foods. The present value of health benefits over 20 years ranges from about $0.6 billion to $23.7 billion, with a primary estimate of $8.3 billion at a 7 percent discount rate, and from about $0.9 billion to $34.5 billion, with a primary estimate of $12.0 billion at a 3 percent discount rate. The annualized monetized health benefits range from $59 million to $2.2 billion, with a primary estimate of $780 million at a 7 percent discount rate, and from $61 million to $2.3 billion, with a primary estimate of $810 million at a 3 percent discount rate.

The present value of (non-health) benefits from avoiding overly broad recalls and market withdrawals and advisories over 20 years ranges from about $2.5 billion to $18.8 billion, with a primary estimate of $6.1 billion at a 7 percent discount rate, and from about $3.6 billion to $27.3 billion, with a primary estimate of $8.9 billion at a 3 percent discount rate. At a 7 percent discount rate over 20 years, these benefits range from $233 million to $1.8 billion, with a primary estimate of $575 million. At a 3 percent discount rate over 20 years, these benefits range from $242 million to $1.8 billion, with a primary estimate of $596 million. Additional benefits of the rule may include increased food supply system efficiencies, such as improvements in supply chain management and inventory control; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions by consumers; reduction of food waste; and other food supply system efficiencies due to a standardized approach to traceability, including an increase in transparency and trust and potential deterrence of fraud.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation or acronym	What it means
ASN	Advance shipping notice.
BOL	Bill of lading.
CSA	Community supported agriculture.
CTE	Critical tracking event.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOIA	Freedom of Information Act.
FSIS	Food Safety and Inspection Service.
FSMA	FDA Food Safety Modernization Act.
FTL	Food Traceability List.
FTE	Full-time equivalent employee.
GPS	Global positioning system.
HACCP	Hazard analysis and critical control point.
KDE	Key data element.
LACF	Low-acid canned food.
NSSP	National Shellfish Sanitation Program.
OMB	Office of Management and Budget.
PTI	Produce Traceability Initiative.
RCR	Rarely consumed raw.
RAC	Raw agricultural commodity.
RTE	Ready-to-eat.
RFR	Reportable Foods Registry.
SECG	Small entity compliance guide.
SOI	Standards of identity.
SME	Subject matter expert.
USDA	U.S. Department of Agriculture.
WGS	Whole genome sequencing.

III. Background

A. Need for the Regulation/History of This Rulemaking

On January 4, 2011, President Obama signed FSMA (Pub. L. 111–353) into law. As a component of FSMA's overhaul of U.S. food safety law to ensure the safety and security of the nation's food supply, section 204 of FSMA requires FDA to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods the Agency designates as high risk to facilitate the rapid and effective traceability of such foods. These recordkeeping requirements are additional to the food traceability requirements under section 414 of the FD&C Act (21 U.S.C. 350c) (added to the FD&C Act in title III, subtitle A, section 306, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188)) and the implementing regulation in subpart J of part 1 of title 21 of the Code of Federal Regulations (CFR) (§§ 1.326 to 1.368) (the subpart J regulation).

Congress directed FDA to adopt the subpart J recordkeeping requirements to allow the Agency to identify the immediate previous sources and immediate subsequent recipients of foods (commonly referred to as ''one-up, one-back'' recordkeeping) to address credible threats of serious adverse health consequences or death to humans or animals. We issued a final rule promulgating the subpart J regulation in 2004 (69 FR 71562, December 9, 2004).

In the case of a foodborne illness outbreak or evidence of contaminated food, the ability to follow the movement of foods through the supply chain—called product tracing or traceability—helps government agencies identify the points in the food supply chain, including the source of the product, where contamination may have occurred and, working with industry, remove the food from the marketplace. Efficient traceability enables the government and the food industry to take action more quickly to prevent illnesses and reduce economic harm.

In the years following the adoption of the subpart J regulation, FDA has learned that the one-up, one-back recordkeeping requirements in those regulations do not capture all the data elements necessary to effectively and rapidly link shipments of food through each point in the supply chain. Among the significant gaps in the subpart J requirements are the following:

- The lack of coverage of all sectors involved in food production,

distribution, and sale (*e.g.,* farms and restaurants are exempt);

- The lack of uniform data collection (*e.g.,* regarding the source of food ingredients used in each lot of finished product; no requirement to record a lot code or other identifier for all foods); and
- An inability to link incoming product with outgoing product within a firm and from one point in the supply chain to the next (see 85 FR 59984 at 59990, September 23, 2020).

These shortcomings of the subpart J regulation have hindered FDA outbreak investigations in many ways, including by making it more difficult to obtain tracing information from point-of-service firms that are exempt from the regulations. Even when such information is available, the records required under subpart J often are inadequate to facilitate swift and accurate traceback through the distribution chain to the producer of a contaminated food.

Recognizing the need for improvement in food traceability, in section 204(d)(1) of FSMA, Congress directed the Agency to adopt additional recordkeeping requirements to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals resulting from foods being adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded with respect to allergen labeling under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). The additional recordkeeping requirements set forth in this final rule, which will be codified in 21 CFR part 1, subpart S (the subpart S regulation), will help FDA more effectively follow the movement of food products and ingredients on the FTL (''FTL foods'') both backward and forward throughout the supply chain.

Even before the enactment of FSMA, FDA had been considering ways to improve food product traceability and increase the speed and accuracy of our traceback and traceforward investigations, including holding public meetings and engaging in a pilot tracing project. Following the enactment of FSMA, FDA continued its work to improve food product traceability and to lay the groundwork for this rulemaking. Section 204(a) of FSMA directed FDA to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food. At FDA's request, and in accordance with that provision, the Institute of Food Technologists (IFT) conducted two product tracing pilots and issued a 2012 final report to FDA regarding those pilot studies (Ref. 1). In 2016, in accordance with section 204(a)(3) of FSMA, FDA submitted a Report to Congress that discussed the findings of the pilot projects and included recommendations for improving the tracking and tracing of food (Ref. 2).

In addition, on February 4, 2014, we issued a notice in the **Federal Register** (79 FR 6596) seeking public comment, scientific data, and other information to inform our draft approach to identifying high-risk foods. Section 204(d)(2)(A) of FSMA requires that the designation of high-risk foods be based on the following factors:

- The known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention (CDC);
- the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
- the point in the manufacturing process of the food where contamination is most likely to occur;
- the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

On September 23, 2020, FDA published a proposed rule entitled ''Requirements for Additional Traceability Records for Certain Foods'' (85 FR 59984), to establish additional recordkeeping requirements for foods on the FTL, a proposed version of which was made available in the public docket for the rulemaking as well as on our website (Ref. 3). At the same time, we made available our ''Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223)'' (RRM–FT Methodological Approach Report) (Ref. 4), which described how we generated the results from the risk-ranking model for food tracing (''RRM–FT'' or ''the Model'') that we used to help develop the FTL. The Model, which was peer reviewed, used a semiquantitative, multicriteria decision analysis risk-ranking approach, consistent with the factors set forth in section 204(d)(2) of FSMA, and it was operationalized with data relevant to those factors to generate results for foods we regulate (85 FR 59984 at 59991). We also made available a memorandum entitled ''Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing'' (Ref. 5), explaining how we designated the foods on the FTL using the results of the RRM–FT.

As stated in the preamble to the proposed rule, the proposed traceability requirements were focused on having persons who manufacture, process, pack, or hold FTL foods maintain and share specific key data elements (KDEs) for certain CTEs in a food's supply chain, consistent with the developing industry consensus approach to food tracing. The information that firms would need to keep and send to their supply chain partners would vary depending on the type of supply chain activity they were performing with respect to an FTL food, from production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes and traceability lot code sources (*i.e.,* the entity that assigned the traceability lot code) for FTL foods, as well as linking the traceability lot codes to other information identifying the foods as they move through the supply chain.

Since the publication of the proposed rule, there is still a need for improved traceability. Foodborne illness continues to have serious public health impacts. In the United States, there are approximately 800 foodborne illness outbreaks reported every year from all foods according to CDC outbreak surveillance reports, including about 200 outbreaks caused by foods covered by this rule (Refs. 6, 16). We estimate that nearly 770,000 illnesses annually in the United States are associated with foods covered by the rule (Ref. 16). Further, many Americans, besides those who become ill, are impacted by supply chain disruptions and temporary shortages due to overly broad recalls and less than fully efficient traceback investigations. A lack of consistent recordkeeping continues to hinder FDA's traceback investigations (Ref. 7). As described in the proposed rule, we have sometimes been unable to determine links between illnesses and specific product distribution due to inconsistent, unstandardized recordkeeping, lack of a deliberate method to connect records, and the frequent lack of lot tracing regarding distribution to specific retail locations. A lack of effective traceability

throughout the food supply has led to delays in product recalls and notification to the public, allowing potentially contaminated foods to remain on the market longer. While this rulemaking does not prevent the occurrence of outbreaks, these recordkeeping requirements can help identify the source of the contaminated food more quickly, potentially reducing the severity of the outbreak.

While parts of the industry have made progress in implementing traceability systems, the success has been confined to a subset of firms and product types, primarily in large firms where there is vertical integration in the supply chain or across the production of relatively homogenous products. Coordination through the supply chain across a wide range of firms varying in size, product mix, and production systems remains burdensome for many firms, especially those not vertically integrated. It is unlikely that without regulation the industry will ever achieve the level of systematic uniformity, accuracy, and efficiency needed to protect public health. The final rule—which applies only to covered foods and maintains the CTE/KDE structure of the proposed rule, but with modifications to address concerns raised in comments—provides a uniform set of requirements and expectations for traceability, reducing the challenges of coordination through the supply chain. The rule will greatly improve the efficiency and accuracy of FDA's traceback and traceforward operations, which should have a direct impact on the public health by allowing us to more quickly identify the source of contaminated food and remove it from the market.

B. Summary of Comments to the Proposed Rule

Although many comments express support for the proposed rule and its purposes, a number of comments request changes to simplify the traceability recordkeeping and record-sending requirements and reduce the burden of the rule on entities throughout the supply chain. Several comments ask that we reduce and simplify the CTEs for which records must be kept and the KDEs that firms must maintain for each event. While many comments acknowledge the importance of documenting the traceability lot code as an FTL food moves through the supply chain, several question how much information on the product and its producer is necessary or appropriate to share with downstream supply chain members.

Some comments ask that we broaden the circumstances under which a traceability lot code may be assigned. Several comments express concern about the feasibility of establishing requirements applicable to the ''first receiver'' of an FTL food, suggesting that others in the supply chain would be better suited to having and maintaining the required KDEs. Several comments request that we streamline the KDEs to be documented for shipping, receiving, and transformation events, and revise the information that shippers would be required to send to the recipients of the FTL foods, including the requirements applicable to farms.

Several comments ask that we clarify the scope of proposed exemptions from the FTL recordkeeping requirements, with some requesting that we broaden those exemptions to cover additional foods and/or firms. In particular, many comments maintain that having to comply with the rule would impose an undue burden on small farms and small RFEs, as well as other small supply chain firms. In addition, some comments request that we establish additional exemptions (different from those we proposed) for certain foods and supply chain entities.

Many comments object to the proposed requirement to make available to FDA, when necessary to help prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to public health, an electronic sortable spreadsheet containing information in required traceability records for specified FTL foods and date ranges. In addition, although the proposed rule would permit firms to use existing records to meet the proposed recordkeeping requirements, several comments assert that the proposed rule would require unnecessary creation of duplicative records.

The comments generally express support for the proposed RRM–FT we used to determine the foods on the FTL, although some comments take issue with certain aspects of the Model as well as how we used it to generate the FTL. In addition, many comments request clarification as to whether particular foods or food products are on the FTL, and several comments ask that the final FTL not include several foods that were on the proposed FTL.

C. General Overview of the Final Rule

In response to comments we received, we have made several changes to the proposed traceability recordkeeping requirements for FTL foods that will make the final rule easier for supply chain entities to understand and comply with, while still ensuring that the rule substantially improves FDA's ability to respond quickly and effectively to foodborne illness outbreaks involving foods on the FTL. We believe the final rule more closely aligns the FTL recordkeeping requirements with developing industry best practices and effectively addresses stakeholder concerns about the complexity of the requirements and the need to protect the confidentiality of commercial information regarding suppliers.

The final rule includes changes to the requirements for a traceability plan (referred to in the proposed rule as ''traceability program records''), including more streamlined requirements for what must be included in the plan and deletion of the proposed requirement to maintain a list of FTL foods shipped. In addition, for those who grow or raise an FTL food, the final rule requires the retention of a relevant farm map containing geographic coordinates instead of the proposed records documenting the growing area coordinates for individual traceability lots of the food.

The final rule also includes changes to certain of the CTEs for which persons subject to the rule must maintain KDEs. Instead of requiring the ''first receiver'' of an FTL food (which the proposed rule had defined as the first person other than a farm who purchases and takes physical possession of an FTL food that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested) to maintain information on the origination, harvesting, cooling, and packing of food, the final rule places similar responsibility on the initial packer of a RAC (other than a food obtained from a fishing vessel) or the first land-based receiver of a food obtained from a fishing vessel. The KDEs required for shipping and receiving FTL foods have been streamlined and the shipping KDEs no longer apply to shipments that occur before a RAC is initially packed. A new CTE has been added to explain the requirements specific to harvesting and cooling of RACs before they are initially packed, and the CTEs for ''transformation'' and ''creation'' of an FTL food have been combined and clarified under a single transformation CTE.

The final rule includes changes to protect the privacy of individuals employed by supply chain entities and the confidentiality of business information concerning suppliers. To address the former, the final rule only requires firms to identify a point of contact within their traceability plan and the point of contact can be identified as a job title (along with a phone number), instead of the person's

name; all of the proposed requirements to provide a point of contact as part of the records sent to other supply chain entities have been deleted. In response to concerns about having to pass forward information on the traceability lot code generator for an FTL food, which could reveal information about a firm's suppliers, the final rule permits firms to provide a traceability lot code source reference, which is an alternative method through which information on the traceability lot code source could be made available to FDA, such as through a web address that provides the location description for the traceability lot code source. If the firm uses a web address as the traceability lot code source reference, the associated website may employ reasonable security measures, such as only being accessible to a government email address, provided the Agency has access to the information at no cost and without delay.

The final rule includes revisions to several of the proposed exemptions from the rule (generally broadening or clarifying the exemptions). We revised exemptions for certain small producers, and we expanded the exemption for farms when food is sold directly to consumers, such that it now covers donations as well as sales. We expanded the exemptions for foods that are subjected to a kill step and commingled RACs to extend these partial exemptions to include certain situations where it is known that the food will be subjected to a kill step (by an entity other than an RFE, restaurant, or consumer) or be commingled in the future, and to include foods that will be changed such that they are no longer on the FTL. Regarding the co-proposal for the exemption of small RFEs (full exemption vs. exemption from the requirement to make available, in certain circumstances, an electronic sortable spreadsheet containing requested tracing information), we have elected to fully exempt certain small RFEs and restaurants but also exempt from the requirement to provide a sortable spreadsheet somewhat larger but still relatively small RFEs and restaurants (along with certain farms and other entities that are relatively small). In addition, in response to comments we have added other partial or full exemptions from the regulations, including for the following: raw bivalve molluscan shellfish; persons who manufacture, process, pack, or hold certain foods subject to regulation by the USDA; certain ad hoc purchases by RFEs and restaurants from other such entities; and food for research or evaluation.

We have not made any changes to the risk-ranking model that we developed, consistent with the factors set forth in section 204(d)(2)(A) of FSMA, to determine which foods should be placed on the FTL. With respect to the FTL itself, on January 11, 2021, we provided additional clarity on the foods on the proposed FTL in response to stakeholder input following the release of the proposed rule (Ref. 8). With the publication of the final rule, we are providing additional description and clarification of FTL foods, including examples of foods that are and are not considered part of certain commodity designations on the FTL.

Finally, in response to the many comments expressing concern about the ability of farms, manufacturers, distributors, retail food establishments, and others to come into compliance with the new traceability recordkeeping requirements within 2 years after the effective date of the final rule, as we had proposed, we are extending the compliance date for all persons subject to the rule to 3 years after its effective date (which is 60 days after the date of publication of the final rule in the **Federal Register**).

IV. Legal Authority

Under section 204(d) of FSMA, in order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, FDA was required to publish a proposed rule to establish recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act and the subpart J regulation, for facilities that manufacture, process, pack, or hold foods that FDA designates under section 204(d)(2) of FSMA as high-risk foods. We published the required proposed rule on September 23, 2020, and we are completing the rulemaking process with this final rule by establishing the subpart S regulation. We are promulgating this regulation under the following authorities:

- Section 204 of FSMA, the specific provisions of which are discussed throughout this document;
- Section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which provides FDA with the authority to promulgate regulations for the efficient enforcement of the FD&C Act; and
- Sections 311, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 243, 264, and 271), which relate to communicable disease, including by providing FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession (see section 361(a) of the PHS Act).

The legal authority for this rulemaking is discussed further in the preamble to the proposed rule (see 85 FR 59984 at 59993 and 59994).

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 1,100 comment submissions on the proposed rule to establish traceability recordkeeping requirements for persons who handle FTL foods (including comments on the FTL itself and the risk-ranking model used to develop it) by the close of the comment period, each containing one or more comments on one or more issues. We received comments from consumers, consumer groups, trade organizations, farmers, industry (*e.g.,* food manufacturers, processors, distributors), public health organizations, State and local governments, foreign governments and organizations, and others.

We describe and respond to the comments in Sections V.B through V.U of this document, as well as certain comments in Sections VI through IX. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Food Traceability List

Included as a reference to this final rule (and as seen in table 1) is the FTL, which sets forth the foods that will be subject to the subpart S requirements. In accordance with section 204(d)(2)(B) of FSMA and § 1.1300 of the final rule, we are publishing the FTL on our website concurrently with the issuance of this final rule. We included as a reference to the proposed rule the RRM–FT Methodological Approach Report (Ref.

4), which discusses the risk-ranking model for food tracing we used to determine the foods on the FTL. As stated in the proposed rule, the RRM–FT uses a semiquantitative, multicriteria decision analysis risk-ranking approach that is consistent with the factors specified in section 204(d)(2) of FSMA for use in designating the foods that will be subject to the additional traceability recordkeeping requirements and is operationalized with data relevant to those factors.

Using the results of the RRM–FT, we tentatively identified foods for which additional traceability records will be required, as we discussed in the Designation of the FTL Memorandum (Ref. 5). Based on that analysis, we developed a tentative list of FTL foods (Ref. 3). In response to questions and comments we received regarding the tentative FTL, in January 2021 we updated the table on our website showing the tentative FTL (Ref. 8). The updated table did not reflect a change in which foods were on the tentative FTL, but it included text to clarify the food products that are included in certain categories of foods on the tentative FTL.

Table 1 shows the current FTL that we are publishing with this final rule. The FTL being published with the final rule has not changed from the tentative list issued with the proposed rule. However, we have provided additional revisions to the descriptions of the commodities on the FTL to address some of the comments we received and provide greater clarity. The process for changing the FTL, which includes advance notice and an opportunity for the public to provide comment, is discussed in Section V.T of this document. We intend to update the FTL approximately every 5 years, subject to available resources. For the initial update to the FTL following publication of the final rule, we will take into consideration the compliance date for the final rule when deciding when to begin the process.

TABLE 1—FOOD TRACEABILITY LIST

Food traceability list	Description
Cheeses, other than hard cheeses, specifically:	
• Cheese (made from pasteurized milk), fresh soft or soft unripened.	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from pasteurized milk), soft ripened or semi-soft.	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from unpasteurized milk), other than hard cheese [1].	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut).	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Finfish (fresh and frozen), specifically:	
• Finfish, histamine-producing species.	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
• Finfish, species potentially contaminated with ciguatoxin.	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
• Finfish, species not associated with histamine or ciguatoxin.	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.[2] Siluriformes fish, such as catfish, are not included.[3]

TABLE 1—FOOD TRACEABILITY LIST—Continued

Food traceability list	Description
Smoked finfish (refrigerated and frozen).	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[4]
Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish.
Molluscan shellfish, bivalves (fresh and frozen)[5].	Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt from the requirements of the rule under § 1.1305(f).
Ready-to-eat deli salads (refrigerated).	Includes all types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads.

[1] "Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, colby cheese as defined in 21 CFR 133.118 and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.

[2] For a more comprehensive list, see Chapter 3 of the Fish and Fishery Products Hazards and Controls Guidance at *https://www.fda.gov/media/80637/download.*

[3] Data for catfish were excluded from the Risk-Ranking Model because Siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture.

[4] "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s).

[5] Under 21 CFR 123.3(h), *molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

We received several comments on the RRM–FT, the designation of foods on the FTL, and whether certain foods should or should not be included on the FTL. We respond to these comments in the following paragraphs.

1. Risk-Ranking Model for Food Tracing

(Comment 1) Several comments express general support for the RRM–FT methodology and the process FDA used to develop the FTL, as well as for our solicitation of stakeholder input. The comments maintain that the methodology is grounded in science and the process (including peer reviews) was rigorous, resulting in a targeted list of foods on the FTL. Conversely, other comments assert that the FTL fails to include key FSMA requirements and that the RRM–FT approach is not consistent with the goal or the statutory factors in section 204(d)(2)(A) of FSMA. These comments assert that the RRM–FT differs significantly from some of the FSMA requirements by adding criteria not in the statute and inappropriately merging multiple statutory factors into one Model criterion.

(Response 1) We appreciate the support for the RRM–FT and disagree with the assertions that it does not align with the statutory factors or that it differs from the FSMA requirements. As discussed in the Response to External Peer Review—Model Review (Ref. 9), subject matter experts (SMEs) reviewed the types of concerns raised in the comments when developing the draft RRM–FT, and peer reviewers generally agreed that the seven criteria we adopted were appropriately within the bounds of the FSMA-mandated factors.

(Comment 2) One comment claims that the RRM–FT methodology and the weighting used were not developed according to best practices for a multicriteria model, and the necessary expertise was not available to develop the Model appropriately. The comment maintains that the RRM–FT uses "an additive weighted approach" that is not appropriate when the model criteria are not preferentially independent because it would likely lead to some double counting of information.

(Response 2) We disagree with this comment. The results of the RRM–FT are founded on well-constructed criteria and the best available data. FDA addressed the issues raised by the comment during the peer review process (Ref. 9). As described in the final version of the RRM–FT Methodological Approach Report (Ref. 10), we recognize that mutual independence of criteria is desirable in a multicriteria-based model such as the RRM–FT. Within the constraints of the FSMA-mandated factors, we acknowledge that there are some correlations among the seven criteria or overlaps of data and information used in scoring, but we have taken steps to minimize potential overlaps. Most importantly, in cases where criteria are correlated, the RRM–FT defines them to represent separate aspects of value (of the data and information) to help ensure that the criteria represent independent preferences in ranking (see Methodological Approach Report, section 5.5 (Ref. 10)). The RRM–FT Methodological Approach Report and the peer review-model review report provide further explanation on how the RRM–FT operationalizes the seven criteria to minimize potential overlaps. FDA relied on the expertise of SMEs both within and outside of the Agency to develop the RRM–FT.

In developing the RRM–FT, we reviewed a number of available risk tools, including some developed by FDA and others from the published literature, including qualitative, semi-quantitative, and quantitative methods. We directly addressed the criteria independence issue by consulting with the project advisory group and multiple external expert panels and by considering comments and suggestions provided by peer reviewers.

(Comment 3) Many comments suggest that data used in the RRM–FT should be timely and reflect current food safety practices adopted by the industry. A few comments express support for using a 20-year timeframe (with appropriate weighting based on the year) for data for outbreaks and recalls and suggest that data older than 20 years not be used. Some comments express concern that the 20-year timeframe used in the RRM–FT is too long and suggest use of a shorter timeframe, such as 10 years, to reflect current industry practices. Whether comments prefer the use of 10 or 20 years, their concerns about older data are that it may not represent the current state of the industry because of advancements in science and food safety management, including the implementation of the produce safety regulation and the regulation on preventive controls for human food promulgated under FSMA. Furthermore, the comments assert that because industry usually attempts to address food safety problems and adopt enhanced food safety practices and mitigations to prevent recurrence of outbreaks, the use of older data may misrepresent risk. A few comments express support for the data weighting method in the RRM–FT, in which a weight of 0.4, 0.7, or 1 is applied

depending on the age of the data, but they request clarification as to whether we will always use the most recent 20 years of data and whether we will continue to use the same data weighting method in future updates of the Model.

(Response 3) We concur that data used in the RRM–FT should be timely and agree with the comment suggesting that a 20-year timeframe for outbreak and recall data is appropriate, while giving lower weight to (down-weighting) the older data. The RRM–FT incorporates a rolling data window in which the most recent 20-year data is used for scoring Criterion 1 (Frequency of Outbreaks and Occurrence of Illnesses), Criterion 7 (Cost of Illness), and Criterion 3 (Likelihood of Contamination), and within the 20-year timeframe, we down-weight older data. We believe a 20-year timeframe with down-weighting for older data provides an appropriate time window and scoring method to accurately capture the history of outbreaks and contamination associated with a commodity.

Criterion 5 (Manufacturing Process Contamination Probability and Industry-Wide Intervention) in the RRM–FT considers the current state of industry-wide interventions applied to each commodity-hazard pair. We acknowledge that industry may make concerted efforts to address food safety problems such as in response to outbreaks, and that food safety management practices may improve because of the implementation of regulations such as those for produce safety or preventive controls for human food, and these efforts are accounted for in the RRM–FT through the scoring of Criterion 5. Furthermore, to the extent that industry-wide preventive controls and interventions reduce food safety risk, the reduction in risk would also be reflected in the scoring, such as when the number of recent outbreaks (not down-weighted) is declining compared to older outbreaks, which would be down-weighted.

(Comment 4) Many comments state the RRM–FT criteria should be weighted differently, with more emphasis given to foods with validated preventive controls and less to epidemiological data. Specifically, some comments claim that the RRM–FT does not give sufficient weight to the three factors specified by Congress in FSMA section 204(d)(2)(A) that are related to contamination and production and processing activities, *i.e.,* factors (ii) (the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food), (iii) (the point in the manufacturing process of the food where contamination is most likely to occur), and (iv) (the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination). According to the comments, the RRM–FT gives too much weight to the other three FSMA factors, which are related to outbreaks or are epidemiological in nature. The comments assert that because the RRM–FT has five criteria to represent the three factors that are epidemiological in nature, this places too much emphasis on those factors in comparison to the two criteria that represent the factors related to the nature of food and manufacturing activities. The comments maintain that the over-emphasis of epidemiology in the Model contradicts Congressional intent and results in certain RACs such as leafy greens, herbs, tomatoes, cucumbers, peppers, and melons being deemed risky when, in the view of the comments, industry and the scientific community have greater food safety concerns about further processing of fresh produce such as fresh-cut fruits and vegetables (*e.g.,* because of a greater potential for contamination and for pathogen growth).

Conversely, other comments maintain that the Model puts too much weight on poor processing conditions rather than on inherent risk. The comments recommend that we weight criteria so that when a food goes through a validated kill step or other preventive control (including hurdle technology), the food is not on the FTL. Similarly, some comments ask FDA to weight Criterion 5 most heavily and not give too much weight to Criterion 6 (Consumption), maintaining that if there are strong industry interventions, the amount consumed is less relevant. Finally, some comments claim the sensitivity analysis in the RRM–FT is very limited and that we have not provided sufficient information to justify equal weighting of the criteria in the Model or the impact of such equal weighting on the ranking.

(Response 4) We do not agree with these comments concerning the appropriate weighting of the statutory risk factors, and the comments have not provided data to support their recommendations. As indicated in the RRM–FT Methodological Approach Report (Ref. 10), the RRM–FT uses the FSMA statutory factors to define the seven criteria used in the Model, and FDA considered different criteria weighting schemes in the approach that was peer reviewed. Peer reviewers generally agreed the Model's seven criteria were appropriate, and there was no general consensus for use of a different weighting scheme other than equal weighting of the criteria (Ref. 9). Therefore, we decided to weight the seven criteria equally in the RRM–FT. With regard to the comments requesting acknowledgment of the importance of a kill step in risk reduction, we agree and, as discussed in Section V.E.5 of this document, § 1.1305(d) of the final rule sets forth exemptions and partial exemptions for FTL foods that receive or will receive a kill step.

(Comment 5) Several comments suggest that FDA consider relevant data representative of the inherent food safety risk, including data relevant to intrinsic characteristics of the food (*e.g.,* pH, application of a validated kill step) and outbreak data from credible sources (both State and Federal Agencies). The comments assert that it is not appropriate to use outbreak data and other information from isolated events or problems specific to a particular facility or consumer misuse of the food, such as data from the Reportable Food Registry (RFR), because this information concerns facility-specific incidents that do not reflect overall risks to public health. The comments also suggest that FDA should have a scientific basis for including any food on the FTL.

(Response 5) The RRM–FT provides the scientific basis for the designation of the foods on the FTL. As described in the RRM–FT Methodological Approach Report (Ref. 10), the RRM–FT uses data and information on the intrinsic characteristics of the food and considers information on validated control measures in risk scoring. The RRM–FT uses the FDA Coordinated Outbreak Response and Evaluation (CORE) outbreak dataset (Ref. 11) that includes the CDC outbreak data for outbreaks in which the outbreak investigation demonstrated an association with FDA-regulated products. In addition, for outbreaks involving *Vibrio* spp. and marine and plant biotoxins, the Model uses data from CDC's National Outbreak Reporting System (NORS). To the extent that State agencies and other health departments report their foodborne illness outbreaks involving microbial and chemical hazards to the NORS, outbreaks relevant to FDA-regulated human foods have been considered in the RRM–FT. To apply the factors specified in FSMA section 204(d)(2)(A), it is necessary to consider both the characteristics of foods and hazards. In the RRM–FT, we classify FDA-regulated human foods into 47 commodity categories. Within each commodity

category, we identify food commodities and associated known or reasonably foreseeable hazards, *i.e.,* commodity-hazard pairs, using outbreak data, contamination data, and other information from multiple sources (Ref. 10). The RRM–FT uses RFR data as a source for scoring Criterion 3 only when sampling data are not available. When RFR data are used in the RRM–FT, these data are aggregated, *e.g.,* RFR reports from 2009 to 2019 are attributed to a commodity-hazard pair (a specific hazard in a specific food such as Shiga toxin-producing *Escherichia coli* O157 (STEC O157) in leafy greens), which minimizes the potential issue raised in the comments about overemphasis of facility-specific problems.

(Comment 6) Several comments state that the FTL should exclude foods that, according to the comments, are ''not inherently dangerous.'' Many comments maintain that fresh produce commodities have varying degrees of food safety risk; furthermore, the comments assert that fresh produce itself is not inherently risky and that risks are introduced by food production conditions and processing activities. These comments maintain that the risk of contamination is much greater with fresh-cut produce than intact RACs and that covering unprocessed produce under the food traceability rule will not improve public health. Several comments suggest that we factor production methods (*e.g.,* controlled environment vs. field environments for growing produce) and growing conditions for RACs into the RRM–FT, or that the designation of foods on the list be specific to where the food was produced. One comment states that the likelihood of contamination for fresh produce varies greatly because growing conditions vary greatly across farms and regions. The comment provides contrasting examples of fresh produce sourced from protected high tunnels irrigated with well water vs. from open fields irrigated with water from a canal near concentrated animal feeding operations. According to the comment, the risk of a fresh produce commodity (*e.g.,* leafy greens) is related to the latter type of growing environment and conditions. Therefore, the comment maintains that FDA should not require all leafy greens to meet the same traceability requirements because this would not be science-based or consistent with requirements in FSMA. Another comment asserts that, compared to field-grown leafy greens, those produced under controlled environments have a significantly lower risk of causing foodborne illness because of different risk factors (including minimal exposure to animals, potable water irrigation through root systems, minimal impacts from weather events, and other control measures). The comment suggests that such ''controlled environment-produced leafy greens'' should be given different consideration in the RRM–FT than other leafy greens.

(Response 6) We disagree with these comments, and the comments do not provide scientific data to support their assertions. As previously stated, the RRM–FT scores commodity-hazard pairs according to data and information relevant for seven criteria that account for the factors specified in FSMA section 204(d)(2)(A). As discussed in the RRM–FT Methodological Approach Report (Ref. 10), the RRM–FT criteria are related not only to the characteristics of the food but also to the production and manufacturing processes at the commodity level. For example, we evaluate the impact of fresh-cut processing by first identifying a variety of commodities under the Produce—RAC commodity category, and a variety of commodities under the Produce—Fresh Cut commodity category; for each of the commodities, we then identify known or reasonably foreseeable hazards, *i.e.,* commodity-hazard pairs for the commodities of Leafy Greens and Leafy Greens (Fresh-cut). Thus, the methodology accommodates on-farm production practices by identifying and evaluating hazards introduced on-farm (*e.g.,* STEC O157 in Leafy Greens), and it accommodates processing activities by identifying and evaluating hazards introduced in a processing facility (*e.g., Listeria monocytogenes* (*L. monocytogenes*) in Leafy Greens (Fresh-cut)). The Model then scores each commodity-hazard pair using data and information relevant to the seven RRM–FT criteria. For example, the impacts of production conditions and processing activities are reflected, on an industry-wide basis, in the data used to score Criterion 3 (Likelihood of Contamination) and the expert judgment used to score Criterion 5 (Manufacturing Process Contamination Probability and Industry-Wide Intervention). As such, the Model does consider production and manufacturing risks, as well as other aspects of risks such as the potential for the food to support growth of a pathogen (if present).

We agree with the comments that not all fresh produce is the same. Therefore, the Model identifies approximately two dozen fresh produce commodities based on the nature of the food and evaluates each of them separately, *e.g.,* Leafy Greens, Melons, Tomatoes, Stem Vegetables (see Ref. 10, Table A–2). In the Model, the identification of commodity-hazard pairs is based on available data and information, *e.g.,* foods and hazards associated with outbreaks and illnesses and detection of hazards in foods. The Model does not rank fresh produce at a more granular level than at the commodity level. Regardless of production practices (*e.g.,* field-grown vs. controlled environment), fresh produce within the same commodity group typically share similar characteristics in the potential for the food to support pathogen growth, and many contamination risk factors in controlled environments are similar to those found in traditional agriculture (Ref. 12). Moreover, we are not aware of data that warrant a separate evaluation based on production practices, and data are not available to evaluate commodity-hazard pairs at that level of granularity for the various criteria in the Model.

(Comment 7) Several comments maintain that the RRM–FT inappropriately grouped foods of different natures. According to the comments, FDA's approach to risk ranking is problematic because it groups different types of commodities together without consideration of the variety in each commodity, and, the comment claims, the risk of the commodity (*e.g.,* melons, leafy greens) varies depending on the variety (*e.g.,* watermelon vs. cantaloupe, spinach vs. lettuce). Several comments state that there are no data to suggest certain fresh herbs (*e.g.,* fresh bay leaf, makrut lime leaf, curry leaf, rosemary leaf) present any significant risk to human health or to support identification of many tropical fruits and leafy greens as high-risk foods. One comment asserts that while foods within a category may share similar characteristics in production and processing, the RRM–FT's analysis of a broad food category cannot adequately consider all the criteria because some criteria are specific to varieties, not commodities (*e.g.,* food safety technologies and innovations are usually developed for particular foods, not commodity groups). The comments suggest that we conduct individual analyses for particular foods and revise the FTL accordingly.

(Response 7) The RRM–FT considers the nature of the food through a categorization scheme that classifies FDA-regulated foods into 47 commodity categories. Furthermore, within each commodity category, the RRM–FT identifies individual commodities. In total, the RRM–FT identifies more than 200 commodities (see Ref. 10, Table A–2).

The Model does not rank commodities such as fresh produce at a more granular level than at the commodity level. We are not aware of scientific evidence that warrants a separate evaluation based on the varieties within a fresh produce commodity. Moreover, data on individual foods, such as specific varietals, are sparse and inconsistent across the variety of foods in the Model and on the FTL. For the purposes of the FTL, we determined that the appropriate level of granularity is at the level of ''commodity,'' *e.g.,* ''tomatoes (fresh)'' rather than ''Roma tomatoes'' or ''cherry tomatoes.'' Food items within the same ''commodity'' designation generally have similar characteristics, associated hazards, and production and supply chain practices and conditions, and peer review for the RRM–FT supported this approach (Ref. 13). Further, data used to assess components of the Model (*e.g.,* outbreak and illness data, likelihood of contamination, degree to which product supports growth, consumption, annual cost of illness) are available and adequate at the ''commodity'' level of granularity.

(Comment 8) A few comments assert that the RRM–FT does not adequately represent FSMA section 204(d)(2)(A) factors (iii) and (iv) (*i.e.,* ''the point in the manufacturing process of the food where contamination is most likely to occur'' and ''the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination'') and that the Model does not appropriately reflect differences in production systems and practices. According to the comments, the RRM–FT uses one criterion (Criterion 5: Manufacturing Process Contamination Probability and Industry-wide Intervention) to represent the two FSMA factors, which minimizes their impact on risk ranking, especially if there is a validated kill step for pathogens in the manufacturing process. The comments suggest that we consider more broadly the point in the overall supply chain where contamination is most likely to occur and include data to represent differences in potential contamination associated with different production, manufacturing, and handling processes and practices. The comments request that we revise the RRM–FT and the FTL to address their concerns and provide the public with an opportunity to comment on the revisions.

(Response 8) We decline to revise the RRM–FT and to solicit additional public comment before issuing the final rule. Regarding FSMA section 204(d)(2)(A) factors (iii) and (iv), these are incorporated into Criterion 5 of the RRM–FT (Manufacturing Process Contamination Probability and Industry-wide Intervention) as well as through the identification of commodity-hazard pairs under the broad range of commodity categories of FDA-regulated human foods. The commodities and the commodity categories (see Table A–1 in the RRM–FT Methodological Approach Report (Ref. 10)) represent a broad range of foods at different points in the supply chain with differences in production, manufacturing, and handling processes and practices. As discussed in the Response to External Peer Review—Model Review (Ref. 9), subject matter experts reviewed and addressed the types of concerns raised in the comments during the development of the draft RRM–FT, and peer reviewers generally agreed that the seven criteria we adopted were appropriately within the bounds of the FSMA-mandated factors, including the representation of FSMA factors (iii) and (iv) in the Model.

(Comment 9) Many comments assert that fresh produce from smaller-scale farms with relatively short supply chains (sometimes just a few miles) have lower risk than produce grown on larger farms, shipped long distance, or transformed without a kill step and shipped long distance. The comments maintain that locally grown commodities on the FTL, such as tomatoes, leafy greens, peppers, and cucumbers, do not have a greater risk than fresh crops not on the FTL. Some comments also assert that it is not scientifically sound to group locally grown and non-locally grown produce into one commodity in the RRM–FT because supply chain conditions and complexity vary between the two, so the food safety risk varies. The comments express concerns that such broad grouping will hurt the local food system, drive up the price of food, and limit the availability of fresh produce without reducing the risk of foodborne illness. Similarly, several comments claim the scoring of Criterion 5 in the RRM–FT is subjective, subject to change over time, and might not adequately represent small farms or local and regional food systems (LRFS). According to the comments, the scoring of Criterion 5, which is based on expert elicitations with several expert panels, reflects outcomes rather than root causes. One comment maintains that the size and type of production system and the length of supply chain are among the root causes of foodborne illness from fresh produce, but these factors are not adequately considered in the Model. Comments also note that the Criterion 5 score could change when industry improves production and manufacturing processes to better manage risk, which could affect both large and small operations. The comments suggest FDA obtain and use qualitative data that represent the scale and diversity of small, local farms and food businesses serving LRFS supply chains for scoring Criterion 5 and for use otherwise in the Model.

(Response 9) We do not agree that locally produced foods are inherently less risky than non-locally produced foods, and the comments do not provide scientific data to support their assertions. The Model does not differentiate locally grown fresh produce because how near to the point of sale the produce was grown does not change the characteristics of the food (*e.g.,* the potential for supporting pathogen growth) or the potential for on-farm contamination. The RRM–FT considers customary shelf life of fresh produce in scoring the potential for growth at a temperature at which the commodity (locally grown or not) is intended to be held and stored. While locally grown produce might be purchased and consumed within a time period shorter than that for non-locally grown produce, data are not available to show the potential for pathogen growth is sufficiently different between the two to result in a different score in Criterion 4 (Growth Potential, with Consideration of Shelf Life). Fresh produce commodities on the FTL, including locally grown produce, score higher than fresh produce commodities not on the FTL based on data relevant to the seven criteria in the RRM–FT. While we do not agree that locally grown FTL food is less risky than non-locally grown food, we understand that small operations may be particularly burdened by the provisions of the rule. We also understand that full traceability records may not be necessary when a consumer or RFE purchases food directly from a farm. Therefore, the final rule provides exemptions from some or all of the provisions of subpart S for certain smaller operations and in certain short supply chain situations, as discussed in sections V.E.2 and V.E.3, respectively, of this document.

With regard to the scoring of Criterion 5, FDA scores the seven criteria in the Model based on available data, both quantitative and qualitative. If quantitative data are not available for a certain criterion, the criterion is scored based on qualitative data. The RRM–FT relies on qualitative information from consultations with SMEs, including external expert panels, to score Criterion 5. The scoring of Criterion 5 is based on

the SMEs' assessments of each of the commodity-hazard pairs based on the status of industry-wide interventions as of 2019 (Ref. 10). The SMEs' assessment is based on the entire industry sector, including consideration of farms and operations of all sizes and scale collectively. It is not feasible to assess a commodity specific to the scale of a farm or LRFS supply chain because data for the seven criteria are unavailable at that level of granularity. In the peer review process, we specifically inquired about the adequacy of the expert elicitation process used to obtain qualitative data and address data gaps in the RRM–FT (Ref. 13), and there was general consensus among the peer reviewers that the process was adequate for the purpose. Changes in industry-wide interventions over time will be assessed as the data in the Model are updated in the future (see Response 488 about updating the Model).

(Comment 10) Several comments state that certain ingredients (*e.g.,* peanut butter) could be considered low risk but, because of their incorporation into many diverse foods, the magnitude of the impact if a contamination issue arises becomes greater, especially if no kill step is applied.

(Response 10) We agree that ingredients that are incorporated into many different foods have the potential to introduce widespread contamination. In the Model, we consider this possibility by including multi-ingredient foods, identifying and evaluating multi-ingredient commodity-hazard pairs based on data (*e.g.,* from outbreaks, recalls, and surveillance studies) and expert knowledge.

(Comment 11) One comment maintains that the RRM–FT does not provide justification for the criteria scores of 1, 3, and 9. According to the comment, these values can inappropriately inflate risk scores, and it is unusual to have the same value for a high, medium, and low score for all criteria when the ranges of values in each of the criteria are different. The comment also maintains that a multi-criteria model should include the elicitation of the value function, but the RRM–FT does not show that such an elicitation was done. The comment asserts that the RRM–FT uses arbitrary scoring bins of 0, 1, 3, and 9, leading to the top bin score of 9 being 9 times as bad as the bin score of 1, and FDA does not justify this difference. Another comment suggests that FDA use more evenly distributed scoring bins, claiming the 0–1–3–9 binning approach could over-inflate the criterion score, especially for Criterion 1 (Frequency of Outbreaks and Occurrence of Illnesses), Criterion 4 (Growth Potential, with Consideration of Shelf Life), and Criterion 5 (Manufacturing Process Contamination Probability and Industry-wide Intervention).

(Response 11) In developing the RRM–FT, we evaluated multiple value functions, including using an evenly distributed scale (1–2–3–4) and essentially a logarithmic scale (0–1–3–9) for scoring Model criteria. The scoring and binning methodology chosen was based on extensive consultations with external and internal SMEs as well as peer review. Given the intended use of the Model, an essentially logarithmic scale was recommended by multiple external panels in the expert elicitation process and the peer reviewers in the Model review panel. A justification of the chosen methodology is provided in the RRM–FT Methodological Approach Report (Ref. 10). The rationale behind using the scoring scale of 0–1–3–9 is that risk is not necessarily operating on a linear scale. Furthermore, using the 0–1–3–9 scale facilitates a greater degree of differentiation between higher- and lower-ranked food-hazard pairs, which is useful for informing the designation of the FTL. The RRM–FT methodology does not consider a criterion score of 9 to be 9 times ''as bad as'' a score of 1. Rather, as is the case with all multi-criteria decision analysis models, results from the RRM–FT provide a risk ranking of alternatives but do not directly quantify risk to the consumer (*e.g.,* the probability of illnesses), which requires a different methodology such as a quantitative risk assessment. The RRM–FT methodology appropriately gives the same criterion score to a range of data points that fall into the same scoring bin because, for its intended purpose, the RRM–FT does not attempt to quantify risk on a continuous risk basis, as would be done in a quantitative risk assessment.

(Comment 12) One comment claims the RRM–FT uses a method to determine the contribution of multiple hazards in which the total risk score for a food is determined by summing the risk scores of the food-hazard pairs associated with the food. According to the comment, this method makes a food associated with multiple hazards more likely to be designated high-risk because it would have a higher score. Furthermore, the comment suggests that FDA consider other factors (such as processing controls) so that a food is not more likely to be designated high-risk simply because it is associated with multiple hazards.

(Response 12) The RRM–FT does not use the summing method stated by the comment; instead, the Model uses an aggregation method that involves exponential transformation, summing, and log transformation taking into consideration the risk scores for all food-hazard pairs under the food. This aggregation method is not sensitive to the number of hazards associated with the commodity, but rather the risk score for the commodity is driven by the highest-scored commodity-hazard pair(s). With regard to considering processing controls, the RRM–FT considers processing controls when scoring Criterion 5, which accounts for steps taken to reduce contamination and industry-wide interventions.

(Comment 13) Several comments claim that Criterion 6 (Consumption) in the RRM–FT does not align with FSMA section 204(d)(2)(A)(v), which directs FDA to consider the ''likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food. . . .'' The comments maintain that section 204(d)(2)(A)(v) was intended to be more about consumer handling of the food, such as whether there is temperature abuse, whether the food is cooked properly, and amount consumed. The comments maintain that the consumption criterion in the RRM–FT (which focuses on frequency and amount of consumption) may skew risk ranking, especially for popular foods. One comment acknowledges that higher consumption of a food could cause an outbreak with greater public health consequences but argues that is not what Congress directed FDA to evaluate.

(Response 13) We disagree with the comments and believe that Criterion 6 in the Model appropriately reflects FSMA factor (v) because consumption patterns affect the likelihood that consuming a particular food will result in a foodborne illness when the food is contaminated. Inclusion of the consumption criterion in the RRM–FT is based on extensive consultation with SMEs including external expert panels, and it has been subject to peer review (Refs. 9 and 13). Additionally, consumption is a standard component of a risk assessment, as described in the Food and Agriculture Organization (FAO)/World Health Organization (WHO) microbiological risk assessment guidance for food (Ref. 14). FDA defines Criterion 6 by using two data indicators, consumption rate and amount consumed (Ref. 10). When contaminated, products that are consumed frequently, in large amount, or both are more likely to cause widespread outbreaks. We think that FSMA factor (ii) (''the likelihood that a particular food has a high potential risk for microbiological or chemical

contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food'') is the factor that relates more directly to the consequence from the potential for temperature abuse during the customary shelf life of the food, and we therefore considered that issue in the scoring of Criterion 4 (Growth Potential, with Consideration of Shelf Life) for the commodity-hazard pair. The RRM–FT does not consider consumer cooking because the commodities in the RRM–FT are defined as foods available for purchase by consumers.

(Comment 14) One comment asserts that the Model does not identify or explain a ''cut-off'' risk score above which foods are on the FTL, which makes it impossible to evaluate the impacts of the Model.

(Response 14) The RRM–FT methodology is designed to evaluate what the risk score is, not what risk score is used to designate a line above which foods are on the FTL. The final version of the Designation of the FTL Memorandum (Ref. 15) describes this cut-off score and explains how FDA uses results from the Model to determine whether a food is on the FTL.

(Comment 15) One comment asserts that the Model attributes fresh-cut leafy green outbreaks to both fresh-cut and RAC leafy green commodities. According to the comment, this inappropriately inflates the risk scores for both categories, particularly in the case of RAC products where it is often unknown if the contamination occurred after processing, and results in the RRM–FT scoring RAC leafy greens as higher risk than fresh-cut leafy greens. The comment asserts that this contradicts industry understanding and well-known science that fresh-cut produce by its very nature presents a higher risk than the same produce in RAC form.

(Response 15) The RRM–FT does not attribute outbreaks associated with fresh-cut leafy greens to both fresh-cut and RAC leafy green commodities. The Model does not ''double count'' outbreaks; each outbreak is attributed to a single commodity-hazard pair, *e.g.,* either the RAC or the fresh-cut product, depending on the source of the outbreak. FDA scores Criterion 1 (Frequency of Outbreaks and Occurrence of Illnesses) in the RRM–FT based on the Agency's determination of the source implicated in an outbreak, *i.e.,* whether it was determined to be a food vehicle (such as fresh salsa) or a contaminated ingredient used in the vehicle (such as contaminated tomatoes used in the fresh salsa) (Ref. 10). We attribute the number of illnesses and outbreaks to a commodity-hazard pair according to information on the contaminated ingredient (*i.e.,* the source of the contamination), not to the food vehicle implicated (if it is different from the contaminated ingredient), when both the contaminated ingredient and the food vehicle were identified in the outbreak investigation. For example, if fresh salsa was implicated in a foodborne illness outbreak but tomatoes were identified as the contaminated ingredient, the outbreak would be attributed to tomatoes and not fresh salsa.

We disagree with the comment's assertion that the RRM–FT methodology contradicts the current scientific understanding of the route of pathogen contamination in fresh produce. We considered public comments on the 2014 draft methodological approach in the development of the RRM–FT (Ref. 4), and we had the methodological approach peer reviewed in 2016 (Refs. 9 and 13). Based on the peer-reviewed approach, we updated the underlying data, where major data sources for scoring in the Model were updated to 2019 or the latest available data (Ref. 10). Consequently, our approach to outbreak attribution is based on the best available information on the source of contamination, which remains consistent with current scientific understanding. For example, the fact that the commodity-hazard pair risk score is higher for the pair ''Leafy greens—STEC O157'' than for the pair ''Leafy greens (fresh-cut)—STEC O157'' (risk score of 430 vs. 310) (Ref. 10) reflects the fact that STEC O157 is more likely to originate in RAC leafy greens (but can sometimes remain in fresh-cut leafy greens after processing). However, for a hazard associated with leafy greens for which the processing environment is a typical route of contamination (such as *L. monocytogenes*), the risk score is higher for ''Leafy greens (fresh-cut)—*L. monocytogenes*'' than ''Leafy greens—*L. monocytogenes*'' (risk score of 370 vs. 330). The RRM–FT systematically scores relevant commodity-hazard pairs for RAC leafy greens and fresh-cut leafy greens. The Model then calculates a risk score for each commodity using an appropriate aggregation method (Ref. 10), where the risk score for the commodity is driven by the risk score for the highest-scored commodity-hazard pair(s); this results in a commodity risk score that is higher for RAC leafy greens than fresh-cut leafy greens.

(Comment 16) One comment suggests that we consider the wide variations in shelf life and pathogen growth potential among dairy products. As an example, the comment compares a pathogen like *L. monocytogenes* in a soft Hispanic-style cheese, which has strong growth potential, to any pathogen in ice cream, which has effectively zero growth potential. The comment maintains that having two indicators for scoring Criterion 4 (*i.e.,* using a scoring matrix of Growth Potential and Shelf Life) is problematic and may skew the criterion score for a commodity as a whole compared to the scores for individual foods. For example, the comment maintains that it does not seem accurate to have the same Criterion 4 score for a dairy product with a short shelf life/strong growth potential as for a dairy product with a moderate shelf life/moderate growth potential.

(Response 16) We agree that it is important to consider the variations in pathogen growth potential. Consistent with the comment's suggestion, results from the Model show a wide range of Criterion 4 scores among commodity-hazard pairs for dairy commodities. To determine the score for Criterion 4, we use a single indicator based on the potential that a food would support the growth of pathogenic microorganisms due to the nature of the food, and the extent of growth as affected by the customary shelf life of the food and the temperature at which the food is intended to be held and stored. This reflects a revision that we made to the draft approach, taking into consideration comments we had received from the public and from peer reviews of the RRM–FT (Refs. 9, 13). The commenter incorrectly stated that Criterion 4 in the 2020 RRM–FT Methodological Approach Report (Ref. 4) used for the proposed rule included two indicators. We changed the Criterion 4 scoring definition to one indicator in the revised Model (2020) in response to comments peer reviewers and stakeholders had made on the 2014 draft. As a result, the revised Model uses only one indicator to score Criterion 4, which is ''Growth potential, with consideration of shelf life,'' instead of using ''Growth potential/shelf life,'' which was evaluated as two separate indicators in the draft approach. The scoring definition for Criterion 4 includes the amount of growth ($\log_{10}$ increase) given customary shelf life. As described in the RRM–FT Methodological Approach Report (Ref. 10), the revised definition allows us to appropriately apply data from growth studies and predictive microbiology databases, as well as avoid potentially skewing the criterion score if two indicators were used.

(Comment 17) One comment expresses concern about treating ''Dairy'' as one group in the RRM–FT and asserts that foods selected in the RRM–FT are not representative of the wide diversity of the dairy industry. The comment states that the dairy industry makes a wide variety of products, including ice cream, yogurt and cultured dairy products, butter, hard cheeses, soft cheeses, sour cream, cottage cheese, dips, canned sweetened condensed and evaporated milks, pasteurized flavored and unflavored fluid milks, dried milk, whey powders, raw milk, and raw milk products. The comment asserts that each of these products has unique intrinsic characteristics and that the manufacturing process of each product may involve a unique combination of processing steps. The comment further maintains that it is not appropriate to combine pasteurized and unpasteurized dairy products into a single category because some dairy products are virtually risk-free, while raw milk and raw milk products are inherently risky. For support, the comment cites CDC data indicating that over 70 percent of outbreaks associated with dairy products are attributed to raw milk and raw milk cheeses. Therefore, the comment suggests that we revise the dairy food classification considering intrinsic properties (*e.g.,* pH and a_w) and potential for pathogen growth in the product, choose representative dairy foods that reflect the diversity of the industry, and ensure that risks from raw milk and raw milk products do not affect the risk scores of other dairy products. The comment specifically recommends that we separate dairy products into three categories—cheese, ice cream, and milk—and further divide the cheese category into four subcategories: soft ripened cheese, semi-soft cheese, hard cheese, and other cheese. The comment also suggests that we amend the food facility registration classification scheme by adding a new category for yogurt and other fermented milks and cultured dairy products because of their unique intrinsic properties. Finally, the comment urges us to put raw milk and raw milk products in a stand-alone category named ''Raw Milk for Consumption and Raw Milk Products.''

(Response 17) We do not believe it is necessary to make the revisions suggested by the comment. We agree that each of the dairy commodities has its unique food characteristics and manufacturing processes. In fact, the RRM–FT considers such unique characteristics and processes, as well as most of the dairy products suggested by the comment, in scoring each of the dairy commodities and associated commodity-hazard pairs.

The RRM–FT does not treat ''Dairy'' as one group but instead includes six separate commodity categories for dairy products (see Ref. 10, Table A–1), several of which contain multiple specific commodities (see Ref. 10, Table A–2). The Model identifies as separate commodities different types of cheeses (fresh cheese, soft-ripened cheese, and hard cheese) made from pasteurized milk. Furthermore, cheeses made from raw milk are classified into their own commodities separate from cheeses made from pasteurized milk. Ultimately the RRM–FT identifies and evaluates 21 individual dairy commodities (see Ref. 10, Table A–2).

The concerns expressed in the comment do not reflect the handling of the dairy commodity categories in the Model (Ref. 10). The RRM–FT uses data relevant to seven criteria for each commodity and associated commodity-hazard pairs to generate risk scores, taking into consideration the intrinsic characteristics of the food (such as the low pH of yogurt) in scoring Criterion 4 (Growth Potential, with Consideration of Shelf Life), among other data. The RRM–FT does consider ''Dairy—Fermented dairy products other than cheese'' as a stand-alone commodity category that includes two separate commodities (Yogurt and Cultured Products (excluding yogurt)) and associated commodity-hazard pairs. Amending the food facility registration scheme to add a new category for yogurt as the comment suggests is beyond the scope of this rulemaking. Additionally, while the RRM–FT does not include a raw milk commodity because FDA prohibits the sale of raw milk in interstate commerce, the RRM–FT evaluates raw milk in two separate commodities, one for hard cheeses made from unpasteurized milk and one for cheeses other than hard made from unpasteurized milk.

(Comment 18) One comment asserts that FDA did not include or consider costs of complying with the FTL traceability rule in Criterion 7 (Cost of Illness) of the RRM–FT and recommends that we include these costs.

(Response 18) The RRM–FT includes public health risk criteria as specified by FSMA section 204(d)(2)(A). Criterion 7 of the RRM–FT is defined as the cost of illness for the commodity-hazard pair; therefore, it is not appropriate to include in this criterion non-public health economic impacts such as the cost of complying with the rule. FDA considers the costs and benefits associated with the rule in the Final Regulatory Impact Analysis (FRIA) (Ref. 16).

(Comment 19) One comment requests clarification on how FDA will address changes in consumer habits. Specifically, for a food that is not on the FTL because FDA has determined that the food is rarely consumed raw, the comment requests clarification on whether covered entities are responsible for knowing that consumer habits have changed such that the product is no longer rarely consumed raw or if the FTL remains the same until FDA changes it. The comment also asks if we will indicate that we are planning to update the FTL due to changes in consumer habits.

(Response 19) The FTL will remain the same until we change it. The process for changing the FTL, which includes advance notice and an opportunity for the public to provide comment, is discussed in Section V.S of this document.

It is possible for a food to be part of a commodity that is on the FTL but to nonetheless be exempt under § 1.1305(e) of the final rule because it is listed as rarely consumed raw in § 112.2(a)(1) (21 CFR 112.2(a)(1)). For example, collards fall within the commodity ''Leafy Greens,'' but they are exempt from the subpart S requirements because they are listed as rarely consumed raw in § 112.2(a)(1). Because any changes to the rarely consumed raw list in § 112.2(a)(1) would have to be made through notice and comment rulemaking, firms would receive notice that the rarely consumed raw list might change and would have an opportunity to provide comments on the potential change.

(Comment 20) Some comments ask FDA to clarify the growing and production processes that were evaluated and used to place foods on the FTL. The comments also request that we clarify, if processes and practices change, how that type of information will be used to support inclusion or removal of foods from the FTL.

(Response 20) The growing and production processes that we evaluated and used to place foods on the FTL are described in the RRM–FT Methodological Approach Report (Ref. 10), specifically in section 3 of the report (''Identification of Food-Hazard Pairs''), where we describe the food classification scheme, and in the description of Criterion 5 (Manufacturing Process Contamination Probability and Industry-wide Intervention), which evaluates the possibility of hazard introduction

during manufacturing and the ability to control contamination with interventions through growing and production practices and processes throughout the supply chain. We will consider changes in industry processes and practices when we update the Model (see Response 488).

(Comment 21) Several comments ask that we make an interactive model tool available for stakeholders to test hypothetical changes to the scores for each criterion in the RRM–FT. Additionally, the comments ask that we make the data inputs and risk scores for all foods evaluated (not just those on the FTL) available to the public to increase transparency and help stakeholders with future business decisions. Comments also request that we provide the commodity category level analyses as well as the analyses for individual commodities in the commodity category. One comment that requests revisions to the RRM–FT further suggests that we conduct a pilot test with an interactive version of the revised RRM–FT to demonstrate to stakeholders how the scores are determined for the criteria and how that results in food being placed on the FTL. This comment suggests that stakeholders be given an opportunity to comment on the revised Model and the demonstration, which the comment maintains would give credibility to the Model and promote public acceptance.

(Response 21) We have already made public a substantial amount of information that allows stakeholders to analyze and interact with information relating to the RRM–FT, including testing hypothetical changes to the Model scores. For example, we provided a web-based tool (Ref. 17), the RRM–FT Methodological Approach Report (Ref. 10), and a full list of references for the data and information used in the Model (see link to references in Ref. 17). These materials provide the details of the methods on which the analyses are based (including examples) with all the information stakeholders need to reproduce such analyses. The tool also provides the total score for each of the commodities on the FTL as well as the criteria scores for the commodity-hazard pairs that make up each commodity on the FTL. In response to comments, we are considering making public the scores for all the foods evaluated in the Model, including those food/hazard pairs not included on the FTL. The Designation of the FTL Memorandum (Ref. 15) describes key aspects of how FDA uses the RRM–FT to designate the FTL.

With regard to the suggested pilot of the Model and additional opportunities for stakeholder comment, we have provided stakeholders with opportunities to comment throughout the development of the FTL. As previously stated, we published our draft approach for developing a risk-ranking model for public comment in 2014. We then refined the approach, taking into consideration the public comments received. Two separate external peer-review panels reviewed a draft model and the data used to generate risk scores with the Model, respectively. Concurrently with issuance of the proposed rule, we made available a revised model and updated the data, taking into consideration comments from the peer reviews. Additionally, we provided opportunities for stakeholders to obtain clarity on how the scores are determined for the criteria and which foods would be placed on the FTL during three public meetings. When we develop a new FTL in the future, we intend to publish a proposed updated FTL in the **Federal Register** for public input, review comments from the public, and publish a final updated FTL in the **Federal Register**. We believe this will provide stakeholders sufficient opportunity to provide input on any potential changes to the FTL.

(Comment 22) Several comments suggest that FDA use the RRM–FT to evaluate the risk of any new food, such as a multi-ingredient food that contains an ingredient on the FTL (FTL ingredient). The comments maintain that the dose-response curve should be considered in each instance and the risk of a multi-ingredient food that contains an FTL food may change depending on the ability of the relevant microbial pathogen(s) to survive and grow in the new food. The comments acknowledge practical challenges in a potentially enormous number of new foods that contain FTL ingredients that would each need to be evaluated. The comments suggest that, if FDA does not have the resources to evaluate all the new foods, it should apply a threshold to the amount of an FTL food that needs to be in a multi-ingredient food for the new food to be on the FTL, or help industry use the RRM–FT methodology to self-assess the risk of a new food to determine whether subpart S would apply.

(Response 22) We decline to use the RRM–FT to make individual evaluations of each multi-ingredient food that contains an FTL food. This would not be practical, nor is it necessary. Elsewhere in the final rule, we are providing additional clarity on which foods containing FTL foods as ingredients are on the FTL (see Response 27). For example, for a food that is specified on the FTL as being fresh or fresh-cut, if the nature of the FTL food has not changed in the new multi-ingredient food containing the FTL food as an ingredient (*e.g.,* bagged salad mix containing lettuce, smoothie containing fresh cantaloupe, sandwich containing fresh-cut tomato), the risk of the FTL food used as an ingredient in the new food is not expected to decrease. In fact, in some cases, the ability of bacterial pathogens to grow could be greater in the fresh FTL food when it is cut or sliced and included in the new multi-ingredient food.

With respect to the dose-response curve, we acknowledge there might be different levels of risk of illness when a different amount of an FTL food is consumed. However, there is no generalizable evidence with regard to risk of illness from a specific amount of the FTL foods that would enable us to set a threshold amount for FTL foods used as ingredients in other foods, as suggested by the comments.

(Comment 23) One comment maintains that in developing the RRM–FT, FDA should have ensured that risk managers agreed the Model criteria were relevant to the decision for designating the FTL. The comment maintains that FDA did not report work done in this area.

(Response 23) We disagree with the comment. FSMA section 204(d)(2)(A) establishes six factors for assessing risk of foods and designating the FTL that are represented by the criteria in the RRM–FT. The RRM–FT Methodological Approach Report (Ref. 10) describes the iterative process for developing the RRM–FT. This process included extensive and iterative consultations with an FDA Project Advisory Group, consisting of members from FDA's Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine, Office of Food Policy and Response, Office of Policy, Legislation and International Affairs, Center for Veterinary Medicine, and Office of Regulatory Affairs, as well as the CDC (Ref. 10). The Project Advisory Group provided both technical and policy perspectives in the development of the Model. Furthermore, as discussed above in Response 2, during the development of the Model we consulted multiple external expert panels and considered comments and suggestions provided by peer reviewers.

(Comment 24) Several comments oppose using customer reviews as data for scoring in the RRM–FT. The comments voice concern with FDA's expressed interest in using artificial intelligence to mine non-traditional data

sources, specifically customer online reviews, as part of our efforts to gather additional data to support risk modeling and inspection prioritization. These comments do not believe customer online reviews will meaningfully contribute to data gathering.

(Response 24) The RRM–FT does not use customer reviews in scoring because the Model only includes data relevant to seven criteria based on the factors specified in section 204(d)(2)(A) of FSMA (Ref. 10), including the number of reported outbreaks and illnesses for commodity-hazard pairs. However, under FDA's New Era of Smarter Food Safety initiative, we will continue to explore ways to utilize non-traditional data sources and the use of artificial intelligence to protect the U.S. food supply. Additional information on this effort can be found in FDA's Blueprint for New Era of Smarter Food Safety (Ref. 18).

(Comment 25) Several comments assert that FDA does not appear to have considered comments they submitted on FDA's draft methodological approach in 2014. Specifically, the comments maintain that some issues they had submitted in 2014 remain not adequately addressed in the RRM–FT (2020 version), including the following claims: (1) the RRM–FT is not aligned with FSMA section 204(d)(2)(A) because it combines factors (iii) and (iv) into one criterion (Criterion 5—Manufacturing Process Contamination Probability and Industry-wide Intervention) and the Model's consumption criterion does not align with FSMA; (2) foods selected are not representative of the diversity of the dairy industry; (3) having two indicators for Criterion 4 (*i.e.,* using a scoring matrix of Growth Potential and Shelf Life) is problematic; (4) use of summing as an aggregation method (*i.e.,* summing risk scores for commodity-hazard pairs to calculate a risk score for the commodity) is not appropriate; and (5) the RRM–FT does not provide a cut-off score for foods on the FTL.

(Response 25) We considered each of these issues that were submitted in comments on the draft methodological approach in 2014 in the iterative process we used to develop and refine the RRM–FT. As previously stated, the iterative approach involved consulting with the RRM–FT Project Advisory Group and multiple external expert panels, and considering comments and suggestions provided by peer reviewers. As previously discussed, we have responded to these issues in this final rule (see Response 26 for discussion of the RRM–FT alignment with statutory factors in FSMA section 204(d)(2)(A); Response 17 for discussion of foods selected in the Dairy group; Response 16 for discussion of the indicators for Criterion 4; Response 12 for discussion of the aggregation method used for risk scores in the RRM–FT; and Response 14 for discussion of the cut-off score for foods on the FTL).

2. Designation of Foods on the FTL

a. General

(Comment 26) Some comments are supportive of the designation of the foods on the FTL. Conversely, other comments raise concerns with how we determine which foods are on the FTL and suggest our approach was not what Congress intended.

(Response 26) We appreciate the comments that are supportive of the FTL. In section 204(d)(1) of FSMA, Congress directed us to establish recordkeeping requirements for certain designated foods that would be additional to the traceability recordkeeping requirements in section 414 of the FD&C Act and the subpart J regulations. In section 204(d)(2) of FSMA, Congress directed us to consider specific factors in determining for which foods additional traceability recordkeeping requirements are needed. To determine which foods should be included on the FTL, we developed the RRM–FT based on the factors Congress identified in section 204(d)(2)(A) of FSMA. The Model considers FDA-regulated human foods, identifies commodities available for purchase at retail, and for each commodity identifies associated known or reasonably foreseeable hazards. The Model scores commodity-hazard pairs according to data and information relevant to the seven criteria described in the RRM–FT Methodological Approach Report (Ref. 10), which are based on the factors Congress identified in section 204(d)(2)(A) of FSMA. A commodity was included on the FTL if its risk score, aggregated across all associated hazards, was 330 or higher in the Model or if the evidence of outbreaks and illnesses and cost of illness scores for one or more associated commodity hazard pairs was ''strong'' (Ref. 15). This approach is science-based and reflects the intent of Congress in identifying the foods for which additional traceability records are necessary.

b. FTL Foods as Ingredients

(Comment 27) Some comments support our proposal to include on the FTL both foods specifically listed as well as foods that contain a listed food as an ingredient. However, many comments oppose this approach. Some comments claim that FDA exceeded its statutory authority by expanding the FTL beyond ''particular'' foods (as specified in section 204(d)(2)(A)(i), (ii), (v), and (vi) of FSMA). Some comments assert that the proposed approach would impose a burden on industry to identify every food that contains an FTL food as an ingredient without a corresponding public health benefit. Other comments maintain that this approach would lead to confusion and a lack of clarity for the food industry and increase the burden, particularly on retailers and distributors. One comment asserts that this approach would reduce consumption of produce because multi-ingredient foods would be formulated to avoid including foods on the FTL, such as certain produce items. Some comments provide examples of products for which we should not require additional recordkeeping for traceability, such as frozen pizza with cheese, granola bars with dried fruit, herbed bread, and quiches that use different types of peppers. Many comments ask that we exempt foods containing FTL foods as ingredients unless they are otherwise a listed food, such as a deli salad containing tomatoes, or to specifically list on the FTL certain multi-ingredient foods that should be covered under the final rule, such as bagged salads. Some comments recommend that the final rule apply only to foods on the FTL and foods containing listed foods as ingredients that will be consumed without a kill step.

(Response 27) We are clarifying our approach to the FTL in response to the comments. For several of the commodities on the FTL, we have clarified which version of the commodity is on the FTL and therefore covered by the final rule. For example, if a commodity is specified as ''fresh'' on the FTL, then only the fresh version of the commodity is covered by the final rule. If such a commodity is used in its fresh form as part of a multi-ingredient food, then the multi-ingredient food would be covered under the final rule. For example, fresh lettuce used in a bagged salad mix, fresh cantaloupe in a commercially prepared smoothie, or a sandwich containing a fresh tomato would be covered, but a frozen pizza with a spinach topping or trail mix with dried papaya would not be covered. We believe this approach is appropriate because the risk of the fresh FTL food would not be diminished just because it is used as an ingredient in a multi-ingredient food, if no kill step is applied or the FTL food is not otherwise changed, for example by drying or

freezing, such that it is no longer on the FTL. Further, the multi-ingredient food may be a key signal in an outbreak investigation that ultimately leads to identification of the contaminated ingredient. For example, we may receive a signal of fresh salsa in an outbreak investigation, and after further investigation be able to attribute the outbreak to the fresh tomatoes in the salsa. This example demonstrates not only why it is important to have the multi-ingredient food covered by the rule (because it is causing illness and serves as a key signal), but also why a commodity such as fresh salsa might not independently appear on the list if it is associated with outbreaks that are not attributed to it in our outbreak database because they are found to have been caused by an ingredient such as fresh tomatoes (see Response 15). Therefore, we believe it is appropriately protective of public health for the subpart S requirements to apply to multi-ingredient foods with FTL foods as ingredients, provided the FTL food remains in the same form (*e.g.,* ''fresh'') that is specified on the FTL. We do not think Congress's use of the word ''particular'' in section 204(d)(2)(A)(i), (ii), (v), and (vi) of FSMA precludes this approach.

For foods on the FTL that are not designated as ''fresh,'' if those FTL foods are used as ingredients in a multi-ingredient food and no kill step is applied or the FTL food is not otherwise changed such that it is no longer on the FTL, then the multi-ingredient food would be covered by the final rule. For example, peanut butter in a sandwich cracker for which no kill step is applied (to either the peanut butter or the peanut butter sandwich cracker) will be covered by the rule. As discussed in Response 75, the commodities on the FTL related to finfish and seafood include both the fresh and frozen forms of those products. As such, freezing finfish or seafood would not be considered a change such that the food is no longer on the FTL, so frozen finfish or seafood would not be exempt from the subpart S requirements.

(Comment 28) One comment asserts that additional recordkeeping requirements are unnecessary for foods containing FTL foods as ingredients because processors already keep records under the preventive controls for human food regulation and the FSVP regulation, which require documentation of application of a kill step and verification of suppliers. In addition, the comment maintains that food companies still have to keep records for the immediate previous source and immediate subsequent recipient of the food under subpart J.

(Response 28) While many food companies are required to keep records under subpart J documenting the immediate previous source and immediate subsequent recipient of their food, FSMA directed FDA to develop a regulation requiring additional traceability records for certain foods beyond what FDA already requires under subpart J. We recognize that food processors also must keep records under other regulations, but many of those records are for purposes other than traceability. For records required under subpart S, § 1.1455(f) specifies that firms may use records kept for other purposes and do not have to duplicate records (see Section V.R.3 of this document). For example, we anticipate that many manufacturers/processors would be able to use records required under existing regulations, such as those requiring documentation of monitoring of a preventive control (see 21 CFR 117.190(a)(2)) or documentation of thermal processing of low-acid canned foods (LACF) (see 21 CFR 113.100), to meet the requirement in § 1.1305(d)(3)(ii) to document application of the kill step to a food.

(Comment 29) One comment requests that we exclude foods from the final rule for which the Harmonized Commodity Description and Coding System does not provide sufficient classification of the food because it would be too confusing, particularly for trading partners, to clearly identify the food on the FTL if there is not a corresponding code in that system. Another comment suggests that we use the Harmonized Commodity Description and Coding System to provide additional clarity on the foods on the FTL.

(Response 29) We decline the comment's suggestion to exempt from the final rule foods that are insufficiently classified under the Harmonized Commodity Description and Coding System. We believe the FTL issued with the final rule (Ref. 19) provides sufficient information for firms to know whether a particular food is on the FTL. While Harmonized Commodity Description and Coding System codes are typically used for tariff and not food safety purposes, we recognize that in some cases providing additional information on FTL foods using classification systems used by importers could be useful. We will explore ways to provide additional guidance for importers as needed regarding identification of foods on the FTL.

c. Changing the Form of an FTL Food

(Comment 30) Many comments request clarification on the version of the food that is covered by the proposed rule and whether a fresh version of an FTL food would be considered an ingredient in a dried or frozen version of the food and be covered, or if the dried or frozen version of the food would not be considered an FTL food. The comments note that the Model contains separate commodity designations for some frozen foods such as frozen fruits and frozen vegetables. If the dried or frozen version is covered by the rule, the comments ask for clarification on which KDEs would apply to the food. The comments maintain that including on the FTL these foods that have changed their form would result in coverage of numerous foods that do not present the same public health risk as listed foods and would increase the rule's economic and resource burden on covered entities.

(Response 30) We have clarified the FTL in response to the comments. For foods that are designated as ''fresh'' on the FTL, if the form of the food is no longer fresh and has been changed (*i.e.,* through freezing, drying, or another change in the form of the food), then the food would no longer be an FTL food. For example, frozen spinach, frozen cut mangoes, dried peppers, or dried herbs would not be covered by the rule if only the fresh form is listed on the FTL. The person changing the FTL food such that it is no longer on the FTL would need to maintain receiving records of the FTL food but would not be required to maintain subpart S records for its subsequent handling of the food (*e.g.,* transformation and shipping), and subsequent recipients of the food would not have to maintain records under the rule.

However, as discussed in Response 75, the commodities on the FTL related to finfish and seafood include both the fresh and frozen forms of those products. As such, freezing finfish or seafood would not be considered a change such that the food is no longer on the FTL, and frozen finfish and seafood are therefore covered by the final rule.

We believe our approach to this issue is appropriate because of how foods are categorized within the Model. For example, the Model includes several commodity designations that could include peppers (*e.g.,* peppers (fresh), frozen vegetables, dried vegetables), but it is the fresh peppers that had a risk score high enough to be included on the FTL. Frozen vegetables and dried vegetables did not have a risk score that

placed them on the FTL (see Response 26 for a description of the method by which foods on the FTL were determined).

d. Clarify Foods on the FTL

(Comment 31) Several comments express appreciation for the additional clarification FDA provided on the FTL on January 11, 2021, and request that we include those clarifications in the final rule. Many comments ask that we provide additional clarity and specificity in describing the foods on the FTL, maintaining that this would reduce confusion for the food industry and regulators.

(Response 31) As the comments note, we provided additional clarity regarding the foods on the FTL on January 11, 2021, in response to stakeholder input following the publication of the proposed rule. The FTL we are issuing with the publication of the final rule maintains those clarifications and provides additional clarifications and descriptions for the commodities on the FTL (Ref. 19). For some commodities, we have added examples of foods that are and are not considered part of that commodity designation on the FTL.

(Comment 32) Multiple comments request that we provide exhaustive lists of the foods for each commodity on the FTL and for commodities not on the FTL.

(Response 32) Considering the variety and range of food products for each commodity, it would be very challenging to provide an exhaustive list of foods for each commodity. As stated in Response 31, we have provided additional clarifications and descriptions for the commodities on the FTL, and for some commodities we have added examples of foods that are and are not considered part of that commodity designation on the FTL. We believe these clarifications and examples will help stakeholders better understand the foods under each commodity on the FTL.

(Comment 33) One comment asks where they can find the commodity risk scores mentioned in the proposed rule.

(Response 33) The risk scores for the commodities on the FTL are available in the RRM–FT Methodological Approach Report (Ref. 10).

(Comment 34) A few comments support the use of the term ''Food Traceability List'' to identify the list of foods that are covered by the rule. The comments note that the term is preferable to use of the term ''high-risk list,'' which could result in consumers avoiding certain foods such as fruits and vegetables due to public perception of the term ''high-risk.'' One comment argues that FDA must use the term ''high-risk list'' in the food traceability regulation to be consistent with the language and intent of FSMA.

(Response 34) While we acknowledge that section 204(d) of FSMA uses the phrase ''high-risk foods,'' we believe the term ''Food Traceability List'' is appropriate for the purposes of this rule. We agree with the concerns raised about potential negative consumer perceptions of a ''high-risk list'' and resulting efforts to avoid foods on the list. Furthermore, the FTL is based on specific concerns related to traceability and is not meant to encompass all possible risk factors associated with foods. To determine which foods should be included on the FTL, we developed the RRM–FT based on the factors that Congress identified in section 204(d)(2)(A) of FSMA. Those factors are specific to what Congress required under FSMA and may not reflect other approaches to assessing risk. Furthermore, in identifying foods for inclusion on the FTL, we focused on hazards for which improved traceability records would help protect the public health. For example, as discussed below (see Response 86), we concluded that enhanced traceability recordkeeping requirements would not greatly improve our ability to identify and respond to undeclared allergens in food. Therefore, although undeclared allergens pose a significant risk, we did not incorporate this risk into our decision of which foods to designate for the FTL. Consequently, to avoid unnecessary consumer concerns and confusion with other risk determinations, we conclude that it is appropriate to use the term ''Food Traceability List'' rather than ''High-Risk Foods List.''

e. Foods vs. Commodities

(Comment 35) Several comments claim that FSMA required FDA to designate ''particular foods'' for the FTL rather than commodities. The comments maintain that some foods within certain commodities, if scored separately, would not have sufficient risk scores to be listed on the FTL. One comment argues that grouping foods into commodities does not accurately capture the risk of individual foods. Some comments assert that the boundaries of the commodities on the FTL are not clearly defined, which could result in confusion and ambiguity for some parts of the industry. These comments maintain that submitting questions through the FDA Technical Assistance Network (TAN) to inquire about coverage of specific foods is complicated and not timely.

(Response 35) We interpret the term ''particular food'' in section 204(d)(2)(A)(i), (ii), (v), and (vi) of FSMA in a way that is reasonable and consistent with section 204(d), and that accurately reflects the specificity of data available to us in developing the FTL. As discussed in Response 7, data on individual foods, such as specific varietals, is sparse and inconsistent across the variety of foods in the Model and on the FTL. For the purposes of the FTL, we determined that the appropriate level of granularity is at the level of ''commodity,'' *e.g.,* ''tomatoes (fresh)'' rather than ''Roma tomatoes'' or ''cherry tomatoes.'' Food items within the same ''commodity'' designation generally have similar characteristics, associated hazards, and production and supply chain practices and conditions. Further, data used to assess components of the Model (*e.g.,* outbreak and illness data, likelihood of contamination, degree to which product supports growth, consumption, annual cost of illness) are available and adequate at the ''commodity'' level of granularity. See also Response 68 for a discussion on the scope of the seafood commodity categories.

As stated in Response 31, we have provided additional clarifications and descriptions for the commodities on the FTL, and for some commodities we have added examples of foods that are or are not considered part of that commodity designation on the FTL. We believe these clarifications and examples will help stakeholders better understand the foods under each commodity on the FTL. As part of our outreach to stakeholders regarding the final rule (see Section V.U.4 of this document), we will continue to use the TAN to provide timely responses to questions about the FTL and the subpart S requirements, recognizing that some answers may take longer depending on the nature of the question.

(Comment 36) One comment argues that listing commodities would make it more difficult to remove foods from the FTL because new food safety technologies are typically applied to individual foods rather than commodities as a group.

(Response 36) As discussed in Section V.T.1 of this document, we plan to periodically conduct a review to determine whether it is appropriate to revise the FTL in accordance with the procedures set forth in § 1.1465 of the final rule. While there are several factors that we must consider in determining which foods are on the FTL, changes in industry practice, such as the use of new food safety technologies, may result in a sufficient change in the risk score of a commodity such that it would no longer be on the FTL.

We encourage the development and adoption of new food safety technologies to improve the safety of specific foods. If a company develops a new food safety technology which they believe provides an additional level of food safety for the food they produce, that company might consider submitting a citizen petition requesting modified requirements or an exemption from subpart S for certain products based on use of that technology, using the procedure set forth in § 1.1370 (see Section V.P of this document). We note that if new technologies provide a ''kill step'' to FTL foods, the food might be exempt from subpart S under § 1.1305(d) of the final rule.

f. Add Foods to the FTL

(Comment 37) Several comments suggest additions to the FTL. A few comments suggest the FTL should be expanded to include all foods or all foods that have caused foodborne illness. A few comments suggest expanding the FTL to include all produce and all seafood. One comment suggests expanding the FTL to include additional foods associated with outbreaks, such as dried and frozen fruits, tahini, pistachios, hazelnuts, and flour.

(Response 37) We decline to make these changes to the FTL. Congress explicitly directed us to establish additional recordkeeping requirements for traceability for foods that meet certain risk-based criteria. To determine which foods should be included on the FTL, we developed the RRM–FT based on the factors that Congress identified in section 204(d)(2)(A) of FSMA. The Model scores commodity-hazard pairs according to data and information relevant to seven criteria described in the RRM–FT Methodological Approach Report (Ref. 10). A commodity was included on the FTL if its risk score, aggregated across all associated hazards, was 330 or higher in the Model or if the evidence of outbreaks and illnesses and cost of illness scores for one or more associated commodity hazard pairs was ''strong'' (Ref. 15). If the foods suggested by the comments are not on the FTL, it is because their risk scores were not high enough to warrant inclusion on the FTL. As noted elsewhere, we intend to revise the FTL on a regular basis based on updates of the data in the Model. If the risk scores for foods (including those specified in the comments) change, those foods could be added to the FTL in a subsequent update to the list.

We recognize that there are foods that have been linked to past outbreaks but that are not on the FTL. Future outbreaks might also occur among foods not on the FTL. No food is completely risk-free, and we encourage all supply chain members to have systems and procedures in place to enable them to rapidly and effectively engage in traceback and traceforward activities for all of their foods, including those not on the FTL. However, Congress made clear that the additional recordkeeping requirements established by this rulemaking should only apply to foods that FDA designated for inclusion on the FTL, and that these requirements should have no effect on foods that are not so designated (see section 204(d)(7) of FSMA).

g. The FTL and the High-Risk Designation

(Comment 38) One comment requests that we not use the FTL for purposes other than the traceability recordkeeping requirements, such as establishing inspection frequencies or setting performance standards. The comment asserts that ''high-risk'' is defined differently depending on its context or use.

(Response 38) We agree that ''high-risk'' is defined differently depending on its context or use. Congress directed us to consider specific factors in determining which foods should have additional recordkeeping requirements for traceability. Those factors were specific to section 204(d) of FSMA. Section 201 of FSMA, which is codified as section 421 of the FD&C Act (21 U.S.C. 350j), directs FDA to consider a different set of factors to identify high-risk facilities for the purpose of determining the frequency of domestic inspections. Performance standards can be used in a wide range of settings, and any risk determination used for a performance standard would have to be appropriate to that context.

h. Description of Foods on the FTL

(Comment 39) One comment requests that we provide the scientific name of plants and animals on the FTL. Another comment requests that we use the naming conventions of the Codex Alimentarius or the Code of Federal Regulations in identifying foods on the FTL.

(Response 39) We decline these requests. The foods identified on the FTL were based, in part, on data from FDA's RFR and facility registration systems, which have existing naming conventions within FDA systems. Further, FDA typically uses the common name of plants and animals in its documents to help ensure that all stakeholders have an understanding of the foods to which regulations or guidance apply. Regarding requests to use other naming conventions, such as those in the Codex Alimentarius or the Code of Federal Regulations, those naming conventions were not developed for traceability, nor do they necessarily conform to FDA's typical naming conventions.

i. Produce

(Comment 40) Several comments ask for clarifications on the types of melons that would be covered in the ''melon'' category and how melons were deemed to be high-risk foods. The comments also request that whole fresh watermelon be excluded from the FTL.

(Response 40) In the melon category, the FTL includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, winter melon, bitter melon, and watermelon. As previously stated, a commodity was included on the FTL if its risk score, aggregated across all associated hazards, was 330 or higher in the Model, or if the evidence of outbreaks and illnesses and cost of illness scores for one or more associated commodity hazard pairs was ''strong.'' Based on the seven criteria used in the Model and the data we have for melons, this commodity has a risk score that warrants its inclusion on the FTL. Response 26 provides a description of the method by which foods, including melons, on the FTL were determined, while Response 6 discusses why the list uses commodity groupings (such as melons) rather than individual foods (such as watermelons).

(Comment 41) Several comments ask for clarification on how tropical fruits were determined to be in the tropical tree fruit category and whether certain fruits like bananas, avocado, and citrus are in that category.

(Response 41) The RRM–FT Methodological Approach Report (Ref. 10) describes the classification of food commodities, including tropical tree fruits. The tropical tree fruit designation allows for a grouping of similar tree fruits, not other tropical fruit, that are typical to locations that are hot and humid and whose longer day lengths allow for fruit maturity. Examples of tropical tree fruits include (but are not limited to) mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Tropical tree fruits do not include non-tree fruits (such as bananas, pineapple, dates, soursop, jujube, passionfruit, loquat, pomegranate, sapodilla, and figs); tree nuts (such as coconut); pit fruit (such as avocado); or citrus (such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo). However, derivatives or components of

some of the fruits that are not considered tropical tree fruits may be on the FTL in other commodity categories, such as coconut butter in the nut butter category, as discussed in this document.

(Comment 42) Several comments ask whether the ''Tropical Tree Fruits (fresh)'' category is limited to high-risk tree fruits and includes other tropical tree fruit products that have undergone processing but not a validated kill step, such as guava paste.

(Response 42) The ''Tropical Tree Fruits (fresh)'' commodity is one of two dozen commodities we identify in the commodity category ''Produce—RAC (raw agricultural commodity)'' based on the consideration of the characteristics of the foods and production and supply chain practices and conditions. The RRM–FT evaluates several commodities for fresh fruits, including Tropical Tree Fruits (*e.g.,* papaya), Tropical Fruits NEC. (*e.g.,* banana), Citrus (*e.g.,* orange), Pome Fruits (*e.g.,* apple), and Pit Fruits (*e.g.,* avocado), and finds that only the Tropical Tree Fruits commodity has a high enough risk score to meet the threshold for inclusion on the FTL. Therefore, the FTL includes fresh tropical tree fruits but does not include other fresh tropical fruits. Fresh guava is covered under the ''Tropical Tree Fruits (fresh)'' commodity. If fresh guava is used as an ingredient in guava paste, the guava paste would also be included on the FLT. However, if the guava paste is subjected to a kill step, the exemption language in § 1.1305(d) would apply.

(Comment 43) Several comments request that we clarify the scope and definition of leafy greens that are on the FTL. Some comments also suggest that the FTL align with the Leafy Greens Marketing Association (LGMA) definition of leafy greens.

(Response 43) We have provided additional clarification to the description of the commodity ''Leafy Greens (fresh)'' on the FTL, specifying that it includes all types of fresh leafy greens (Ref. 19). Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. The ''Leafy Greens (fresh)'' category does not include whole head cabbages such as green cabbage, red cabbage, and savoy cabbage, nor does it include banana leaf, grape leaf, and leaves that grow on trees. Also note that fresh leafy greens listed as rarely consumed raw in § 112.2(a)(1), such as collards, are exempt from the requirements of subpart S under § 1.1305(e) of the final rule.

We believe the description of ''Leafy Greens (fresh)'' that is on the FTL is generally aligned with the LGMA list of leafy greens. However, we acknowledge that there are some differences. The LGMA list includes whole head cabbages, which are not on the FTL, and spring mix, which is not part of the ''Leafy Greens (fresh)'' category on the FTL (but which is nonetheless on the FTL as part of the commodity ''Leafy Greens (fresh-cut)''). The FTL description of ''Leafy Greens (fresh)'' includes some leafy greens that are not on the LGMA list, such as chicory, watercress, pak choi, and sorrel.

(Comment 44) A few comments request that collards be removed from the proposed FTL as they are listed in the produce safety regulation (in § 112.2(a)(1)) as rarely consumed raw.

(Response 44) Collards are exempt from the subpart S requirements under § 1.1305(e) of the final rule because they are currently listed as rarely consumed raw in § 112.2(a)(1). Otherwise, collards would be subject to subpart S because they are part of the leafy greens commodity category. To avoid confusion, we have removed collards from the list of examples of leafy greens on the FTL.

(Comment 45) One comment requests that we individually list, with the applicable plant part(s), every fruit, vegetable, and culinary herb that is subject to the rule, or expand the language in each category to fully describe the intended subjects, including information such as the species name(s), the plant part(s), the botanical characteristics (*e.g.,* whether the plant grows on the ground vs. a tree or a climbing vine) and other information as appropriate to provide clear and accurate descriptions.

(Response 45) We do not agree that this level of detail is necessary. Furthermore, adding botanical names could inadvertently include or exclude commodities not intended to be on or off the FTL. However, the revised FTL (Ref. 19) points out differences when necessary, such as between beet root and beet greens, as well as dill leaves and dill seed. The revised FTL also includes additional examples of foods on the FTL.

(Comment 46) Some comments ask that we confirm that ''frozen'' and ''fresh-frozen'' vegetables are not included on the FTL.

(Response 46) Vegetables that are sold as ''frozen'' or ''fresh-frozen'' are not included on the FTL because this product category was analyzed separately from vegetables that are sold in other forms (*e.g.,* fresh, dried), and frozen/fresh-frozen vegetables did not meet the scoring criteria for inclusion on the FTL.

(Comment 47) One comment agrees with FDA that whole apples, pears, cherries, and fresh berries should not be on the FTL.

(Response 47) Whole apples, pears, cherries, and fresh berries did not have risk scores high enough to be included on the FTL and therefore are not covered by the final rule.

(Comment 48) Several comments request that we limit the FTL to sprouts, fresh produce, and/or high-risk herbs like cilantro with risk scores above the cutoff threshold of 330, and then phase in other foods as part of subsequent FTL updates. The comments maintain that this would allow FDA to ''test'' its traceability approach in the final rule, especially since some sectors of the produce industry have experience with traceability via participation in private traceability initiatives.

(Response 48) We decline to adopt the phased-in approach suggested by the comments. Congress directed FDA to identify foods for which additional recordkeeping requirements for traceability are necessary to protect the public health. Limiting the foods on the FTL to a subset of the commodities that had risk scores that merited inclusion on the list would not be based in science and would reduce the public health protections anticipated for the food traceability regulation.

(Comment 49) A comment suggests that we clarify whether fresh-cut produce that is ''rarely consumed raw'' under the produce safety regulation falls under the subpart S requirements for fresh-cut produce. One comment suggests that we provide more clarity about which fresh-cut produce is included on the FTL, and additional clarity on the methodology used to reach these conclusions.

(Response 49) Produce that is ''rarely consumed raw'' according to the produce safety regulation (§ 112.2(a)(1)) is exempt from the subpart S regulations under § 1.1305(e) for the entirety of the supply chain, regardless of whether it is fresh-cut. For example, although all fresh-cut fruits and vegetables are on the FTL, a fresh-cut ''rarely consumed raw'' vegetable such as fresh diced butternut squash would be exempt under § 1.1305(e) because the fact that the butternut squash is fresh-cut does not change its status as ''rarely consumed raw.''

(Comment 50) Some comments suggest that we reevaluate coverage of mung bean sprouts under the FTL. These comments maintain that mung bean sprouts should be considered rarely consumed raw and assert that few food safety issues have been linked to mung bean sprouts and mung beans.

The comments also ask us to reevaluate mung bean sprout consumption data using more recent datasets.

(Response 50) Fresh mung bean sprouts, as well as other types of fresh sprouts, are covered by the produce safety regulation and are not considered to be ''rarely consumed raw'' under § 112.2(a)(1). Section 112.2(a)(1) codifies an exhaustive list of all produce that is considered ''rarely consumed raw,'' and revising that list is outside the scope of this rulemaking. The commodity risk scores for fresh sprouts, including mung bean sprouts, qualified this commodity for inclusion on the FTL, as it has associated commodity-hazard pairs with criteria scores in the moderate to strong range (Ref. 15, Table 1 and Appendix I). We further note that, according to the FDA CORE Outbreak Dataset (Ref. 11), between 1999–2019 there were eight documented outbreaks related to consumption of mung bean sprouts, resulting in 319 illnesses and at least 2 deaths.

j. Herbs and Spices

(Comment 51) One comment asks that we clarify that it is the fresh version of herbs that are on the FTL and not the dried form (*i.e.,* spices). The comment further maintains that tomatoes and peppers that are dried or will be dried for spices or seasonings should not be included on the FTL. The comment also asks for clarification on whether capsicum annum pepper, if grown to become a spice, would be covered by the rule. Another comment asserts that herbs that are destined to be dried should not be covered by the rule because those herbs are grown, processed, and consumed differently than fresh herbs. Another comment recommends that spices, seasonings, and flavorings not be included on the FTL. Another comment states that it understands that dried herbs and spices are not covered by the rule because they are a separate commodity in the Model and are not on the FTL.

(Response 51) In the additional information on the FTL that we provided on January 11, 2021, we noted that the form of herbs on the FTL is the fresh form. Spices, seasonings, and flavorings are not included on the FTL and therefore are not covered by the final rule. In Response 30, we provide additional clarity regarding foods on the FTL that are designated as ''fresh.'' Section 1.1305(d)(4) and (d)(5) of the final rule (see Section V.E.5 of this document) provide further clarification that if a food is changed such that it is no longer on the FTL, then the food would not be covered. Therefore, dried herbs, dried tomatoes, and dried peppers would not be covered by the final rule because the FTL only includes the fresh versions of those foods.

In addition, under § 1.1305(d)(6), if an FTL food is destined to be changed (*e.g.,* through freezing, drying, or another change in form of the food) such that it is no longer on the FTL, then that food would not be covered from the point at which it is known that the FTL food is destined to be changed, provided that the entities have a written agreement as described in Response 196.

Regarding the capsicum annum pepper, if the peppers are destined to be dried for spices and the pepper shipper has a written agreement with the receiver that the peppers will be dried, then, as noted above, the shipper and receiver of the pepper would not be required to keep subpart S records for the food. However, if the pepper shipper does not have a written agreement, the shipper would need to maintain the relevant subpart S records.

(Comment 52) Comments request that we provide more clarity regarding the specific part of the herb plant that is covered under the FTL.

(Response 52) For fresh herbs, any part of the herb that is fresh and sold for human consumption would be covered under the FTL.

(Comment 53) One comment asks that we limit the FTL to fresh culinary herbs rather than all herbs.

(Response 53) As discussed in Response 51, we have clarified that the form of herbs on the FTL is the fresh form. We believe that further clarification and distinction as ''culinary'' herbs is not necessary. The ''Herbs (fresh)'' commodity is one of two dozen commodities we identify in the commodity category ''Produce—RAC'' based on the consideration of the characteristics of the foods and production and supply chain practices and conditions. The Model scores the commodity-hazard pairs at the commodity level *(e.g.,* all fresh herbs) regardless of the purpose of use because we are not aware of scientific evidence that fresh produce within the same commodity does not share a similarity in the characteristics of the food and in how they are produced. Furthermore, we are not sure how the phrase ''culinary herbs'' would be defined. In the Model, the ''Herbs (fresh)'' commodity has criteria scores high enough to meet the threshold for inclusion on the FTL.

k. Deli Salads

(Comment 54) Several comments assert that ''deli salad'' is a vague term that has different meanings in some sectors of the food industry, and other comments request that we clarify how we interpret the deli salad category for the RRM–FT. Some comments ask that we specify whether an ''antipasti'' salad would be considered a deli salad.

(Response 54) The ready-to-eat (RTE) deli salads commodity in the RRM–FT includes prepared refrigerated and RTE deli salads (*e.g.,* potato salad, egg salad, pasta salad, seafood salad). While the term ''deli salad'' appears to be a broad term, it is intended to capture multiple types of RTE deli salads, including the aforementioned examples as well as a prepared antipasti salad. However, a prepared, RTE antipasti salad could include meat as an ingredient, which may place it under the jurisdiction of USDA and therefore make it exempt from the requirements of subpart S under § 1.1305(g).

(Comment 55) Several comments request exemption of deli salads from the subpart S requirements. Some comments assert that RTE deli salads like pasta and potato salad that are processed and prepared using hurdle technology or other controls to minimize pathogen growth should not be included on the FTL. Similarly, other comments assert that these types of RTE salads that are processed and prepared using controls such as pH and preservatives (*e.g.,* antimicrobials and *Listeria* inhibitors) do not pose the same risk as RTE salads that do not use the hurdle approach.

(Response 55) While we acknowledge that the use of preservatives and antimicrobials in deli salads helps to minimize bacterial growth, the data provided in the comments do not change how we score deli salads in the RRM–FT. The hurdle approach, as opposed to a kill step, can vary widely in terms of procedure and is not consistently applied throughout industry.

Therefore, based on the available data, we conclude it is not appropriate to grant a blanket exemption for deli salads processed using hurdle technology or related procedures.

l. Nut Butters

(Comment 56) Some comments ask us to include all butters (nut, soy, and seed) on the FTL that are considered allergenic. Other comments question why soy and seed butters in general were not included on the FTL. These comments assert that soy and seed butters have similar manufacturing processes and supply chain standards, and thus pose the same risk as nut butters. Additionally, some comments assert that consumption patterns might be shifting from peanut butter to seed butter due to allergies.

(Response 56) We decline to include all butters considered allergenic or all soy and seed butters on the FTL. As previously stated, we developed a risk-ranking model for food tracing based on the factors in section 204(d)(2)(A) of FSMA. A commodity was included on the FTL if its risk score, aggregated across all associated hazards, was 330 or higher in the Model, or if the evidence of outbreaks and illnesses and cost of illness scores for one or more associated commodity hazard pairs was ''strong.'' Using the RRM–FT, we evaluated nut butters (*e.g.,* made from tree nuts and peanuts) and soy and seed butters (*e.g.,* made from edible seeds) as separate commodities and found that only the nut butters had a risk score high enough to meet the threshold for inclusion on the FTL. Therefore, only nut butters are covered by the rule. As previously stated, we will periodically review data and information relevant to the RRM–FT criteria for commodity-hazard pairs, including the consideration of consumption patterns and food safety improvements across commodities.

The inclusion of nut butters on the FTL does not relate to the fact that nut butters can be allergenic. See Response 86 for a discussion of how we assessed the risks that are related to allergens.

(Comment 57) Several comments request clarification on whether nut butters made with raw nuts pose the same level of risk as nuts that are roasted, even when applying a process control during the roasting process that results in a 4- to 5-log reduction of the pertinent pathogen.

(Response 57) We acknowledge that adequate process controls resulting in a 4- to 5-log reduction in the pertinent pathogen should minimize the risk associated with nuts. However, it is the nut butter, not the nuts, that is on the FTL and covered by the final rule. The nut butters commodity, regardless of whether the ingredient nuts were raw or roasted, ranked high in the RRM–FT, which is why nut butters are included on the FTL. While applying a validated roasting process control for peanuts may mitigate the associated hazard, we continue to see multiple outbreaks associated with recontamination of peanuts and peanut butter after the roasting step. We also know from previous FDA investigations that there are sources of environmental pathogens (*e.g., Salmonella* spp., *L. monocytogenes*) in facilities, and routes of contamination for these pathogens into the nut butters have been associated with employee practices, insanitary conditions, and inadequate sanitation practices. Using roasted nuts that have undergone a properly designed and implemented process control should mitigate the hazard associated with this ingredient; however, it does not reduce the risk of the potentially significant hazards posed by the exposed nut butters in the post-processing environment.

(Comment 58) Several comments ask whether nut meals and powders, nut flours, nut flavoring extracts, and similar commodities are on the FTL. Some comments request that we clarify whether peanut butter chips fall under the nut butter category on the FTL. Some comments assert that peanut butter chips should not be considered nut butters but should be a separate commodity that is exempt from the rule.

(Response 58) ''Nut meals and powders,'' ''Flours (wheat, rice or soy),'' and ''Flavorings'' are all separate commodity designations from the ''nut butters'' designation. These commodities were assessed separately in the RRM–FT and did not have risk scores that would include them on the FTL.

Peanut butter chips are not in the ''nut butters'' commodity. However, if peanut butter chips are produced using peanut butter as an ingredient, they are covered by the rule because they contain an ingredient on the FTL (peanut butter). However, if a kill step is applied to the peanut butter chips, the exemption in § 1.1305(d) would apply.

(Comment 59) Some comments request that we clarify whether ''coconut butter'' and ''Chinese chestnut butter'' are covered by the rule under the nut butter category. The comments maintain that ''coconut'' qualifies as a ''tree nut'' for purposes of the Food Allergen Labeling and Consumer Protection Act of 2004, but that in many countries it is not considered a ''tree nut'' because it does not meet common definitions of ''nut,'' nor does it grow on ''trees.'' The comments suggest that if we intend ''nut butter'' to include coconut butter, we should say so explicitly in the FTL and have data appropriate to deem coconut nut butter a ''high-risk food.''

(Response 59) As discussed in Response 39, we use data from FDA's RFR and facility registration systems to help determine commodity designations for the FTL. Based on those classification systems, we consider coconut to be a nut; therefore, coconut butter is included on the FTL as a nut butter. This is consistent with 21 CFR 170.3, which also classifies coconut as a nut. We consider Chinese chestnut to be a tree nut and, therefore, Chinese chestnut butter also is an FTL food subject to the subpart S requirements. We have added both coconut butter and chestnut butter to the FTL as examples of ''nut butters'' to clarify that they are included in this category. See the RRM–FT results tool (Ref. 17) for information about risks associated with nut butters.

(Comment 60) One comment expresses support for the fact that almonds/tree nuts are not on the FTL. The comment further asserts that domestically sold almonds are required to apply a kill step, which the comment argues is relevant when considering risk of a created product that is on the FTL, such as nut butter.

(Response 60) Nuts are not on the FTL; however, nut butters are on the FTL and subject to the rule, regardless of how the raw ingredients are processed. For example, almond butter is on the FTL and is covered by the rule regardless of whether the almonds received a kill step before being processed into almond butter. The RRM–FT considers potential hazards that may be introduced from exposure to the processing environment after a lethality treatment (Refs. 20 and 21), *e.g.,* contamination of *Salmonella* spp. in a nut butter after roasting (which is a kill step for the nut, but not a kill step for the nut butter). Based on available data for the seven criteria in the RRM–FT, the risk score for the commodity ''nut butters'' meets the criteria for inclusion on the FTL.

(Comment 61) Several comments outline initiatives the peanut butter industry has undertaken to significantly reduce the risk of outbreaks and illness from peanut butter and peanut butter products. Some comments maintain that nut butter scored low on contamination under the RRM–FT, but peanut butter scored high for frequency of consumption, number of outbreaks, and severity of illness. Other comments assert that nut butter was included on the FTL primarily due to the high-profile recalls that occurred before the adoption of the preventive controls for human food regulation. The comments argue that because of the efforts by industry and the fact that major peanut butter outbreaks occurred several years in the past, peanut butter should not be included on the FTL.

(Response 61) We appreciate the industry interventions to reduce the risk of outbreaks and illnesses caused by peanut butter and peanut butter products. However, we disagree that these efforts justify removal of peanut butter from the FTL at this time. As previously stated, a commodity was included on the FTL if its risk score, aggregated across all associated hazards, was 330 or higher in the Model, or if the evidence of outbreaks and illnesses and cost of illness scores for one or more

associated commodity hazard pairs was ''strong.'' Based on the seven criteria used in the Model and the data we have for peanut and tree nut butters, these products have risk scores that warrant their inclusion on the FTL. We further disagree with the comments asserting that the high-profile nut butter recalls that occurred before the adoption of the preventive controls for human food regulation were the primary reason nut butters made the FTL. As with all commodities, the RRM–FT scores for nut butters are specific to data and information on these foods relevant to the seven criteria used in the Model. The most recent information concerning industry intervention efforts considered in the RRM–FT was from 2019. Further, the RRM–FT down-weights older data. As stated in Response 488, we will periodically review data and information relevant to the RRM–FT seven criteria for commodity-hazard pairs, including the consideration of food safety improvements across commodities, to determine whether revisions to the FTL may be appropriate.

m. Cheese

(Comment 62) One comment asks for an explanation of why the RRM–FT ranks some cheese commodities from pasteurized milk higher than some cheese commodities from unpasteurized milk.

(Response 62) The RRM–FT scores commodity-hazard pairs according to data and information relevant to seven criteria described in the Methods report (Ref. 10). The semi-quantitative RRM–FT model does not directly quantify the probability of illnesses (*e.g.,* the risk of illnesses per year or per serving for a consumer) but rather provides a ranking of commodities based on risk scores. The model results ranked the ''Cheese (made from pasteurized milk), soft ripened or semi-soft'' commodity and the ''Cheese (made from pasteurized milk), fresh soft or soft unripened'' commodity higher than the ''Cheese (made from unpasteurized milk), other than hard cheese'' commodity.

A 2015 FDA/Health Canada quantitative risk assessment (Ref. 22) of soft-ripened cheese showed that on a per serving basis, the risk to consumers was higher for raw (unpasteurized) milk soft-ripened cheese than for pasteurized milk soft-ripened cheese. The RRM–FT results do not conflict with the quantitative risk assessment results. However, the RRM–FT is more aligned with a risk estimate on a population basis. For example, it includes a criterion that captures the percentage of the population that consumes the food in addition to the amount consumed per serving. When contaminated foods are consumed by a large percentage of the population, they are more likely to cause outbreaks or multiple illnesses compared to contaminated foods consumed by only a limited percentage of the population, given similar prevalence and levels of contamination and serving size. While all seven criteria contribute to the overall risk score of each of these commodities, the consumption criterion (Criterion 6) is the key to understanding the relative ranking of cheese made from unpasteurized milk to cheese made from pasteurized milk. In the RRM–FT, data indicated that cheeses made with unpasteurized milk are consumed by a much smaller percentage of the population than counterpart cheeses made with pasteurized milk, while the amount consumed per serving was approximately the same. If the percentage of the population consuming unpasteurized milk cheese was more comparable to that of the other cheeses, the risk score for the ''Cheese (made from unpasteurized milk), other than hard cheese'' commodity would have been at least as high as the risk score for the highest scoring pasteurized milk cheese commodity on the FTL. The RRM–FT results tool (Ref. 17) provides more information on the risk scores for relevant commodity-hazard pairs.

(Comment 63) One comment suggests that the cheeses on the FTL should be limited to Hispanic soft cheese made from raw milk, queso fresco, Latin-style soft cheeses, and soft cheeses. Another comment suggests that cheeses on the FTL be limited to soft uncured cheeses with no kill step, asserting that those are the only cheeses that have triggered a specific FDA warning and related consumer food safety education.

(Response 63) We decline to limit the cheeses on the FTL to Hispanic soft cheese made from raw milk, queso fresco, Latin-style soft cheeses, and soft cheeses, in particular soft uncured cheeses. Cheeses other than these had commodity risk scores under the RRM–FT that warranted their inclusion on the FTL. The commodity risk score for cheese (made from pasteurized milk) soft ripened or semi-soft was 490; the commodity risk score for cheese (made from pasteurized milk) fresh soft or soft unripened was 430; and the commodity risk score for cheese (made from unpasteurized milk) other than hard cheese was 410. Because each of these cheese commodities had a commodity risk score above 330, they are all included on the FTL.

(Comment 64) Several comments request that various cheeses be removed from the FTL, including cream cheese, processed mozzarella cheese, cheese made from pasteurized milk, processed cheese, process cheese products, and LACF cheese. One comment notes that cottage cheese is typically produced in Grade ''A'' milk plants regulated under the Pasteurized Milk Ordinance (PMO) and argues that the production process in those plants results in a product that does not support the survival and/or growth of bacteria. Another comment asks whether pasteurization of the milk that is used to make cheese is considered a kill step.

(Response 64) Cottage cheese is covered by the final rule because it is included on the FTL in the commodity ''Cheese (made from pasteurized milk), fresh soft or soft unripened.'' However, we recognize that much of the cottage cheese produced in the United States is regulated under the PMO, a Federal program that includes specific requirements for processing and frequent testing and inspection by regulatory authorities. Therefore, we are considering initiating a process under § 1.1360 to determine whether to exempt cottage cheese regulated under the PMO from the subpart S requirements.

As discussed in Section V.E.5 of this document, if a person applies a kill step, such as pasteurization, to a cheese on the FTL, the person is eligible for a partial exemption from subpart S under § 1.1305(d)(3). Therefore, pasteurized process and pasteurized prepared cheese and cheese products (*e.g.,* pasteurized process cheese, pasteurized process cheese food, pasteurized cheese spread, pasteurized blended cheese, pasteurized prepared cheese product), as well as processed mozzarella cheese, would be eligible for the partial exemption in § 1.1305(d)(3). LACF cheeses are a separate category in the RRM–FT and are not on the FTL.

Regarding cheese made with pasteurized milk, as discussed in Response 62, the commodity risk scores for both ''Cheese (made from pasteurized milk), soft ripened or semi-soft'' and ''Cheese (made from pasteurized milk), fresh soft or soft unripened'' were both high enough to merit inclusion on the FTL. Similar to the previous discussion in Response 60 regarding peanut butter made from roasted peanuts, these two categories of cheeses made from pasteurized milk are on the list regardless of the fact that one of their ingredients was previously subjected to a kill step.

(Comment 65) Many comments request clarity and definitions for the cheese categories, as well as information on which specific cheeses within the categories are on the FTL. The

comments ask that the categories be based on a science- and risk-based assessment. Some comments question whether the cheese categories are based on relevant standards of identity (SOI) or moisture level in the cheeses, further noting that there is no SOI that defines the term ''soft cheese'' or academic consensus on the definition of ''soft cheese.'' The comments maintain that the category ''Cheeses, other than hard cheeses'' could include many low-risk and semi-soft cheeses (*e.g.,* Asiago and Manchego), and they ask whether the category also includes non-hard cheeses packed in wax (*e.g.,* fontina in wax). In addition, some comments express concern that FDA inspectors may apply terms like ''soft cheese'' inconsistently and over-inclusively due to a lack of clarity and definitions for the cheese categories.

(Response 65) The commodity ''Cheese'' is broken down into three categories on the FTL:

- Cheese (made from pasteurized milk), fresh soft or soft unripened. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna;
- Cheese (made from pasteurized milk), soft ripened or semi-soft. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, Monterey jack, and muenster; and
- Cheese (made from unpasteurized milk), other than hard cheese, which includes all cheeses made with unpasteurized milk, other than hard cheeses.

These three categories encompass all cheeses except hard cheeses. Although we cannot provide an exhaustive list of cheeses on the FTL, we have revised the FTL to provide additional clarification of the cheese categories, better align with the RRM–FT, and provide examples of cheeses in each category. The FTL now states the commodity is ''Cheeses, other than hard cheeses'' and specifies that ''hard cheeses'' include hard cheeses as defined in § 133.150 (21 CFR 133.150), Colby cheese as defined in 21 CFR 133.118, and caciocavallo siciliano cheese as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, Romano, and parmesan. Even though there is not a clear definition of ''fresh soft'' or ''soft unripened'' cheese (note that ''soft ripened'' cheese is defined in 21 CFR 133.182), the fact that the only category of cheese that is not on the FTL is hard cheese should eliminate concerns of inconsistency in applying the final rule. Packaging and wrapping do not affect whether or not a cheese is on the FTL.

We have further clarified that the cheese commodities that are on the FTL do not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged. This is a result of how foods are categorized within the Model (see Response 26 for a description of the method by which foods on the FTL were determined). Therefore, if a cheese that is on the FTL in its unfrozen form becomes frozen—for example, as part of a frozen pizza—that would be considered a change such that the food is no longer on the FTL and therefore no longer covered by the final rule (see Response 27). Cheeses that are shelf stable at ambient temperature or aseptically processed and packaged are also not on the FTL and are therefore not covered by the final rule.

(Comment 66) One comment asks how firms can ensure that the preceding entity in the supply chain has properly classified the cheese so that it does not create an undue burden or put the receiving firm's own compliance at risk.

(Response 66) We expect persons who manufacture, process, pack, or hold any FTL food covered by the final rule to be in compliance with the regulations. Persons subject to the rule are responsible for knowing whether they must keep subpart S records, independent of any assessment or classifications made by persons preceding them in the supply chain. We expect firms to work with their suppliers to be familiar with the products they are providing, and we note that other regulations, such as those on preventive controls for human food and foreign supplier verification programs (FSVP), require covered entities to work with their suppliers to help ensure compliance with those regulations.

n. Seafood

(Comment 67) Comments specific to seafood assert that the scope of the FTL exceeds the definition of ''high-risk'' stated in section 204 of FSMA. The comments ask that we modify the RRM–FT risk criteria by limiting it to outbreak and recall data, and be more specific in identifying high-risk commodities (*e.g.,* scombrotoxin-forming species, RTE seafood) rather than using broad categories (*e.g.,* finfish).

(Response 67) As discussed in Response 4, section 204(d)(2)(A) of FSMA sets forth the factors that FDA is required to consider in designating foods for inclusion on the FTL. Because the factors are established in the statute, we cannot limit the risk criteria in the RRM–FT to outbreak and recall data.

As discussed in Response 35, we determined that the appropriate level of granularity for designating foods on the list is at the level of ''commodity'' (*e.g.,* ''Finfish (histamine-producing species'')). In the FTL published with the final rule, we have provided additional clarifications and descriptions for the commodities on the FTL, for example by separately identifying the finfish commodities and providing additional examples for each commodity designation.

(Comment 68) Some comments suggest that the RRM–FT fails to recognize the variability of hazards associated with individual seafood species and products in identifying foods for inclusion on the list, and instead focuses on overly broad commodity groups with limited commonalities. Some comments object to the assumption that ''items within the same 'commodity' designation generally have similar characteristics, associated hazards, and production and supply-chain practices and conditions.''

(Response 68) We disagree with the comments. The RRM–FT considers the nature of the food through a categorization scheme that classifies FDA-regulated foods into 47 commodity categories. The 47 commodity categories represent categories of foods available to consumers from various supply chains and different production, manufacturing, and handling processes and practices. Furthermore, within each commodity category, the RRM–FT identifies more than 200 individual commodities, again taking into consideration the nature of foods as well as the characteristics of their production and manufacturing processes. For example, the commodity category ''Seafood-Finfish'' includes four commodities that are on the FTL because they have a risk score that meets the threshold for inclusion on the FTL: ''Finfish—finfish—histamine-producing species,'' ''Finfish—finfish—species not associated with histamine or ciguatoxin,'' ''Smoked finfish,'' and ''Finfish—finfish—species potentially contaminated with ciguatoxin.'' The identification of individual commodities allows for consideration of the differences in the nature of the food, the range of hazards, and the production and manufacturing processes. Therefore, we have considered variability of hazards through the identification of species-specific hazards and hazards associated with processing. The identification of commodity-hazard pairs is based on available data and information, *e.g.,* foods and hazards

associated with outbreaks and illnesses and detection of hazards in foods. We use information from RFR reports, published literature, scientific studies, technical reports from governmental and other organizations, FDA surveillance and testing data, a review of world-wide published risk assessments, and expert knowledge. As discussed in Response 35, in reviewing the data and developing the FTL, we determined that the appropriate level of granularity is at the level of ''commodity.'' The peer reviewers for the Model (Ref. 13) made a variety of suggestions on the food classification, particularly modifications at the commodity level, so that it would be appropriate and supportable by available data. The peer reviewers supported grouping foods with similar ecology and manufacturing conditions (even if not yet involved in documented outbreaks). Further, data used to assess components of the Model (*e.g.,* outbreak and illness data, likelihood of contamination, degree to which product supports growth, consumption, and annual cost of illness) are available and adequate at the ''commodity'' level of granularity.

(Comment 69) Many comments address the seafood species and products included on the FTL and compare these seafood products to FDA's seafood safety guidance, ''Fish and Fishery Products Hazards and Controls'' (Ref. 23), which is used by regulators and industry in identifying likely food safety hazards associated with fish and fishery products. The comments assert that the FTL is inconsistent with FDA's existing guidance and ask that the final rule provide a rationale for this purported inconsistency.

(Response 69) The purpose of the Fish and Fishery Products Hazards and Controls guidance is to help firms identify hazards reasonably likely to occur and develop a seafood hazard analysis critical control point (HACCP) plan to control these hazards. The guidance is a science-based tool firms use to help develop preventive controls for the seafood they handle. The purpose of the FTL, however, is to improve traceability in the event of a foodborne illness outbreak involving foods on the list. As discussed in Response 5, the FTL is a list of food commodities informed by a risk-ranking model that ranks food-hazard pairs based on seven criteria.

(Comment 70) Some comments assert that very few seafood species and products were associated with food safety hazards that originate from the growing environment. The comments suggest that FDA exclude products that have only been associated with recalls related to hazards introduced during processing from the burden of tracing back to the harvest waters.

(Response 70) We disagree with these comments. Seafood food safety hazards can be introduced throughout the supply chain. Natural marine toxins and pathogens are examples of the hazards that are in the growing environment and can contaminate seafood. In the RRM–FT, we identify and evaluate both species-related (from the growing environment) and process-related hazards that are known or reasonably foreseeable for more than a dozen seafood commodities (Ref. 17), which is consistent with the intent of this regulation to enhance FDA's ability to trace foods on the FTL throughout the supply chains of those foods.

(Comment 71) Several comments contend that very few illnesses can be attributed to the consumption of shrimp in general and that domestic wild-caught shrimp have a drastically lower rate of consumption in the United States when compared to aquacultured shrimp. The comments further maintain that the open ocean environment in which domestic wild-caught shrimp are harvested is unlikely to present any safety hazards, and they recommend removing domestic wild-caught shrimp from the FTL. Conversely, the comments assert that aquacultured shrimp, whose growing conditions have been associated with introduction of food safety hazards, is more likely to present a potential health hazard. The comments do not request that we exclude foreign wild-caught shrimp from the FTL.

(Response 71) The RRM–FT did not differentiate between wild-caught and aquacultured shrimp. We acknowledge that hazards introduced from the growing waters for wild-caught shrimp and aquacultured shrimp may differ. However, there are commonalities in hazards being introduced after harvest, such as the addition of sodium metabisulfites to prevent melanosis and pathogen hazards introduced during handling and processing after capture, as well as commonalities in the potential for shrimp (regardless of wild-caught or aquaculture) to support pathogen growth. The RRM–FT considers the totality of the food chain in the interest of public safety. As previously discussed, we balanced a number of factors in determining the granularity of commodity definitions, including the characteristics of the food and availability of data used to evaluate the seven criteria for commodity-hazard pairs. Shrimp (both wild-caught and aquaculture) is evaluated in the commodity ''Crustaceans'' (see Response 35 for further discussion of why we evaluate risks at the ''commodity'' level).

(Comment 72) Several comments assert that the requirements of the proposed rule are duplicative and not beneficial in the case of canned tuna. The comments maintain that: existing harvest certification requirements provide traceability to the vessel; LACF product coding requirements and National Oceanic and Atmospheric Administration (NOAA) product traceability requirements provide traceability throughout the food chain; FDA's safety requirements and recommendations in other regulations and guidance documents address food safety hazards; and canned tuna has a history of being safe based on global recall data.

(Response 72) Because the commodity ''Canned Seafood'' in the RRM–FT, which includes canned tuna, did not score high enough to be on the FTL, canned tuna is not on the FTL and therefore is not covered by the final rule.

(Comment 73) Some comments request that the allowance for a ''kill step'' exemption not exclude smoked fish from the FTL given the history of contamination in the finished product due to cross-contamination after smoking.

(Response 73) We agree that smoked finfish should be included on the FTL. The ''smoked finfish'' commodity in the RRM–FT includes both hot and cold smoked finfish. Based on available data for the seven criteria in the RRM–FT, the risk score for ''smoked finfish'' is high enough to merit inclusion on the FTL. Therefore, both hot and cold smoked finfish are included on the FTL. We note that the hot smoking step typically is not applied to the finished product, so it does not address potential environmental contamination introduced after smoking when the finfish is sliced and otherwise handled before packaging. The RRM–FT demonstrated that food safety hazards can be introduced from exposure to the processing environment after the lethality treatment (*e.g.,* contamination of *L. monocytogenes* in smoked finfish after smoking).

(Comment 74) Many comments object to the inclusion on the FTL of the category ''Finfish, species not associated with histamine or ciguatoxin.'' The comments argue that those species have no associated species-related safety hazards or have only species-related hazards that are controlled because the

products are normally consumed cooked.

(Response 74) Finfish species not associated with histamine or ciguatoxin are on the FTL in part because they are highly consumed and may be contaminated with microbial hazards that can cause severe illnesses (*e.g., L. monocytogenes, Vibrio parahaemolyticus, Salmonella* spp.). While there are relatively few documented outbreaks for this finfish commodity, it is often difficult to identify the source associated with *L. monocytogenes* outbreaks due to factors such as long incubation time and sporadic illnesses, which complicates outbreak investigations. Further, data for this commodity in the RRM–FT indicate the likelihood of contamination is above 1 percent (*i.e.,* Criterion 3 score of 9), and consumption and severity of illness both score high. Given these high scores, the risk score for the finfish commodity is above the line for inclusion on the FTL.

(Comment 75) Some comments assert that frozen seafood products present less of a risk than refrigerated products because maintaining seafood in frozen form inhibits pathogen growth and potentially eliminates parasites. The comments request that we consider the safety effects of freezing as part of risk profiles when identifying high-risk products.

(Response 75) We agree that freezing can inhibit the growth of pre-existing pathogens and additional development of scombrotoxin and potentially can eliminate parasites. However, freezing does not remove the presence of pathogens in the way that a kill step does; it does not eliminate scombrotoxin that may have formed before freezing and it does not eliminate the presence of ciguatoxin. In addition, thawing of the product within the commercial seafood chain re-introduces the potential for pathogen growth and scombrotoxin formation. It is not uncommon for seafood products to be thawed and then refrozen as they move through the supply chain, and because the description of a commodity within the RRM–FT refers to the state in which the product appears at retail, such seafood is classified as ''frozen'' despite having previously been thawed. This is one reason why, for many seafood commodities, we have classified fresh and frozen products together within the Model, rather than separating them into different commodities. Because the Model identified many such seafood commodities as scoring high enough to be included on the FTL, the enhanced traceability recordkeeping requirements of subpart S apply to these types of seafood regardless of whether they are sold fresh or frozen. The updated version of the FTL we are publishing with this final rule specifies when the frozen form of a product is included on the list.

(Comment 76) Several comments support expanding the FTL to include all seafood products, most notably Siluriformes such as catfish, which are regulated by USDA, and scallop adductor muscles, which the RRM–FT identifies as ''low risk.''

(Response 76) All fish of the order Siluriformes, including catfish, are considered ''amenable species'' under the Federal Meat Inspection Act (see 21 U.S.C. 601(w)(2)) and are subject to exclusive USDA jurisdiction at certain points in the food production chain. FDA does not have the authority to impose recordkeeping requirements on facilities that are under exclusive USDA jurisdiction. Consequently, as discussed in Section V.E.8 of this document, the final rule (in § 1.1305(g)) provides an exemption for such food during the time it is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). In addition, we are choosing not to cover food after it is within the exclusive jurisdiction of USDA because the most successful traceability efforts will have an unbroken chain of records. Similarly, we chose not to include Siluriformes such as catfish in the risk-ranking model that we used to identify foods for inclusion on the FTL. Because Siluriformes are subject to exclusive USDA jurisdiction at certain points in the food production chain, we are unable to ensure an unbroken chain of traceability records. Therefore, we are not expanding the FTL to include Siluriformes such as catfish as requested.

We also decline to expand the FTL to include scallop adductor muscle. As discussed in Section V.E.7 of this document, the final rule (in § 1.1305(f)) exempts from the subpart S requirements raw bivalve molluscan shellfish, including scallops, that are: covered by the requirements of the National Shellfish Sanitation Program (NSSP); subject to the requirements of part 123, subpart C (21 CFR part 123, subpart C), and § 1240.60 (21 CFR 1240.60); or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. The final product form of the adductor muscle only is not covered by the NSSP requirements or subject to the requirements of part 123, subpart C, and § 1240.60 (Ref. 23). We have adopted this same approach and rationale in the final rule.

(Comment 77) Several comments recommend expanding the FTL to include all seafood products as a means of preventing economic fraud, including species substitution, by ensuring product traceability throughout the supply chain. One comment suggests that feed for aquaculture be covered under the rule to help ensure that products that may have been created through forced labor or illegal fishing do not enter the U.S. market.

(Response 77) FSMA section 204(d) defines the scope of this rule and limits its coverage to only those foods that FDA designates for inclusion on the FTL, based on the factors Congress provided in section 204(d)(2)(A). The purpose of the rule is to enhance traceability to be able to rapidly and effectively identify recipients of a food on the FTL to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death. We cannot expand the scope of the rule to address other concerns, such as forced labor or illegal fishing. However, under FDA's New Era of Smarter Food Safety initiative, we will continue to explore ways to encourage all entities in the supply chain to adopt tracing technologies and harmonize tracing activities to support end-to-end traceability throughout the food safety system. Additional information on this initiative can be found in FDA's Blueprint for New Era of Smarter Food Safety (Ref. 18).

o. Dietary Supplements

(Comment 78) One comment supports the fact that dietary supplements are not on the FTL and therefore not covered by the rule, as the comment maintains that dietary supplements are rarely implicated in foodborne illness outbreaks. One comment suggests that because dried spices and dried vegetables are not covered by the rule, dietary supplements that include dried herbs and vegetables also should not be covered by the rule. The comment further suggests that dietary supplements that include fish or krill oil also should not be covered. One comment asserts that herbs used in dietary supplements should not be covered by the rule because dietary supplements are not covered. Another comment maintains that including fresh herbs used in dietary supplements under the commodity ''Herbs (fresh)'' is not supported by evidence because, according to the comment, FDA uses RFR data to identify hazards for fresh

herbs, but dietary supplements are not included in RFR reporting.

(Response 78) The RRM–FT includes data regarding dietary supplements, and dietary supplements are a separate commodity in the Model. The commodity ''Dietary supplements'' did not score high enough to merit inclusion on the FTL. Many ingredients that are often found in dietary supplements, such as dried herbs, dried vegetables, fish oil, and krill oil, are also not on the FTL. Dietary supplements containing these ingredients are therefore not covered by the rule. However, if a dietary supplement uses fresh herbs, such as in some refrigerated dietary supplements, those supplements would be covered by the rule because, as discussed in Response 27, the rule covers multi-ingredient products that contain specifically listed FTL foods as ingredients, as long as the form of the ingredient is the same as the form that appears on the FTL (*e.g.,* ''fresh'').

p. Animal Food

In the preamble to the proposed rule, we stated that although section 204(d) of FSMA does not exclude food for animals, we did not include animal foods in the RRM–FT. We stated that the RRM–FT was designed to account only for humans and cannot accommodate applicability to other animal species. However, we stated that we might revisit the issue of animal foods when we conduct any future reassessments of the Model (see 85 FR 59984 at 59991).

(Comment 79) Some comments agree that animal food should not be covered under the same risk-ranking model as human food. These comments generally agree that a primary reason the RRM–FT should not be used for animal food is because animal illness data associated with animal food is not tracked, not generally available, or not tracked accurately. Some comments maintain that because animal food should not be covered by the same risk-ranking model as human food, the RRM–FT cannot be used to place animal food on the FTL.

On the other hand, some comments assert that animal food should be included on the FTL. These comments state that animal food was not excluded from section 204(d) of FSMA, and they maintain that because illness in both humans and animals has been attributed to animal food, animal food should not be excluded from the subpart S requirements. One comment maintains that tracing of animal feed could help ensure that pathogens and bacteria are not introduced at the feed stage of the supply chain.

(Response 79) We agree with the comments asserting that animal food should not be covered under the same risk-ranking model as human food. Information on some of the key criteria used to develop the Model, including factors specified by Congress in section 204(d)(2)(A) of FSMA, does not exist for animal food. As discussed in the preamble to the proposed rule, we do not at this time have reliable data sources or ways to generate data related to animal illness caused by consumption of animal food. In addition, the RRM–FT does not consider the variation in species that would be needed, as risk of hazards may be species-dependent and vary within a species, and can be dependent on the animal's life stage or class of production (*e.g.,* a dry dairy cattle vs. a lactating dairy cow). For these reasons, the current RRM–FT is not appropriate for animal food, and there are no animal foods on the FTL. However, we may consider development of an animal food risk-ranking model in the future.

(Comment 80) Some comments ask that we confirm that animal food made with food or the by-products of foods on the FTL is not subject to the regulation.

(Response 80) We agree that animal food that is made with food (or by-products from production of food) on the FTL would not be subject to the subpart S requirements.

(Comment 81) Some comments ask us to use a formal notice and comment process if we intend to update or develop a risk-ranking model specific to animal food that would be used to place animal food on the FTL.

(Response 81) We intend to seek public input on an animal food risk-ranking model if, in the future, we opt to develop such a model. We have a variety of ways (*e.g.,* public meeting, formal notice and comment) we can seek public input if we were to undertake work on an animal food risk-ranking model. Although we cannot commit to a specific mechanism for obtaining public input, we are committed to seeking public input on any potential risk-ranking model for animal food.

q. Foods Regulated by the USDA

(Comment 82) Some comments ask for clarity on whether a multi-ingredient food that is regulated by USDA's Food Safety and Inspection Service (FSIS) but contains an FTL food as an ingredient would be covered by the rule. The comment cites an as example a chicken salad containing diced celery.

(Response 82) As discussed in Response 76, we have provided clarity on this topic by adding § 1.1305(g) to the final rule. Section 1.1305(g) states that the subpart S requirements do not apply to persons who manufacture, process, pack, or hold food on the FTL during or after the time when the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

Thus, when an FDA-regulated facility ships an FTL food to an exclusively FSIS-regulated facility, the shipper must maintain and send shipping KDEs to the FSIS facility in accordance with the final rule. These records can be used by the FSIS facility if traceback of the food products is necessary. KDEs are not required to be maintained by the FSIS facility or any subsequent receivers of food from the FSIS facility.

While FDA maintains regulatory jurisdiction at retail for all foods, including any food that contains an FTL food as an ingredient, we are choosing not to exercise our authority in these specific circumstances for the purposes of the final rule. The most successful traceability efforts will have an unbroken chain of records. FDA does not have the authority to impose recordkeeping requirements on facilities that are under exclusive USDA jurisdiction. When an FTL food is used as an ingredient in a food regulated by FSIS and tracing records are not kept by the FSIS-regulated facility, the chain of traceability records is broken, and it would be difficult for the RFE that receives the food to maintain the required records. Therefore, we are exempting from the subpart S requirements all persons who manufacture, process, pack, or hold food on the FTL both during and after the time when the food is within the exclusive jurisdiction of the USDA.

In the case of the specific example cited by the comment, chicken salad would be regulated by FSIS and would not be subject to the FTL traceability regulation, even if the chicken salad contains foods like fresh-cut celery or fresh-cut onions that are on the FTL. However, the supplier of the FTL food, such as fresh-cut celery or fresh-cut onions, must maintain and send shipping KDEs to the chicken salad manufacturer. If that chicken salad was subsequently used as an ingredient in another product, such as a closed-faced sandwich, that is regulated by FDA, we would still not consider that chicken salad sandwich to be covered by the rule because the food was previously held in a facility that was within the exclusive jurisdiction of the USDA.

(Comment 83) One comment asks that we coordinate with the USDA and consider covering animal proteins under

the FTL traceability regulation in the future.

(Response 83) Some animal proteins, including beef, lamb, chicken, turkey, and pork, are under the exclusive jurisdiction of the USDA at certain points in the food production chain. Similar to our decision regarding Siluriformes such as catfish (see Response 76), we chose not to include these animal proteins in the Model because we would be unable to ensure an unbroken chain of traceability records. Congress directed FDA to coordinate with the USDA on section 204(d)(6)(A) of FSMA related to farm to school and farm to institution programs, which we have done, and we will continue to coordinate with the USDA as we implement the final rule.

r. Root-Cause Analyses

(Comment 84) One comment suggests that conducting more root-cause analyses of foodborne illness outbreaks could provide additional information useful for inclusion in the Model and may provide additional clarity for certain commodity designations.

(Response 84) We agree that root-cause analyses of outbreaks are an important tool to help better understand how foods become contaminated with certain pathogens. The RRM–FT used data available at the time we developed the Model and produced the FTL. Results of some root-cause analyses were available and considered when identifying food/hazard pairs in the Model. For example, we reviewed some outbreaks for which we were able to identify post-kill step contamination in processing facilities as a root cause of the outbreak, and data concerning these outbreaks were included in the Model. As we update the data for the Model in the future, any additional available information from root-cause analyses will be included.

s. Other Factors

(Comment 85) Several comments urge us to consider additional factors in developing the FTL, such as the fact that traceability records are already required under subpart J; that food manufacturers keep records under the regulation on preventive controls for human food, some of which they argue may be traceability-related; and that food manufacturers have greater insight into their supply chains as a result of other FSMA regulations, including the preventive controls and FSVP regulations.

(Response 85) Congress required FDA to designate foods for which additional traceability recordkeeping requirements are appropriate and necessary to protect the public health, based on specific factors outlined in section 204(d)(2)(A) of FSMA. While many food companies are required to keep records under subpart J documenting the immediate previous source and immediate subsequent recipient of their food, FSMA directed FDA to develop a regulation requiring additional traceability records for foods designated as high-risk. We recognize that food processors must keep records under other regulations, but many of those records are for purposes other than facilitating traceability. To meet requirements under the FTL traceability rule, the final rule allows firms to use records kept for other purposes and does not require firms to duplicate existing records (see § 1.1455(f)).

t. Hazards

(Comment 86) One comment agrees with FDA's decision, as described in the Designation of the FTL Memorandum (Ref. 5), to consider biological hazards and acute hazards, and not chemical hazards related to chronic exposure or food allergens, in developing the FTL. Another comment cites reports about heavy metals in baby food and recommends that we consider whether traceability records would be useful for addressing chronic exposures to chemical hazards such as lead.

(Response 86) We appreciate the comments that agree with the focus on biological and acute hazards for the FTL traceability regulation. Our traceability activities generally focus on foods contaminated with biological or acute chemical toxins that present an immediate public health risk. In contrast, enhanced recordkeeping for traceability would not be similarly useful for addressing adverse health effects of chronic exposure to chemical hazards such as lead or other toxic elements. For food allergens, we have found that consumers with food allergies usually can identify the food or ingredient that most likely caused the allergic reaction, including the brand and packaging of the food in most cases. We can then rapidly identify the source of the allergen-containing food and take appropriate regulatory action. Therefore, additional recordkeeping for traceability would not greatly enhance our ability to identify and respond to undeclared allergens in food. Therefore, we have determined that for the purposes of developing the FTL, we will only consider results from the Model for microbial hazards and acute chemical toxins.

u. Food Code

(Comment 87) One comment notes that the foods on the FTL are different from foods identified as potentially hazardous in the Food Code. The comment maintains that this could be potentially confusing for restaurants and restaurant employees. Therefore, the comment suggests that the Food Code be updated to reflect the foods on the FTL and that guidance for control of the hazards be provided.

(Response 87) The Food Code is a separate program and modifications to it are beyond the scope of this rulemaking. Changes to the Food Code are made through the Conference for Food Protection, which has a separate process for revisions and updates.

C. General Comments on the Proposal

Many comments make general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In addition, many comments address issues with the proposed rule that do not involve a specific proposed provision or that concern multiple provisions. In the following paragraphs, we discuss and respond to such general comments.

1. General Support for and Opposition to the Proposed Rule

(Comment 88) Many comments express general support for the proposed rule. Some comments state that existing traceability recordkeeping requirements are inadequate, current traceability capability in the industry is lacking, and there is a need to modernize and standardize traceability processes. Some comments suggest that the rule will: save lives and reduce illnesses by enabling faster identification of contaminated food and recipients of the food; help FDA conduct investigations and enable the Agency to skip steps in the supply chain; facilitate faster, more targeted recalls at lower cost and reduce broad market withdrawals; reduce the number and frequency of public health warnings and recall announcements; help consumers feel safer about the food they eat by increasing the transparency between consumers and producers; help prevent needless food waste when possibly unsafe products must be discarded; yield improvements in inventory control and firms' ability to keep accurate shipping and receiving records; prevent underconsumption of FTL foods due to safety concerns; and reduce liability damage costs to manufacturers. Several comments maintain that the benefits of the rule,

including a reduced risk of adverse economic consequences for entities in the supply chain, outweigh the costs of meeting the additional recordkeeping requirements.

On the other hand, many comments express opposition to the proposed rule. One comment maintains that the rule would cause hardships for producers and force more importation of food produced in less sanitary systems. Several comments maintain that compliance with the rule would be infeasible or too costly for many supply chain entities, including many farms, producers, and RFEs, and that the costs of the rule would outweigh its public health benefits. Some comments contend that the rule would increase costs to consumers and limit consumers' ability to obtain fresh, local food. Some comments assert that existing traceability requirements are adequate and additional regulation of farms and firms would be unnecessary and burdensome. Some comments maintain that many common industry supply chain operations would not fit within the proposed rule's framework for CTEs. Some comments contend that the rule would create a barrier to firms looking to enter the industry or the U.S. market, as well as to firms that are reluctant to adopt technology. Some comments assert that while other FSMA rules have essentially codified existing food safety best practices, the proposed rule would create an entirely new and at times duplicative recordkeeping system. Several comments claim that the rule assigns demanding responsibilities to industry with little or no additional safety benefits beyond existing controls.

(Response 88) As directed by Congress in section 204(d)(1) of FSMA, we are establishing additional traceability recordkeeping requirements for foods we have designated as high-risk in accordance with the criteria Congress specified in section 204(d)(2)(A) of FSMA. Consistent with Congress' directive, we believe that the requirements of the final rule will help the Agency better protect the public health by enabling us to more rapidly and effectively identify recipients of a food to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. We believe that the final rule addresses many of the limitations of the existing traceability recordkeeping requirements in subpart J as discussed in Response 105, and will help us respond more quickly and effectively to foodborne illness outbreaks and recall events involving FTL foods, which will benefit both public health and the food industry. As discussed later in this document, the final rule includes several changes to, and additional exemptions from, the proposed requirements that we believe will reduce the burden of the rule on entities throughout the supply chain while still producing the benefits of faster and more efficient traceability. We note that the rule will apply to imported FTL foods as well as domestically produced FTL foods, and that the rule would not require duplication of records. Specific comments relating to the costs and benefits of the rule are discussed in Section VII of this document.

(Comment 89) Some comments maintain that the rule would increase the costs of production and cause the price of food to increase for consumers and throughout the supply chain.

(Response 89) The FRIA (Ref. 16) attempts to comprehensively represent the total costs of compliance with the rule to industry and society as a whole. Section II.F of the FRIA estimates compliance costs to various covered domestic entities depending on their size and role in the supply chain, and section II.H discusses costs to foreign entities. However, we do not determine the exact incidence of those costs, which might be passed on to other entities in the supply chain. We acknowledge consumer concerns about food prices, but we do not think that the rule will cause food and ingredient prices to rise substantially, although depending on entities' market power some costs of the rule might be passed all the way to consumers and retail buyers. We believe that the exemptions and partial exemptions in the final rule (see Section V.E of this document), along with the streamlining and simplification of certain requirements (see Response 104), should help to limit the potential impact of the rule on prices for ingredients and final goods if some of the costs of the rule are passed on to consumers and retail buyers.

(Comment 90) Some comments assert that the rule would decrease food availability because the difficulty of complying would force some small producers to close. Some comments maintain that small operations have proven key to local food security when larger operations have been forced to temporarily shut down during emergencies, such as the COVID–19 pandemic. Some comments assert that if small farms shut down there will be reduced access to healthy food.

(Response 90) We do not agree that the rule will substantially reduce food availability, reduce access to healthy food, or force businesses to close. The comments did not provide any evidence that shutdowns would occur or that food access would be restricted because of the rule. As previously discussed, we have made changes in the final rule to reduce the chances that any business, especially smaller firms and farms, will feel so burdened by the requirements that it must shut down.

(Comment 91) One comment asserts that the unintended consequences of the rule could include increasing food waste from the elimination of grocery returns.

(Response 91) We disagree with the comment that the rule will increase food waste by discouraging or eliminating grocery returns. The rule does not create any recordkeeping requirements relating to the sale of food to consumers or to the return of such food by consumers.

2. Treatment of Different Sizes and Types of Entities

(Comment 92) Several comments assert that the rule favors and is intended for larger entities in food supply chains. Some comments contend that FDA failed to seek input on the proposed recordkeeping requirements from smaller firms and farms. Some comments assert that by unnecessarily burdening small businesses, the rule would further encourage the consolidation of the food system, which the comments maintain has led to more outbreaks. Some comments assert that many smaller firms and farms lack the money, technology, and infrastructure to meet the proposed requirements, and that the rule will have a more severe impact on smaller firms that will need to develop a traceability system from scratch. Some comments maintain that the cost of complying with the rule will force many smaller firms out of business without any corresponding benefit to the public health. Some comments assert that many smaller retailers will stop doing business with local food vendors because many of those small suppliers will be unable to meet the new requirements. Some comments assert that the exemptions in the proposed rule are overly narrow in scope or inappropriately targeted, so changes are needed to ensure the rule can be feasibly implemented by smaller entities.

(Response 92) We do not agree that the final rule favors or is intended for larger firms. As discussed later in this document, the final rule includes several full and partial exemptions that apply to smaller entities such as small farms, RFEs, and other entities, including additional exemptions not included in the proposed rule. In addition, we believe that all entities subject to the rule will be able to meet

the requirements that apply to them. As discussed later in this document, we have reduced the amount of information on CTEs that entities are required to keep and to provide to their customers. And although we encourage the use of electronic records and communications for traceability, the final rule does not require electronic recordkeeping or any technologies for records maintenance or supply chain communications. Nevertheless, we understand that coming into compliance with the final rule might pose more challenges for entities with fewer resources and less experience in traceability, and we intend to provide outreach and guidance to help smaller entities understand and comply with the applicable requirements of the final rule. In addition, in accordance with section 204(h) of FSMA, not later than 180 days after promulgation of this final rule we will issue a small entity compliance guide (SECG) that explains the requirements of subpart S in plain language, with the goal of assisting small entities, including farms and small businesses, in complying with these new requirements.

(Comment 93) Some comments assert that the proposed rule places an undue burden on small farms, including those just above the proposed exemption threshold; that small farms could not comply or would have significant difficulty complying with the rule; and that the rule could cause some small farms to go out of business and cause consolidation in the industry. Some comments state that FDA should support small farms, not burden them. Some comments provide the following reasons why the rule would potentially hurt small farms: (1) the industry is already overregulated, and the COVID–19 pandemic and the current state of the economy mean any new burden will be difficult for small farms to bear; (2) the proposed requirements are too numerous and too stringent; (3) small farms would have to hire additional staff to keep the records, or the rule would depress worker ''profits'' by forcing them to perform additional unpaid recordkeeping work; (4) small farms do not have electronic capabilities, especially in underserved (in electronic infrastructure) geographic regions and in some religious communities; (5) the requirements of the rule would be a barrier to entry and growth for small-scale farms, and the rule would make it difficult for them to compete with larger farms; and (6) many of the crops on the FTL are mainstays of small farms. Some comments simply maintain that the rule is overburdensome, while others ask that we exempt small farms or small-scale farms from the rule, or simply not issue any final rule.

(Response 93) We appreciate that this rule for the first time will establish traceability recordkeeping requirements applicable to farms, and that complying with the subpart S requirements may place a burden on many smaller farms, particularly in the economic environment accompanying the COVID–19 pandemic. We agree it is important to try to reduce the burden of the rule on businesses that may have fewer resources to apply to compliance, while minimizing the additional health risk caused by consumer exposure to products that would otherwise be covered by the regulation. Therefore, as discussed in Section V.E.2 of this document, the final rule includes exemptions and partial exemptions for smaller farms. Furthermore, as discussed in Section V.I, the final rule streamlines the KDE requirements, including by eliminating the proposed requirements for growers. Because of these exemptions, revised KDEs, and the flexibility provided in the final rule, we conclude that the rule will not establish significant barriers to entry for farms or be the cause of significant consolidation in the industry. Further, as discussed in Section V.U.4 of this document, we will provide education, training, and technical assistance to farmers, and we will be issuing materials, including an SECG, specifically aimed at assisting smaller farms in complying with the requirements of this rule.

Regarding the comments about electronic capabilities, we note that the only portion of the final rule that requires such capabilities is the electronic sortable spreadsheet requirement in § 1.1455(c)(3)(ii). Under § 1.1455(c)(3)(iii)(A), farms with annual sales of no more than $250,000 are exempt from this requirement. Furthermore, under § 1.1455(c)(3)(iv), FDA will withdraw a request for an electronic sortable spreadsheet to accommodate a religious belief of a person asked to provide such a spreadsheet.

(Comment 94) One comment states that, in addition to exempting small and medium producers and retailers, larger retailers should only be required to obtain tracking information from very large producers so as not to overburden small producers that would otherwise be exempt.

(Response 94) We do not agree that large retailers should only have to keep records of FTL foods obtained from very large producers, as this could significantly reduce the traceability information available to FDA in some circumstances. However, we recognize that when firms obtain food from suppliers that are not subject to subpart S, they might not receive certain information their supplier would be required to provide if they were subject to the rule. Therefore, as discussed in Section V.N.2 of this document, the final rule clarifies the traceability information to be kept when a person receives an FTL food from a person to whom subpart S does not apply.

(Comment 95) Some comments assert that Congress recognized in the 2002 Bioterrorism Act that foods can be traced without imposing requirements on the first or last links in the supply chain, *i.e.,* the farmer/rancher and the entity that sells or serves the food to the consumer, and that Congress reaffirmed this approach to traceability in FSMA. These comments also maintain that, in FSMA, Congress also recognized the importance of protecting small and local food businesses from expensive regulations not needed for small operations, and that FDA incorporated this principle in adopting other regulations under FSMA, such as the provisions for ''very small businesses'' in the preventive controls regulation. The comments maintain that FDA is contradicting these principles and imposing costly, burdensome requirements on farms, RFEs, and very small businesses.

(Response 95) We do not agree with the comments' characterizations. Unlike the Bioterrorism Act traceability provisions (section 414(b) of the FD&C Act), section 204(d)(1) of FSMA does not exclude entities at the beginning (*e.g.,* farms) or end (*e.g.,* restaurants) of the supply chain from the scope of the law. Rather, in referring to entities such as farms and grocery stores, Congress recognized the importance of ensuring traceability to both ends of the supply chain. With respect to smaller businesses, the different components of FSMA were designed to serve different food safety purposes, and they do not specify a uniform approach to the application of implementing regulations to smaller firms and farms. In any event, as discussed later in this document, the final rule fully exempts from subpart S certain small food producers and small RFEs and restaurants, and provides partial exemptions for certain other smaller entities, as well as exemptions relating to short supply chains.

(Comment 96) Some comments maintain that the proposed requirements should only be applied to large firms because foodborne illness outbreaks are only a concern with large firms. One comment asserts that the rule

could lead to an increase in foodborne illnesses since small firms cause fewer illnesses and have the highest level of traceability, and they will likely cease production due to the cost of compliance. Some comments state that foodborne illness outbreaks are always traced back to large farming operations, such as ''mega-farm'' facilities, concentrated animal-feeding operations (CAFOs), monocrop operations, and those that sell through aggregators and large distributors. One comment suggests that small firms have every incentive to ensure their foods are safe because their customers know the source of the products and will make it known if their products cause illness. One comment maintains that outbreaks only become a factor with central processing facilities, where items from across the country are processed and packaged, and that there is no reason to impose the recordkeeping requirements on items with a short supply chain from producer to consumer. One comment asserts that, although the rule is intended to fix a problem caused by firms being too large to maintain healthy standards, it will ruin the small producers who are not the source of the problem.

(Response 96) We do not agree with the comments that foodborne illness outbreaks are only associated with larger food producers and facilities, and the comments do not provide data to support this assertion. Firm size does not change the characteristics of the food (*e.g.,* the potential for supporting pathogen growth). Nevertheless, as stated in section V.E.2 of this document, the final rule includes several exemptions and partial exemptions for smaller entities, including those involved in shorter supply chains, and we do not believe that the rule imposes an unnecessary or unreasonable burden on those entities that are subject to these recordkeeping requirements.

(Comment 97) Some comments suggest that most foodborne illnesses result from contamination in the middle of the supply chain and ask that the rule account for the lower risk associated with farms and restaurants.

(Response 97) As discussed in the preamble to the proposed rule (85 FR 59984 at 59990), point-of-service firms (foodservice and retail) affect almost every traceback investigation FDA conducts because information concerning consumer purchases from point-of-service firms often is used to initiate a traceback. Coverage of RFEs and restaurants is therefore a vital part of the subpart S requirements.

By including section 204 in FSMA, Congress recognized the need for improvement of food tracking and tracing generally and traceability recordkeeping requirements in particular. In not excluding farms and restaurants from the scope of these requirements, Congress also recognized the importance of ensuring traceability to both ends of the supply chain. While we realize that contamination in the middle of the supply chain can result in foodborne illness outbreaks, in recent years, numerous outbreaks that CORE has worked on related to FTL foods have been linked to growers and other entities at the start of the supply chain (Ref. 7). The requirements of this rule will help ensure that the food industry maintains the traceability information we have determined is needed to enable us to respond quickly and effectively to foodborne illness outbreaks and recall events.

While we continue to believe that traceability is important at the beginning and end of the supply chain, we recognize that various full or partial exemptions are appropriate to provide certain farms as well as RFEs and restaurants with flexibility and/or relief in meeting the subpart S requirements, while ensuring that appropriate measures are in place to allow for efficient traceability activities when needed. These full and partial exemptions are discussed in Section V.E of this document.

(Comment 98) One comment asserts that because many growers take on a significant recordkeeping burden to comply with food safety requirements at the request of their customers, FDA should ensure that the subpart S requirements can easily integrate with a farm's existing food safety protocols and complement rather than duplicate food safety efforts already occurring in the marketplace.

(Response 98) We agree with the comment. We believe that the requirements in the final rule applicable to farms coordinate well with food safety measures many farms have adopted in recent years in response to the demands of their customers. In addition, as discussed in Response 104, we believe the KDEs-for-CTEs recordkeeping approach the final rule establishes is generally consistent with traceability plans and systems in place in many supply chains. Moreover, as discussed in Section V.E.2 of this document, smaller farms that might be especially burdened by additional traceability requirements for FTL foods are exempt from the final rule.

(Comment 99) One comment maintains that the rule would penalize a farm for being diversified and having total sales that prevent exemption. The comment maintains that while the inclusion of an exemption by reference to the produce safety regulation is laudable, the rule would nevertheless have a disproportionate impact on diversified farms.

(Response 99) We do not agree that the rule has a disproportionate or improper impact on diversified farms. In accordance with section 204(d)(1) of FSMA, the rule applies to persons who manufacture, process, pack, or hold foods on the FTL. Although the fact that a farm grows several different RACs might increase the chances that the farm grows a RAC that is on the FTL, being subject to the rule with respect to that FTL food would not constitute a penalty but rather the appropriate application of the recordkeeping requirements Congress concluded were necessary to protect against the risks posed by such foods. Furthermore, if growing several crops enables a farm to achieve a level of sales making it ineligible for exemption as a small producer, the size of its earnings would make it less likely that compliance with subpart S would pose an undue burden on the farm.

3. Application of the Rule to All Foods

(Comment 100) Some comments suggest that the proposed traceability recordkeeping requirements be applied to all foods, not just foods on the FTL. One comment acknowledges that FSMA limited the additional recordkeeping requirements to foods on the FTL but maintains that this approach is flawed and suggests that it be reconsidered. One comment asserts that FDA could have relied on other provisions of the FD&C Act to more broadly apply the proposed traceability requirements, and they encourage all food producers and processers to voluntarily follow the final rule. One comment commends FDA for recommending adoption of end-to-end digital traceability systems for all foods but recognizes that the Agency is statutorily restricted from requiring traceability for foods beyond those on the FTL.

On the other hand, several comments raise concerns that firms may have to keep traceability records for all foods, not just FTL foods, based on supply chain pressures. One comment asserts that to ensure compliance, some firms likely will request all information required under the rule for receivers from all their suppliers, regardless of whether the food or the supplier is exempt from the rule, which will effectively force all manufacturers to comply with the rule's requirements for shipping records. Some comments maintain that the rule will indirectly affect non-FTL foods because many

firms will not have the capacity to operate two sets of recordkeeping systems for their products. One comment asserts that the rule is not feasible for the entire food sector and that it is unlikely that food companies could voluntarily adopt this approach for many ingredients not on the FTL. One comment asserts that the rule should not be applied to all foods, adding that any future decision to extend additional traceability recordkeeping requirements to non-high-risk foods would depend on a decision by Congress to impose additional regulatory costs throughout the food chain, including on segments that, according to the comment, present no or limited risks.

(Response 100) The subpart S requirements set forth in the final rule apply only to persons who manufacture, process, pack, or hold foods on the FTL; the rule does not apply to non-FTL foods. Section 204(d)(7) of FSMA states that the recordkeeping requirements FDA establishes under section 204(d)(1) shall have no effect on foods that the Agency has not designated as high-risk foods under section 204(d)(2), and that foods not so designated are subject solely to the one-up, one-back recordkeeping requirements under section 414 of the FD&C Act and subpart J of the regulations. In accordance with section 204(d)(7) of FSMA, subpart S does not impose any requirements with respect to non-FTL foods.

However, as stated in the preamble to the proposed rule, we believe that applying to all foods the approach to recordkeeping required under subpart S for FTL foods would benefit both industry and American consumers by facilitating faster traceback and identification of contaminated food, thereby limiting the adverse impact of an outbreak on consumers and affected sectors of the food industry. Although we acknowledge that conducting more robust recordkeeping for all foods might not be feasible for all firms, especially those with fewer resources to devote to traceability measures, we hope all entities in the supply chain recognize the importance of subpart S's emphasis on the documenting and sharing of lot code information as a product moves through its supply chain.

4. Application of the Rule to Imported Foods

(Comment 101) Some comments urge FDA to uphold a ''level playing field'' by requiring both domestic and foreign firms to comply with the traceability recordkeeping requirements for FTL foods. One comment contends that once a product is manufactured and shipped, imported product traceability details are no longer maintained; if the product does not bear the imported product's traceability information, a traceback to the point of origin and any root-cause analysis is limited. The comment asserts that this lack of information could subject domestic produce and produce growing areas to a product or market recall even though all traceability rules are followed. One comment states that, considering the potential expense incurred, it is critical that both domestic and imported foods adhere to the same traceability requirements.

(Response 101) The requirements of the final rule apply to all persons who manufacture, process, pack, or hold foods on the FTL (unless an exemption applies), regardless of whether the person is in the United States or a foreign country. It is possible that, with respect to some imported FTL foods, the rule requires documentation of the production of the food that not all importers or other entities currently maintain, but they will be required to do so under subpart S. For example, regardless of whether an FTL food is domestic or foreign in origin, the rule requires that shippers of FTL foods provide information on the traceability lot code source of the food and that receivers of FTL foods record the traceability lot code source information. In short, the final rule applies equally to domestic and foreign persons who manufacture, process, pack, or hold FTL foods.

(Comment 102) Two comments ask that we explain how the proposed traceability requirements and the FSVP regulation differ.

(Response 102) The subpart S traceability recordkeeping requirements are designed to help FDA more quickly identify the source of a foodborne illness outbreak and remove contaminated food from the marketplace. These requirements apply to persons who manufacture, process, pack, or hold foods on the FTL. The FSVP regulation (subpart L of 21 CFR part 1), on the other hand, is designed to help ensure that persons who import food into the United States verify that the foreign supplier uses processes and procedures that provide the same level of public health protection as the FDA requirements on standards for produce safety and preventive controls for human and animal food, as applicable, and to ensure that the food is not adulterated under section 402 of the FD&C Act or misbranded with respect to labeling for the presence of major food allergens under section 403(w) of the FD&C Act. In short, while this final rule focuses on improving traceability for both domestic and foreign foods on the FTL, the FSVP regulation is intended to help ensure that importers take certain steps to verify, before importing food, that the imported food meets applicable FDA food safety requirements.

(Comment 103) Several comments express concern about foreign compliance with the rule, particularly because some foreign suppliers of FTL foods might not know that their products will be exported to the United States. The comments state that this would be especially problematic because the proposed rule would require firms to pass traceability lot codes forward through the supply chain while prohibiting assignment or changing of codes except at initial packing and transformation. The comments assert that the rule would be burdensome because the requirements might be applied to products that might not ultimately be exported to the United States. The comments further maintain that complying with the rule would be practically and technically difficult for many operations because they would need to update their traceability systems to comply.

(Response 103) FDA is aware that many firms, both domestic and foreign, will have to update their traceability systems to comply with the rule. However, we think the subpart S requirements are justified in light of the benefits associated with more efficient and effective tracing during foodborne illness outbreaks. Regarding the concern that some foreign suppliers may have to provide traceability information for products that, in the end, are not exported to the United States, U.S. importers will need to work with their upstream suppliers in foreign countries to ensure there is an understanding of the potential for foods on the FTL list to be exported to the United States and the traceability information required for these products. The final rule provides flexibility in how this information is provided, which should make maintenance and sharing of the information easier as firms can decide the method that is best suited to their operations. We expect that much of the information required to be provided to customers under the rule is already being shared between trading partners, and firms would not be required to duplicate those records to comply with the rule.

5. Reduction and Simplification of Requirements

(Comment 104) Many comments request that FDA simplify the proposed recordkeeping requirements by reducing the number of CTEs for which firms

must keep records and streamlining the number of KDEs they must record for each CTE. Several comments claim that the proposed rule is needlessly complex, overly prescriptive, and goes beyond what is necessary for traceback purposes. Several comments maintain that the required KDEs should be limited to information that is absolutely necessary. Some comments assert that the rule would impose redundant requirements or requirements of minimal value. Several comments assert that the proposed CTE/KDE structure is too complex to understand how the rule would apply to each food a firm handles. One comment maintains that the burden this complexity will place on industry will detract from the effectiveness of recordkeeping programs and prevent the rule from achieving its intended public health benefit. Some comments suggest that a simpler system would make the rule more readily understandable and accurately implemented by industry at a lower cost. Some comments assert that FDA could fulfill its statutory mandate and achieve similar public health benefits through simpler and less costly alternatives that leverage already successful traceability recordkeeping systems, like those of foodservice distributors.

(Response 104) We agree with the comments that the requirements of the rule should be as simple and few as possible while still enabling the rule to achieve its purpose of improving the traceability of FTL foods. In response to comments, we have made several revisions to the CTEs for which records must be maintained, and we have streamlined and simplified the KDEs required to be kept and provided to the recipient of shipped food. As discussed later in this document, for each of the CTEs we have tried to streamline the KDEs so that they include only the information we need to conduct timely and efficient investigations into foodborne illness outbreaks, as well as information that firms must provide to their customers to ensure consistency and enable them to meet their requirements under subpart S. We believe the changes we have made to the CTE/KDE requirements will make it easier for those persons who are subject to the rule to understand and comply with the applicable requirements, thereby making the rule more effective yet less burdensome. The CTE/KDE approach in the final rule is generally consistent with approaches taken by existing traceability programs, which we think will assist with implementation. Where appropriate and possible, we have revised or deleted proposed requirements to avoid unnecessary burden, provided additional opportunities for flexibility, and better aligned the requirements with current industry practices.

(Comment 105) Some comments maintain that the rule should focus on key gaps in the existing traceability recordkeeping requirements in subpart J. One comment suggests that we amend subpart J to require covered entities to maintain lot code information and asks us to consider ways to combine the requirements of subpart J and proposed subpart S to enhance traceability. Some comments assert that although creating and maintaining traceability lot codes and linking the codes throughout the supply chain are needed to fill gaps we have identified in the subpart J requirements, we should issue guidance to address any other shortcomings of these requirements rather than adopt new requirements.

(Response 105) We agree with the comments that the rule should focus on addressing important gaps in the subpart J recordkeeping requirements, and that is what we have done with subpart S. The preamble to the proposed rule cites the lack of lot codes as a key shortcoming of subpart J, and the final rule makes recording traceability lot codes and providing them to customers as part of certain CTEs a critical component of the subpart S requirements. The final rule addresses another gap in the subpart J requirements by more completely covering the sectors of the supply chain, from farms and other food producers at the beginning of the chain to RFEs and other entities at the end of the chain. Further, firms that are currently complying with subpart J recordkeeping can use those records to satisfy many of the subpart S requirements. Consistent with Congress' directive to establish additional recordkeeping requirements for traceability, and because the scope of subparts J and S are not the same, we established a new regulation. We believe that putting these requirements into a guidance, without also issuing a regulation, would not be appropriate.

(Comment 106) Several comments specify each of the KDEs they believe are unnecessary or inapplicable to some or all FTL foods, including such KDEs as the following: the entry number for imported products; the category code/term, category description, brand name, commodity, and variety; the physical location name; location identifiers; the point of contact for lot code generators; the date and time for a CTE; location information for where the CTE occurred; and the name of the transporter.

(Response 106) As stated in Response 104, we have made several changes to the KDEs that must be kept and provided for each CTE in the supply chain. We address the comments on which KDEs are appropriate and necessary for each CTE in the individual sections of this document concerning the relevant CTEs.

(Comment 107) One comment objects to imposing different requirements for different CTEs under the rule.

(Response 107) We do not believe it would be appropriate to require maintenance of the same KDEs for each supply chain event, as some information is not available at all steps in the supply chain and some entities are better suited than others to keep and provide information for certain CTEs. Consequently, the final rule tailors the KDEs that must be kept and provided for each CTE according to the information it is reasonable and appropriate for entities to maintain to facilitate effective traceability.

(Comment 108) Several comments object to the proposed requirements to provide certain traceability information to their customers for certain CTEs, such as shipping. One comment asserts that the proposed rule would require unnecessary repeated sharing of data, rather than focusing on just one or a few responsible parties. One comment asserts that the rule necessitates that trading partners repeatedly reshare attributes associated with products, locations, and business entities instead of acknowledging that those attributes are populated by one or a few parties who are responsible for that data.

(Response 108) We do not agree with the comments that it is unnecessary to require certain entities in the supply chain to share information with persons to whom they send FTL foods. As discussed more fully below, the final rule requires entities that engage in certain activities with respect to FTL foods (*e.g.,* initial packing, receiving, transformation) to keep records of certain KDEs so that this information is available to FDA if necessary to assist in our investigation of a foodborne illness outbreak. To help ensure that these firms have the required information, the rule also requires for certain CTEs (*e.g.,* shipping) that firms provide information to persons to whom they send the food. In many cases, firms already provide this information to their customers in the normal course of business, although perhaps not all firms provide all the KDEs specified in the final rule. To the extent that any of the required information is already being kept within a firm's record system, the firm does not need to duplicate these existing records

to satisfy the requirements under subpart S. In addition, as discussed below, the final rule includes changes designed to place responsibility for the maintenance of certain records on the entities in the supply chain that are best suited to the task.

(Comment 109) Several comments suggest that FDA require firms to pass forward two standardized pieces of information (not specified in the comment) identifying the originator or creator of a product in a method that does not require the disclosure of confidential business information, rather than requiring an elaborate set of additional KDEs. The comments maintain that such a requirement, coupled with adequate enforcement of the subpart J requirements, would allow for effective tracking and tracing of foods on the FTL. Alternatively, the comments suggest that FDA allow use of a linking identifier already established by the receivers and shippers—such as a purchase order (PO) number, bill of lading (BOL), or other reference document—that links products being shipped to products received. The comments assert that this approach would be an effective alternative to a lot code-based system while being less cumbersome and costly to implement.

(Response 109) We disagree with the comments to the extent that they suggest we are requiring unnecessary recordkeeping. As previously stated, we have tailored the required KDEs to specific CTEs in the supply chain so that the different entities in the chain can provide FDA with information we need to conduct an outbreak investigation involving an FTL food. Requiring documentation of traceability lot codes and related information at different stages of production and distribution will enable us to skip steps in the supply chain, link a food to the firms that have handled it, and ultimately lead us back to the source of the food. Relying solely on PO numbers, BOLs, and other reference documents to link products between each shipper and receiver in a supply chain would not allow us to skip steps and trace a product back to its source in an efficient and timely manner to mitigate potential foodborne illnesses. Regarding the comments' concerns about the disclosure of confidential commercial information, the final rule includes changes to proposed requirements related to points of contact and lot code generators to address these concerns, as discussed in Sections V.F.28 and V.M.2 of this document.

(Comment 110) Several comments suggest that the KDEs focus on lot numbers. One comment asserts that FDA could require an endless number of data points, but that would not be necessary if there was a mandatory requirement for lot codes to be present on all forms of documentation that support the transaction. One comment suggests that the proposed timeframe and implementation process for the rule would be more manageable with a smaller data set transmitted between trading partners—the lot code tied to product and contact information for the brand owner—and increased flexibility on how to reach the objective. One comment maintains that the lot number along with the company name and product identification should be enough to ''unlock'' other needed information with the originator. Some comments maintain that the rule should focus on the appropriate assignment of traceability lot codes linked to the date of harvest and preservation of traceability lot codes throughout the supply chain. One comment maintains that the proposed rule seems to codify approaches (*e.g.,* use of reference records, dates, times, product descriptions, identifiers) that have proven to be imperfect and cumbersome, and which the IFT in the 2012 traceability pilot report identified as ''conditional'' data elements (*e.g.,* back-up plans when the batch/lot number was not available). This comment maintains that the lot number is the critical data element, combined with information regarding the entity responsible for the lot number and the item description. One comment maintains that the lot number tied to the product and accompanied by contact information for the entity responsible for production (rather than handling) of that product is sufficient to trace products. The comment further asserts that if some of the information proposed to be shared between trading partners were instead required to be tied to the lot number/product and maintained by the originator, creator, or transformer, and made available upon written request, FDA's objectives could be met at a lower cost to the industry and with improved implementation and compliance.

On the other hand, one comment argues that lot codes often are missing for produce and maintains that documents supplied with purchases do not contain any traceability information beyond an item's description, the product number/stock-keeping unit (SKU), the PO number, and the name of the supplier. Furthermore, the comment asserts that most distributors do not have the ability or capacity to record lot numbers, which the comment maintains would have to be read from the box or label and entered manually into a database.

(Response 110) We agree with the comments asserting that lot codes are a critical component of effective traceability records. As stated in Response 345, recording traceability lot codes when handling FTL foods and providing the codes to supply chain partners as part of certain CTEs is a core component of the subpart S requirements. Recognizing that the absence of required lot code information is a key weakness of the subpart J traceability requirements, the final rule directs that traceability lot codes be assigned and recorded when FTL foods are initially packed (or, for foods obtained from a fishing vessel, first processed on land) or transformed, and the traceability lot code must be recorded at subsequent stops in the food's supply chain. To help ensure that entities in the supply chain can document the traceability lot code for the FTL foods they receive, the final rule requires shippers of FTL foods to provide this information to receivers. To help ensure that accurate traceability lot code information for FTL foods is maintained, the rule requires firms to keep records linking traceability lot codes to information on the food and its producer. This additional information is not meant as a ''back-up plan,'' but instead can prove independently useful, as discussed in more detail below in response to comments about specific KDEs. To further aid traceability to the producers and manufacturers of FTL foods, the final rule requires firms to provide to the recipients of the food they ship information that enables identification of the source of the traceability lot code assigned to the food. In short, we believe the final rule appropriately makes traceability lot codes a KDE of critical importance to the traceability recordkeeping requirements in subpart S, but we also believe that the other KDEs required by subpart S are essential to rapid and effective traceability.

For receivers of shipments that may be missing lot codes, § 1.1345(b) sets forth the requirements for when an FTL food is received from a person who is exempt from subpart S. This includes assigning a traceability lot code if one has not already been assigned. In a situation where the shipper is covered by subpart S but nonetheless failed to provide the required traceability lot code, we urge supply chain partners to work together to address such discrepancies. With respect to the comment that most distributors do not have the ability to record lot numbers,

we do not agree. We believe that the majority of distributors receive lot code information for the foods they receive and they are able to record this information, although they might not have the capability to do so electronically. Although we encourage the use of electronic records for traceability, the final rule does not require them.

(Comment 111) One comment maintains that the more information and data that are required, the more likely there will be errors. One comment asserts that the rule would force use of advance shipping notices (ASNs) due to the complexity of operations, the number of items carried in facilities, and the view that manual activity is prone to human error.

(Response 111) We do not agree that maintaining the records required under the final rule will lead to errors in recordkeeping. Many firms already keep all or most of the required KDEs as part of their existing tracing or business records. To the extent that errors occur, we believe that availability of the required information will make it more likely that FDA could nevertheless obtain the information needed in conducting an outbreak investigation or assisting in a product recall. With respect to ASNs, the final rule does not require the use of any particular type of reference document to meet applicable subpart S requirements.

(Comment 112) One comment maintains that there is broad-based adoption of traceability technologies and records collection at the beginning of the supply chain for certain commodities. The comment supports requiring RFEs to capture the traceability lot code assigned originally to a food but not prescribing how information is shared through the supply chain, and asks that we reduce the number of KDEs that must be shared.

(Response 112) As previously stated, we agree that traceability lot codes are a crucial component of this rule, including as maintained by RFEs for the FTL foods they receive. As discussed below, the final rule provides greater flexibility in how information can be shared through the supply chain, including with respect to information on the traceability lot code source for an FTL food, and streamlines and simplifies the KDEs required for some CTEs.

(Comment 113) One comment asserts that required KDEs other than the lot code will discourage, complicate, and delay implementation of the rule. On the other hand, one comment maintains that when a lot code is available, additional KDEs, such as the physical location name and the time a food was shipped, received, transformed, or created, add value to traceability.

(Response 113) As stated in Response 345, records of traceability lot codes are critical for ensuring the traceability of FTL foods. However, to effectively conduct investigations into foodborne illness outbreaks, FDA needs to be able to review other traceability information on foods such as shipment information and information on the entities that have produced and handled the foods to ensure we can follow the supply chain history of the product. The lot code alone without these additional KDEs would not provide all of the information necessary to determine the flow of product through sometimes complicated supply chains. Consequently, for CTEs involving FTL foods, the final rule requires firms to record the applicable traceability lot code for the food along with other KDEs, including essential information describing the product and persons who handled the product, such as the source of the product's traceability lot code. Sections V.I through V.O of this document discuss the KDEs that firms will be required to keep for particular CTEs under the final rule.

(Comment 114) One comment asks that we make explicit in the rule that the traceability lot code requirements are data retrieval requirements rather than standards specifying how, where, or by whom traceability information must be stored and transferred. The comment further asks for confirmation that the subpart S requirements can be fulfilled by providing to FDA, in the format and timeframe requested, the relevant information for which a company is responsible, regardless of how (or where) that information is managed within a company's internal systems or through its relations with third-party service providers or supply chain partners.

(Response 114) The final rule requires entities who perform certain CTEs (*e.g.,* initial packing, shipping, receiving) with FTL foods to keep records of certain KDEs relevant to those events, and in some cases to provide certain KDEs to other entities in the food's supply chain. We believe that these requirements are necessary to ensure that adequate traceability information is available to FDA and supply chain entities to quickly and effectively respond to foodborne illness outbreaks.

As discussed in section V.R.1 of this document, the final rule does not adopt standards for the format in which required information must be stored or shared. Under § 1.1315(a)(1), a firm's traceability plan must include a description of the procedures used to maintain the records the firm is required to keep under subpart S, including the format and location of these records. When requested by FDA, the information required under subpart S must be provided to us in accordance with § 1.1455. We agree that the record production requirements in § 1.1455 can be fulfilled by providing to FDA the relevant information for which a company is responsible, regardless of how (or where) that information is managed within a company's internal systems or through its relations with third-party service providers or supply chain partners, as long as the requirements of § 1.1455 are satisfied. The final rule specifies that offsite storage of records is permitted (see § 1.1455(c)(2)), that firms may have another entity establish and maintain required records on their behalf (see § 1.1455(b)), and that electronic records are permitted and may include valid, working electronic links to the required information (see § 1.1455(a)(1)). We believe that these provisions provide the flexibility that the comment requests.

(Comment 115) One comment asserts that the written order of the proposed requirements does not follow the logical flow of the product through the supply chain. As an example, the comment notes that shipping is the last CTE addressed in the codified even though it covers shipment by a farm. The comment suggests that we reorder the provisions to begin with origination of food (including records for growing and for shipping by the originator) and proceeding to the requirements applicable to first receivers, followed by those for receiving, transformation, and creation.

(Response 115) We agree with the comment that a reordering of some of the proposed CTE recordkeeping requirements is appropriate. As stated in Response 357, the final rule begins with a reduced list of KDEs for activities that occur before a RAC is initially packed. Next, it states the requirements for the initial packing of RACs other than food obtained from a fishing vessel and for the first land-based processing of food obtained from a fishing vessel (which, as discussed in Response 384, have replaced the proposed requirements for first receivers). The final rule then specifies the requirements for the CTEs of shipping and receiving of FTL foods, concluding with the requirements applicable to transformation (which under the final rule includes events we called ''creation'' in the proposed rule). We believe this reordering more closely

aligns with the movement of foods through the supply chain.

6. Use of Traceability Lot Codes

(Comment 116) Some comments assert that the industry's current practice of using records such as POs or BOLs allows distributors to sufficiently track which lots are in the shipments they receive and where product from that shipment goes. One comment maintains that the 2012 IFT Final Report found that identifiers such as POs and BOLs can be used for tracing and suggests that such an approach would be better than the system in the proposed rule requiring traceability lot codes and many other KDEs. The comment maintains that distributors' current practices result in broader but more effective recalls because they provide greater confidence that affected products were removed. The comment argues that the proposed rule's focus on tracing individual lots of FTL foods could lead to an insufficient and prolonged product withdrawal, which could be a public health risk.

(Response 116) We do not agree that the use of POs or BOLs alone, without inclusion of the traceability lot code and other KDEs required under subpart S, is sufficient to enable us to effectively and efficiently trace food through the supply chain. The assignment of a traceability lot code, combined with other identifying KDEs, allows a food product to be uniquely identified and provides information needed to link shipments of a food between different entities in the supply chain. During an outbreak or recall event, FDA routinely requests lot code information from firms to effectively link movement of foods throughout the supply chain. The availability of traceability lot codes along an entire supply chain will improve our ability to identify the specific food involved in a contamination event and to determine the appropriate scope of a recall event. The accurate and timely provision of the traceability lot code for a product as it moves through the supply chain is a critical component of the subpart S requirements.

(Comment 117) One comment maintains that maintaining traceability lot codes should be encouraged but not required because, according to the comment, experience in the meat and poultry industry shows that lot codes rarely narrow the scope of an outbreak to a specific lot or lots, since consumers generally do not have the packaging material with lot codes at the time of illness onset. The comment asserts that consumer purchase reports from retailers, which do not contain lot codes, are useful in outbreak investigations. The comment also maintains that most outbreaks with successful traceback investigations are able to identify a source and result in recalls with much wider scope than a single lot, even when lots are traceable.

(Response 117) We disagree that entities should not be required to keep traceability lot codes because food packaging may not be available during an investigation. The reason for requiring entities, including RFEs and restaurants, to keep records containing the traceability lot code upon receipt of an FTL food is to provide a mechanism for determining what traceability lots were available for purchase or consumption during the timeframe of exposure without requiring the consumer to retain packaging. Once traceability lot codes that were available for purchase or consumption are identified, we can do a traceback of those lots and obtain additional information on the food, including ingredients and their sources.

(Comment 118) One comment suggests that the traceability lot code should only be linked to the business name of the firm that originated the product and the date of production rather than the location of production. The comment maintains that this information is the most important to support effective traceback. The comment further suggests that firms should be required to link the traceability lot code to existing industry records to support root-cause investigations, rather than specifically requiring KDEs and CTEs.

(Response 118) We do not agree that the traceability lot code, the business name, and the date of production alone are sufficient to enable effective tracing of foods, nor do we agree that linking the traceability lot code to existing industry records would be sufficient. Our experience performing traceability investigations has demonstrated that identifying the food and actual location of production, processing, or packing can be extremely challenging and time-consuming using only information that is maintained in accordance with current requirements and business practices, including in reference documents such as BOLs and ASNs, and we think it would continue to be challenging if we only required the traceability lot code to be linked to the business name of the originating firm and the date of production. In many cases, the business name of a firm may not correspond to the physical location address where the food was handled but to the headquarters address for an entity. Since some businesses may have multiple locations in addition to a headquarters address, linking the traceability lot code to the physical location where the food was handled is critical to ensuring timely and accurate information for traceback investigations. Furthermore, linking the traceability lot code to the other required KDEs will provide critical traceability information, including information about the type of food and its movement through the supply chain. In Section V.C.5 of this document we explain how we have streamlined the KDEs to include only the information that we think is essential to effective and efficient traceability.

7. Need for Flexibility

(Comment 119) Many comments urge us to establish flexible requirements that can work with different types of food, firms, business models, and traceability approaches. One comment suggests that the rule should be flexible enough to accommodate industry practices and simple enough that it can be adopted uniformly across industry. One comment asserts that the rule must account for many different business models and supply chains involved in getting fresh produce from the farm to the point of service/retail, but one comment maintains that it is not practical or feasible to have different systems for different crops. Several comments ask that the rule provide additional flexibility to minimize the costs of compliance for smaller entities. One comment contends that an inflexible, labor-intensive, or one-size-fits-all approach could be economically disastrous for small farms, those that prioritize diversified production, and those who are already participating in certifications (such as USDA organic) that require extensive recordkeeping. One comment asserts that although the rule provides strong protections from additional recordkeeping requirements where food is sold directly to consumers, where there are supply chain intermediaries, even in relatively short, low-volume supply chains, the rule does not offer size- and risk-appropriate flexibility.

(Response 119) As stated in the preamble to the proposed rule, we believe it is consistent with best industry practice to adopt a recordkeeping approach for FTL foods that is based on maintaining and sharing relevant KDEs for the different CTEs in the supply chain. However, within this framework of standard requirements, the final rule includes provisions that take into account the different type of foods and supply chain entities that are subject to the subpart S requirements

and allows firms considerable flexibility in meeting those requirements. For example, the rule does not specify a particular format in which required information must be maintained and shared. Although we strongly encourage the use of electronic recordkeeping for traceability, persons subject to the rule may keep their records in paper or electronic form. Firms can contract with others to establish and maintain records required under subpart S on their behalf as long as the firm can provide the information to FDA in accordance with the rule. To protect certain confidential business information, the rule allows firms the flexibility to provide their customers with a reference to the information instead of directly identifying the traceability lot code source of an FTL food they handle.

Recognizing that there are differences in the production and distribution of different types of foods, the final rule establishes separate KDE requirements for the initial packing of RACs that are not obtained from a fishing vessel and for the first land-based processing of food obtained from a fishing vessel. The final rule also exempts certain types of food from the scope of the subpart S requirements. In addition, the final rule exempts certain smaller food producers and smaller RFEs and other food service providers, including many farms and firms that are a part of short, local supply chains. Finally, the final rule provides flexibility to all supply chain entities by allowing them to rely on any records they have already created or obtained for business or other purposes to meet the recordkeeping requirements for subpart S.

8. Outcome- or Performance-Based Approach

(Comment 120) Several comments suggest that we adopt an ''outcome-based'' or ''performance-based'' approach to the recordkeeping requirements instead of what they describe as the proposed ''prescriptive'' approach specifying particular information that must be maintained regarding specific events. Some comments suggest that the rule should regard firms as compliant if they are able to provide FDA with requested information (linking outgoing products to incoming ingredients) within a short time (*e.g.,* 24 hours). One comment maintains that FDA has said tracebacks are most efficient when traceability information is available at the point of sale; therefore, the comment suggests that we focus on that objective instead of prescribing how information must be shared throughout the supply chain. One comment suggests that we consider the lessons learned from the meat and poultry industry's implementation of traceability programs under the regulation of the USDA's FSIS, which the comment maintains require only that establishments have procedures in place to recall products when needed without dictating how to achieve the result. One comment suggests that we consider requirements that are less prescriptive and can adapt to the future, including advancements in technology. One comment asserts that FDA's clear articulation of the objective of having details (including the lot number assigned to the product, the brand owner, and contact information for the brand owner) at the point of sale, without prescribing the mechanism by which that information is shared through the supply chain, will afford the flexibility that will facilitate adoption of the rule in the short term and encourage innovation consistent with FDA's New Era of Smarter Food Safety in the longer term.

(Response 120) Although we appreciate the benefits of ''performance-based'' approaches to regulation noted by the comments, we believe that the interconnected nature of effective food traceability and the varying levels of tracing capability throughout the industry require an approach for FTL foods specifying certain KDEs that must be kept and shared in the context of certain supply chain events, while allowing flexibility in how the required records are maintained and shared. Although we agree it is very important for FDA to have traceability information available at the point of sale, our investigations of foodborne illness outbreaks often require us to obtain information from other supply chain members as well. We think it is important for the final rule to specify the information that must be available to us from each point in the supply chain; otherwise, we are uncertain that the majority of entities subject to the rule would be able to provide the needed information on an FTL food and the firms that have produced or handled the FTL food in a timely manner.

In addition, ''performance-based'' approaches generally work best when each covered entity is responsible only for information it generates; however, for this rule to deliver the anticipated traceback efficiencies and public health gains, information must not only be generated by individual firms, but also passed along the chain. As noted in the comment, it is important to have traceability information available at the point of sale. The rule helps to ensure that restaurants and RFEs have the necessary information by requiring entities earlier in the supply chain to provide information that will ultimately reach these establishments. However, as stated in Response 460, the final rule provides flexibility in the manner in which information is stored and shared with others in accordance with subpart S requirements. Finally, we agree with the comments urging that the requirements be capable of being adapted to future technological advancements. As discussed in Section V.R.1 of this document, we are not mandating the use of any particular technical standards for the maintenance and transmission of the KDEs required under subpart S.

(Comment 121) One comment concludes that the requirement for the electronic sortable spreadsheet is consistent with the recommendation in the 2012 IFT Final Report that FDA accept CTEs and KDEs in summary form.

(Response 121) We agree that the sortable spreadsheet requirement is consistent with the 2012 IFT Final Report regarding pilot projects for improving traceability (Ref. 1).

9. Consistency With Section 204(d)(1) of FSMA

As discussed in the following paragraphs, several comments assert that the proposed rule is inconsistent with specifications regarding the traceability recordkeeping requirements set forth in section 204(d)(1) of FSMA.

(Comment 122) One comment asserts that the proposed KDEs would include information that is not ''reasonably available,'' contrary to section 204(d)(1)(A) of FSMA, because fishing vessels, aquaculture operations, and subsequent supply chain steps do not know the final destination of the products due to global competition within the seafood industry.

(Response 122) We disagree with the comment. Under the final rule, owners, operators, and agents in charge of fishing vessels are largely exempt from the rule with respect to FTL foods produced through the use of the vessel. As discussed in section V.L of this document, we believe that aquaculture farms and firms that conduct the initial packing of FTL foods from aquaculture farms will have the information needed to comply with relevant requirements under the rule. As discussed in Responses 101 and 528, the rule applies equally to both foreign and domestic firms, and we expect that foreign firms will be able to work with their supply chain partners to determine whether their products will be sold in the United States, as they already must do in order

to comply with several existing FDA regulations.

(Comment 123) Some comments assert that the proposed rule fails to ensure that the public health benefits ''outweigh the cost of compliance'' as required by section 204(d)(1)(D) of FSMA. One comment maintains that this is particularly so for foodservice distributors, who engage in hundreds of thousands of transactions on a daily basis that would be subject to the rule's requirements, and therefore would be required to establish and maintain thousands of new records every day, many of which the comment asserts are not maintained under current practices.

(Response 123) We disagree. Section 204(d)(1)(D) of FSMA states that FDA should ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements. As discussed in the FRIA (Ref. 16), the public health benefits of subpart S are expected to outweigh the costs of compliance with the rule. Currently, the traceability records of foodservice distributors are often essential to FDA's ability to conduct rapid and effective traceback operations. In addition, we believe that most foodservice distributors, like other types of supply chain entities subject to the final rule, generally will not have to establish thousands of new records but instead will be able to rely on records they keep in their current business practices to meet most of their requirements under subpart S.

(Comment 124) Several comments assert that the proposed requirements are not ''scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens,'' as required under section 204(d)(1)(E) of FSMA. Some comments maintain that FDA should not use a one-size-fits-all approach. One comment suggests that we use the best data available on food production risks at different scales; some comments urge us to adopt requirements that are size- and risk-appropriate and practicable for small farms and other small food businesses. Some comments assert that the proposed rule does not meet the ''scale-appropriate'' requirement because it favors firms with long supply chains over local firms with short supply chains, whose operations are said to pose lesser safety concerns. One comment maintains that in the cases where there are supply-chain intermediaries—even in relatively short, low-volume supply chains—the proposed rule does not offer size- and risk-appropriate flexibility. One comment asserts that we overestimated the degree to which some farms—particularly small contract farms, which would have responsibilities as shippers—have ready access to computer spreadsheet programs and similar electronic recordkeeping technology. Some comments suggest that we adjust the requirements to better reflect the scale and short supply chains of smaller growers and food hubs. One comment maintains that the proposed rule is not appropriate for LRFS markets and supply chains.

(Response 124) We do not agree with the comments. As stated in Response 107, due to the interconnected nature of traceability operations, establishing different requirements for different types and sizes of supply chain entities would be impractical and ineffective. Nevertheless, recognizing the different impact that the rule might have on different types and sizes of firms, the final rule exempts certain types of food from the subpart S requirements and also exempts or partially exempts certain smaller food producers, RFEs, and other food service providers, including many farms and firms that are a part of short, local supply chains. In addition, recognizing that smaller firms might not have electronic recordkeeping capability, the final rule does not require the use of electronic records, and it provides exemptions to certain smaller farms and firms from the requirement to make available to FDA an electronic sortable spreadsheet containing information on specified FTL foods under certain circumstances. We believe that the supply chain entities that must comply with the rule have the capability to do so. However, as discussed in section V.U.4 of this document, we anticipate that we will need to conduct different outreach and training activities to help different types and sizes of firms come into compliance with the rule. In addition, firms facing unique economic hardship due to the requirements may submit to FDA a request for a waiver of one or more of the requirements under subpart S (see Section V.Q of this document).

(Comment 125) Some comments assert that the proposed rule does not meet Congress' directive to ''not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business'' (section 204(d)(1)(E) of FSMA). One comment maintains that the proposed rule would create an entirely new—and at times duplicative—recordkeeping system for the food industry. Some comments assert that there is overlap between the proposed requirements and the existing traceability recordkeeping requirements in subpart J, and request that FDA not create situations where firms need to keep duplicative records for subparts S and J. One comment asserts that FDA and NOAA already require seafood companies to capture the same or similar KDEs for harvesting and importing—KDEs the comment maintains the rule would not accept. The comment claims that without the flexibility to use different KDEs that provide data comparable to that contained in the acceptable records, companies would be compelled to maintain and report multiple records containing the same or virtually the same information.

(Response 125) We disagree with the comments. The final rule specifies that firms are not required to duplicate existing records (such as those kept in the ordinary course of business or maintained to comply with other regulations) if they contain the information required by subpart S, and firms may supplement any such existing records as necessary to include all required information. For some firms, the records they maintain to comply with subpart J contain much of the information that is required under subpart S, and these firms will not need to duplicate these records to comply with subpart S. Similarly, if a firm that handles seafood keeps records required by FDA or NOAA that include information required under subpart S, it will not need to duplicate those records to meet subpart S requirements.

(Comment 126) One comment asserts that there is duplication in the proposed requirements to establish and maintain reference record types and reference record numbers for several CTEs.

(Response 126) We do not agree that the requirements in the final rule to document the reference document type and number applicable to a tracking event require maintenance of duplicate records. If the reference document type and number are already present in the firm's records for the relevant CTE—for example, if they are indicated on the reference document itself and the firm maintains the reference document to meet the requirements of the rule—then the firm would not be required to make a duplicate record that contains the reference document type and number.

(Comment 127) One comment asserts that by requiring the collection of highly detailed data linked to the lot code and available in other records, FDA has proposed a duplicative, burdensome system. The comment maintains that the duplicative nature is evident in requiring the creation of individual pieces of information linked to the lot

code and requiring a link to identify the underlying records containing information that must be linked to the lot code.

(Response 127) We disagree. The final rule does not require firms to create additional, duplicative documents for the sole purpose of linking the KDEs to the relevant traceability lot code. For firms that maintain paper records, one way such linkage may be achieved would be by having the traceability lot code appear on the reference documents the firm keeps to document the required KDEs. For firms that maintain records electronically, linkage could be achieved simply by including the traceability lot code in the same row of a spreadsheet or database that documents the required KDEs for a tracking event. Regardless of whether the records are kept on paper or electronically, the rule does not require creation or maintenance of duplicate records.

(Comment 128) Some comments support the rule's flexibility regarding the ways in which a traceability lot code may be linked to other data elements.

(Response 128) We believe that the final rule allows for flexibility and accommodates current business practices while ensuring that entities subject to the rule remain responsible for recordkeeping requirements to facilitate traceback during an outbreak investigation.

(Comment 129) One comment asserts that the proposed rule is inconsistent with the requirement in section 204(d)(1)(F) of FSMA to ''minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food.'' The comment asserts that passing forward KDEs from a shipper to a receiver will create demands for multiple different record formats based on unique business systems, resulting in an ever-increasing number of differing traceability data requirements.

(Response 129) We disagree. In general, the recordkeeping requirements of the final rule are not specific to the type of FTL food that is handled (although slightly different KDEs are required for the initial packing of a RAC not obtained from a fishing vessel compared to those required for the first land-based processing of a food obtained from a fishing vessel, and initial packers of sprouts must keep additional information regarding the seeds used for sprouting). Because the rule does not specify a particular form in which required records must be maintained or provided, it is possible that different firms may ask their suppliers to provide required information in different formats. However, we think the benefits of giving firms flexibility regarding how they maintain and share information—which many comments emphasize as important—outweigh the potential issues that could arise from different customers requesting records in different formats. We encourage supply chain partners to work together to harmonize how best to share the required information to minimize issues related to multiple record formats.

(Comment 130) One comment asserts that the proposed rule runs afoul of the requirement in section 204(d)(1)(G) of FSMA that this regulation ''to the extent practicable, not require a facility to change business systems to comply. . . .'' The comment contends that the proposed rule would force seafood businesses to revise their current systems for shipping and receiving documents to capture, maintain, and manage the required information. The comment asserts that some companies will have no choice but to incorporate tandem codes (the new traceability lot code and the conventional inventory code) even though these codes capture almost exactly the same information.

(Response 130) We disagree with the comment. As stated in Response 460, although the rule requires maintenance of certain KDEs for particular CTEs, it provides flexibility as to the form of the records in which the required information is kept. Because not all firms currently keep all of the information required under the final rule, we anticipate that firms may make changes to their traceability operations to come into compliance with the subpart S requirements. However, the rule does not mandate a change in business systems, and in many cases we think that relatively small changes to existing business systems will be sufficient to allow firms, including those that handle seafood products on the FTL, to comply with subpart S. With respect to the claim that firms will need to establish ''tandem'' lot codes because the conventional inventory code and the traceability lot code might reflect different information, we note that the traceability lot code itself does not have to incorporate all required KDE information, such as in bar code form. Instead, the final rule requires firms to keep records that link the traceability lot code for an FTL food to the other KDEs required for the relevant CTE (*e.g.,* initial packing, transforming). Therefore, firms should not have to change their current lot codes or create separate traceability lot codes solely because a traceability lot code must be linked to other KDEs for an event. Any type of lot code that an industry or firm currently utilizes can be used as the ''traceability lot code'' as long as it is passed through the supply chain and is only changed in the circumstances specified in the rule.

(Comment 131) Some comments contend that the proposed rule violates the prohibition in section 204(d)(1)(L)(i) of FSMA that the rule must not require ''a full pedigree, or a record of the complete previous distribution history of the food from the point of origin of such food. . . .'' One comment asks that the final rule delete all recordkeeping requirements that the comment asserts would require a full pedigree or distribution history of the food, including proposed §§ 1.1335(f) and 1.1350(a)(4), which concern requirements to maintain records identifying the traceability lot code generator when receiving and shipping an FTL food.

(Response 131) We do not agree that the rule requires entities to document a full pedigree for FTL foods they handle. Neither the proposed rule nor this final rule would require a full pedigree or a record of the complete previous distribution history of the food from the point of origin of such food. Although the final rule includes requirements for certain KDEs to be passed through the supply chain, including the location description of the traceability lot code source or a traceability lot code source reference, this does not constitute a requirement to maintain or provide a full pedigree of the food or a record of its complete previous distribution history from the point of origin.

10. Focus and Purpose of the Regulation

(Comment 132) Comments express different views on what should be the focus of the rule. One comment asserts that FDA should focus on outbreak prevention rather than response. One comment maintains that the rule should focus on helping FDA conduct supply chain tracebacks to a specific business in a timely manner, instead of issuing overly broad outbreak statements. Some comments assert that many of the proposed requirements are intended to help FDA conduct root-cause investigations of outbreaks rather than facilitate effective traceback. On the other hand, some comments express support for the use of data generated from tracing to advance understanding of root causes of foodborne illness outbreaks.

(Response 132) Congress stated that the goal of this rulemaking is to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne

illness outbreak and to address credible threats of serious adverse health consequences or death. The final rule is therefore designed to help FDA respond more quickly and effectively once an outbreak or contamination event is identified, rather than to prevent contamination (which is the focus of several other FSMA regulations, including the produce safety regulation and regulations on preventive controls for human and animal foods). As stated in the preamble to the proposed rule, the purpose of the subpart S requirements is to reduce the harm to public health caused by foodborne illness outbreaks by enabling faster traceback and traceforward operations to identify the source of outbreaks and more quickly remove contaminated foods from the marketplace. In addition, the rule will benefit industry by helping to narrow the scope of necessary recall actions. In the preamble to the proposed rule, we also noted that being able to more quickly identify the source of a contaminated product can help us conduct more timely root-cause analysis, which could produce information that aids our understanding of how contamination may have occurred and help prevent future outbreaks. Thus, although facilitating root-cause analysis is not the principal focus of the rule, we can improve the safety of the food supply by using information needed to conduct efficient traceback operations to understand and address the causes of foodborne illness.

(Comment 133) One comment maintains that the rule should focus on what is essential for tracing food products rather than on supply chain transparency, which the comment states is a business benefit and is not necessary for food safety.

(Response 133) We disagree with the comment to the extent that it implies that the rule is focused on supply chain transparency rather than traceability. The rule is designed to enable faster and more efficient traceback and traceforward of FTL foods in response to foodborne illness outbreaks. While the rule requires disclosure of traceability information, it does so in the interest of promoting better traceability, not to increase supply chain transparency. As discussed later in this document, the final rule includes changes to the proposed requirements that will enable firms to protect the confidentiality of certain information.

(Comment 134) Some comments suggest that the proposed rule is improperly focused on establishing chain of custody for enforcement purposes at the expense of rapid identification of the source of outbreaks.

(Response 134) We disagree. As previously stated, as directed by Congress, the rule is intended to help us more quickly and efficiently identify the source of a contaminated FTL food in an investigation into a foodborne illness outbreak, which will reduce harm to consumers and economic loss to industry. Requirements such as those concerning documentation of the immediate previous source or the immediate subsequent recipient of a food are designed to help us more rapidly identify the source of an outbreak and remove all contaminated food from the marketplace, not to help us prepare an enforcement action. Although it is possible that information maintained in accordance with this rule and reviewed by FDA in an outbreak investigation (or to address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded) might be relevant in a subsequent enforcement action regarding the production or distribution of contaminated food, the subpart S requirements were not designed to establish chain of custody as an enforcement tool.

(Comment 135) One comment expresses concern that it is still taking too long to identify outbreaks and collect and analyze the epidemiological information needed to begin the traceback process, though the comment maintains that this is because of factors outside FDA's control. One comment states that its understanding is that, while it is not specifically addressed in the proposed rule, FDA will use traceback results to verify or challenge the assumptions of the epidemiological investigation.

(Response 135) As with all of our investigations into foodborne illness outbreaks, we will continue to work closely with the CDC to identify the source of outbreaks involving foods and prevent additional illnesses.

(Comment 136) One comment suggests that we consider an approach that focuses on foods for which the maintenance of detailed traceability records would provide a public health benefit.

(Response 136) As directed by Congress, we have developed traceability recordkeeping requirements for foods that, in accordance with the risk factors specified in section 204(d)(2)(A) of FSMA, we have designated for inclusion on the FTL. The FTL consists of foods for which we have concluded that additional traceability recordkeeping requirements are needed to better protect the public health.

(Comment 137) Some comments ask that we state which specific aspects of the outbreak investigation process will be improved by the rule and those not affected.

(Response 137) In the preamble to the proposed rule, we discussed several aspects of our investigations into foodborne illness outbreaks that we believe will be aided by having access to the additional traceability information required under the proposed rule, such as speeding up an investigation by obtaining more accurate and detailed information on a food at an RFE, improving our ability to solve outbreaks linked to multi-ingredient foods (by making it less burdensome to obtain records for multiple commodities), more quickly determining the breadth and number of potentially contaminated products (possibly narrowing the scope of recall), and being able to more quickly notify the public of potentially contaminated food in the marketplace. We believe that this rule will improve many of the significant steps of a traceback investigation.

(Comment 138) Some comments assert that the rule should focus more on RFEs than other entities in the supply chain. One comment maintains that restaurants, caterers, salad bars and delis within a retail operation, and wholesalers are the sectors of the food industry that have been the least likely to keep the product-level documentation necessary for assisting in a quick response to food safety events. One comment asserts that barriers to efficient traceback investigations are most often due to deficiencies at the retailer and food service level, but expresses concern that FDA's proposed solution is overly broad in its proposed remedies. One comment expresses support for FDA being able to ''skip steps'' (points in a supply chain that do not transform or create products, such as distributors) during an outbreak investigation, but states that this would only be possible if the point of sale or service can provide FDA with the lot number as assigned by the originator, transformer, or creator of the food, along with the item description and contact information for the entity responsible for that lot number. The comment maintains that the economic burden associated with the rule can be lessened, without compromising FDA's ability to conduct a traceback, by focusing additional recordkeeping requirements at the RFE and points of transformation, and not at supply chain entities who do not transform or sell/serve product directly to consumers.

(Response 138) We do not agree with the comments with respect to limiting additional recordkeeping requirements only at RFEs and points of transformation. Although the FTL recordkeeping requirements apply to RFEs (except those exempt from the rule, *e.g.,* due to their smaller size), they are not the only supply chain entities from which FDA needs to obtain information during a foodborne illness outbreak investigation. As the comments assert, and as we discussed in the preamble to the proposed rule, having RFEs keep the traceability information required under subpart S will greatly benefit our ability to conduct effective traceback operations and identify the source of contaminated food. Nevertheless, for the FTL recordkeeping requirements to provide the enhanced traceability they are designed to achieve, they need to encompass farms, manufacturers, distributors, and other entities in the supply chains for FTL foods.

11. Use of Other Information Available to FDA

(Comment 139) Several comments suggest that in developing and implementing these traceability recordkeeping requirements, FDA should rely on information that is in existing Agency databases. One comment suggests that the databases maintained to support the food facility registration, prior notice, and import entry processes have some of the same information the proposed rule would require, and asks that the Agency explore how to use this information rather than requiring the supply chain to report duplicate information. Similarly, one comment requests that we assess whether information in the registration database and traceability records that are already maintained could be leveraged to assist with outbreak investigations to limit the KDEs required under the rule. This comment suggests that we assess whether a subset of the information provided by a facility every 2 years when it registers, including facility address and emergency contact information, could satisfy any of the proposed KDE requirements, including the requirement for receivers and shippers to maintain and send information on the lot code generator. Noting that registered facilities must provide a Data Universal Numbering System (DUNS) number when they register, the comment asks that we determine if the DUNS number provides access to any required tracing information.

(Response 139) We acknowledge that some of the information required under subpart S might also be submitted to FDA to comply with other regulatory requirements, such as those concerning food facility registration, prior notice, and import entry. However, at present the databases containing this information have considerable unvalidated information and multiple entries for the same location. Given that accurate and up-to-date information about specific transactions is critical during a traceback investigation, it is difficult to rely on these data sources for contact information and for conducting traceback operations when investigating foodborne illness outbreaks. However, as previously stated, the final rule allows firms to use existing records (whether created in the normal course of business, to meet other regulatory requirements, or for any other purpose) to meet their subpart S requirements as long as the records contain the required information—in other words, firms will not have to create duplicate records. It is likely that many firms will be able to rely on some of the information they submit to FDA for other regulatory purposes to also meet their recordkeeping requirements under subpart S, which should lessen the recordkeeping burden posed by the new requirements.

(Comment 140) One comment asks that FDA consider how to collaborate with other government agencies such as the NOAA National Marine Fisheries Service, which has databases containing domestic vessel identification and fishing permit information as well as federally collected harvest information reported by the Seafood Dealer Receiver.

(Response 140) Although FDA coordinates with other Federal agencies, including NOAA, where appropriate, section 204(d) of FSMA directs us to establish recordkeeping requirements for foods on the FTL, which include certain seafood products (*e.g.,* finfish, crustaceans). Therefore, persons who manufacture, process, pack, or hold seafood that is on the FTL are subject to certain recordkeeping requirements (except that, as discussed later in this document, raw bivalve molluscan shellfish is exempt from the rule, and a partial exemption applies for food obtained from a fishing vessel). Nevertheless, under the final rule, firms may use records they maintain to meet requirements under NOAA or other regulations to meet their subpart S requirements (*i.e.,* they will not have to maintain duplicate records). Note also that, as discussed in Response 266, the final rule does not include the proposed requirement to keep a record of the vessel identification number or license number for a fishing vessel used to produce an FTL food.

(Comment 141) One comment encourages FDA to gather additional sales and inventory data not included within the scope of this rule to help focus the date range of requested records. The comment states that, in the proposed rule, FDA encourages RFEs to share data that can help identify consumer purchases, and the comment asserts that industry-led leafy green traceability pilot programs have demonstrated that varying kinds of data exist that can help narrow the scope of a records request.

(Response 141) We will use any information available to us to help us narrow the time period for traceability records for possibly contaminated FTL foods we might request to see in an outbreak investigation. As stated in the preamble to the proposed rule, if an RFE has consumer purchase data or other potentially relevant data not required under subpart S that they are willing to share with us, we will try to use such data to help us narrow the scope of our traceability records request.

12. Consumer Concerns

(Comment 142) One comment expresses concern about how the rule might affect consumers' ability to identify foods (such as during an outbreak). The comment asks how a consumer could identify what item was involved once a food was purchased from a store. The comment states that some of items posing the greatest concern are items bought from a bin of items or from a shelf with bulk produce where lots can be combined, which the comment maintains would necessitate guesswork on behalf of the consumer.

(Response 142) The final rule does not establish any requirements for consumers, nor does it require RFEs to keep records regarding sales they make to consumers. However, if consumers believe they have purchased food that caused illness, we encourage them to contact their local or State health department or FDA and provide whatever information they have regarding the food and illness experienced so that government officials can investigate the potential contamination. In the event of a recall, the information disseminated to consumers is generally tailored to assist them in identifying the items that have been recalled (*e.g.,* by stating the places where the food was sold, the brand names it was sold under, pictures of the recalled product, and any lot information that appeared on the consumer packaging).

13. Relationship to Subpart J Requirements

(Comment 143) One comment suggests that we consider ways to combine the traceability recordkeeping requirements in subpart J with the proposed subpart S requirements to enhance traceability. The comment notes that although FDA has the authority under the Bioterrorism Act to impose recordkeeping requirements on distributors, importers, and transporters (among other entities), these entities are not required to maintain lot code information under subpart J.

(Response 143) As specified in section 204(d) of FSMA, the subpart S requirements apply only to persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the FTL. Such persons include food distributors (because they hold food) and some importers (if they take physical possession of the food they import). As stated in the preamble to the proposed rule, we have exempted transporters from subpart S because in our outbreak investigations we generally are able to obtain the traceability information we need from others in the supply chain, and if necessary we can review records that transporters must keep in accordance with subpart J. As stated in the preamble to the proposed rule, we encourage all entities in the supply chain to maintain lot code information for all foods they handle to improve traceability.

14. Effect on Different Supply Chain Entities

(Comment 144) One comment asks that we consider structuring the rule by including provisions specific to different sectors of the industry and that we use terminology consistent with that used in the different industry sectors. The comment maintains that the words ''originate, transform, or create'' are unnecessarily confusing for the produce growing industry.

(Response 144) We decline to establish different recordkeeping requirements with different terminology for each of the many different sectors of the food industry. Instead, for most CTEs, the final rule specifies one set of KDEs that are appropriate and relevant for all industry sectors. The KDEs required in the final rule for each CTE are KDEs which will facilitate tracing of food, regardless of the type of food or sector of the industry. One exception is for certain provisions concerning seafood obtained from a fishing vessel, because of the difference between growing or manufacturing foods on land and harvesting food from bodies of water. Another exception is for sprouts, which have unique food safety concerns related to the use of seeds for sprouting.

As stated in Response 104, we have made several changes to simplify and streamline the proposed requirements. These changes include deleting the terms ''originating'' and ''originator,'' and deleting the ''creation'' CTE and merging the proposed requirements for creation with the requirements for transformation.

(Comment 145) Some comments express concern about the effect of the rule on particular food industry components. For example, one comment maintains that the rule might have a disproportionate impact on traditional cheese production, distribution, and sale, and increase the cost of artisanal products.

(Response 145) We have put in place a set of requirements that is flexible so that entities of any size are able to comply with the final rule to more efficiently and effectively trace potentially contaminated food through the supply chain to protect public health. However, we understand that small operations may be particularly burdened by the provisions of the rule. Therefore, the final rule provides exemptions from some or all of the provisions of subpart S for certain smaller operations and in certain short supply chain situations, as discussed in sections V.E.2 and V.E.3, respectively, of this document.

(Comment 146) One comment expresses concern about the effect of the rule on foodservice distributors. The comment maintains that foodservice distributors' ability to comply with the rule will be highly dependent on whether upstream suppliers provide the records necessary to facilitate compliance. The comment says that distributors' customers often choose the suppliers from which the distributors must source their products, leaving the distributors with limited leverage to require that suppliers provide the required records. The comment adds that distributors often must use multiple suppliers for the same product, which requires the use of different procurement methods that can impact the records distributors would have to keep for each product and how they would need to be transmitted. The comment maintains that accounting for the regulated status of each product would thus require a case-by-case analysis of both the products being received and the characteristics of individual suppliers, including an assessment of whether specific products or suppliers are wholly or partially exempt from the rule. The comment further states that these assessments likely would also vary depending on the sourcing of the product, which can change on a regular basis due to activities by distributors or suppliers.

(Response 146) The final rule requires a firm that ships an FTL food to provide certain KDEs to the next entity in the supply chain. Regardless of how many different firms might supply a foodservice distributor with the same FTL food, all of these suppliers will need to provide the same set of KDEs to the distributor. We understand that if an entity is receiving a food from an exempt firm, the shipment might not be accompanied by the records required under subpart S. Therefore, we have modified the requirements in the final rule for the receiver of a food from an exempt firm so that receivers can still comply with their obligations under the rule. The final rule requires firms, as part of their traceability plans, to be able to identify the FTL foods they handle; this will help ensure that firms keep and provide (to their supply chain partners) the required KDEs in accordance with the rule. If suppliers comply with their subpart S requirements, foodservice distributors will have the information they need to meet their requirements as receivers and subsequent shippers of the foods.

(Comment 147) One comment asks FDA to ensure that the final rule can easily integrate with a farm's existing food safety protocols.

(Response 147) The subpart S requirements applicable to farms, primarily the requirement to maintain a traceability plan (including a farm map) as stated in § 1.1315, can be incorporated into a farm's existing food safety operations, including any existing tracing protocols the farm may have in place. Similarly, for farms that are engaged in harvesting, cooling, and initial packing activities as defined in the final rule, the applicable subpart S requirements will not conflict with the protocols the farms are following to comply with the produce safety regulation or other food safety regulations.

15. Requests To Exempt Certain Foods or Align the Subpart S Requirements With Existing Regulations

(Comment 148) Several comments ask that we align the rule's requirements for seafood with the requirements in the Seafood Import Monitoring Program (SIMP) and other programs to avoid duplication and allow companies to use the information they maintain under those programs to meet their requirements under the traceability rule. One comment asks that we examine

areas within the proposed requirements that overlap with existing data collection efforts (*e.g.,* SIMP and FDA's seafood hazard analysis critical control point (HACCP) regulation (part 123)). The comment asserts that, where possible, data collection across these programs (and between government agencies) should be streamlined and made interoperable to reduce the reporting burden and remove unnecessary duplication. One comment asks that we align the KDEs and CTEs with SIMP, including the traceability lot code, International Fisheries Trade Permit, International Maritime Organization (IMO) number, and species identity. One comment asserts that where the KDEs required under this rule overlap with information collected under other requirements (such as SIMP and the NOAA 370 Form), alignment would improve efficiency and cost-effectiveness of compliance. One comment asserts that because robust traceability requirements exist for many species, exemptions from or alignment of the rule to other food or seafood traceability regulations will be necessary to minimize duplication of recordkeeping requirements. Some comments suggest that we align the requirements in the rule applicable to seafood with the Global Dialogue on Seafood Traceability (GDST); another comment asserts that the emphasis on event-based traceability in the proposed rule is similar to the approach taken in the GDST. One comment maintains that seafood exporters should be permitted to use existing documentation and the systems already in place to meet the traceability requirements. One comment states that commercial trip tickets, broken out by species, follow the product from the vessel to the dealer and should adequately cover traceability requirements for that portion of the supply chain as well as at the processor level.

(Response 148) We agree with the comments that persons who manufacture, process, pack, or hold seafood that is on the FTL should be allowed to use information they maintain for other regulatory purposes to meet applicable requirements under subpart S. Under § 1.1455(f), firms may use existing records if they contain information required to be kept under subpart S, so those in the seafood industry will not need to duplicate these records to comply with the final rule. With respect to requirements under SIMP, we agree there is some alignment with the traceability recordkeeping requirements under subpart S, which should result in entities in the seafood industry having to create fewer records to comply with subpart S than would otherwise be required.

(Comment 149) One comment suggests that the KDEs that are recorded for imported seafood should also be reported to regulators. The comment maintains that the architecture for a database for importers to report the KDEs required by the rule is already in place as a result of SIMP through the International Trade Data System (ITDS) and the Automated Commercial Environment portal.

(Response 149) We do not agree with the comment. The final rule requires persons who manufacture, process, pack, or hold FTL foods to maintain KDEs related to particular tracking events for review by FDA upon request. As discussed in Response 466, FDA investigators may request the records required under subpart S under a range of circumstances, including during routine inspections and in the event of an outbreak investigation, recall, or other threat to public health. We do not believe it is necessary to also require firms to routinely report the required KDEs for any FTL foods, whether of foreign or domestic origin.

(Comment 150) One comment asks how the rule relates to certificate of catch requirements for wild-caught seafood.

(Response 150) The final rule establishes recordkeeping requirements to effectively and efficiently trace food products throughout the supply chain. To the extent catch certificates contain information required by this subpart, those existing records can be used to comply with the final rule.

(Comment 151) One comment maintains that for farms that are certified organic, the organic production records coupled with the name of the farm should provide enough traceability for responding to outbreaks because these farms are already required to track which field a product was harvested from, the date it was harvested, and other information.

(Response 151) We disagree. The USDA National Organic Program does not require all the KDEs required under the final rule to effectively and efficiently trace food through the supply chain. However, any existing records that an organic farm may keep under the National Organic Program (or other certification program) that contain information required by subpart S, such as the field where product was harvested or the date of harvest, can be used for compliance with the final rule. Duplicate records would not need to be kept, which would reduce the burden on these farms.

16. Requests for Issuance of a Supplemental Proposed Rule

(Comment 152) Several comments ask that we issue a revised or supplemental proposed rule to give the public an opportunity to consider changes to the proposed requirements, which the comments expect to be significant. One comment notes that FDA issued revised proposed rules in more than one major FSMA rulemaking. Some comments assert that, because fundamental changes to the proposed rule's basic framework might be needed, providing notice and comment for a revised proposal is necessary under the Administrative Procedure Act (APA) to avoid concerns that the final rule might not be a ''logical outgrowth'' of the proposed rule. One comment asserts that, due to numerous ''legal issues'' with the proposed rule and purported flaws with the proposed rule's economic impact assessment, FDA must issue a revised proposed rule that meets the requirements of the FD&C Act, the Regulatory Flexibility Act, and the APA. One comment maintains that compliance with the consent decree in U.S. District Court applicable to the rulemaking cannot be at the expense of other applicable legal requirements, including the APA and section 204 of FSMA.

(Response 152) We do not agree that it is necessary to issue a revised or supplemental proposed rule before issuing a final rule. The APA does not require the issuance of a revised or supplemental rule with respect to this rulemaking, and although FDA did take such action in some other FSMA rulemakings, it is not the Agency's common practice to issue revised or supplemental proposed rules. As previously discussed, the final rule contains several changes to the proposed rule in response to comments we received. However, we have not substantially altered the basic framework and approach set forth in the proposed rule, and we believe the changes we have made to the proposed requirements are logical outgrowths of the proposed rule. Throughout this document we will explain the changes, including how they relate to what was proposed.

D. Scope (§ 1.1300)

We proposed to specify (in § 1.1300) that, except as specified otherwise in subpart S, the requirements would apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional

traceability records are required in accordance with section 204(d)(2) of FSMA, *i.e.,* the FTL. Proposed § 1.1300 also stated that we will publish the FTL on our website in accordance with section 204(d)(2)(B) of FSMA.

On our own initiative, we have added our website, ''*www.fda.gov,*'' to proposed § 1.1300, as we do not expect the website to change. We are finalizing the remainder of § 1.1300 as proposed. We respond to the comments on proposed § 1.1300 in the following paragraphs.

(Comment 153) One comment recommends that FDA replace the term ''person'' with the term ''business entity.''

(Response 153) We decline to make this change. The final rule defines ''person'' as it is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as well as in subpart J, *i.e.,* as including an individual, partnership, corporation, and association. We believe this appropriately specifies the entities who are covered under the final rule.

(Comment 154) A few comments recommend that FDA replace the term ''person'' with the term ''facility'' as defined in section 415(c)(1) of the FD&C Act (21 U.S.C. 350d(c)(1)). The comments assert that because Congress directed FDA (in section 204(d)(1) of FSMA) to establish additional recordkeeping requirements for ''facilities'' that manufacture, process, pack, or hold certain foods, the rule should apply only to facilities as that term is defined in section 415(c)(1) of the FD&C Act. Several comments maintain that farms, ''farm mixed-type facilities,'' restaurants, and other RFEs should not be subject to the rule, asserting that they are not facilities, they are not mentioned in section 204(d), and they have been excluded from the term ''facility'' in section 415(c)(1) of the FD&C Act. Some comments maintain that applying the rule only to facilities would be consistent with other FSMA regulations. Several comments assert that entities that are not subject to FDA's food facility registration requirements in part 1, subpart H, such as farms and grocery stores, should be exempt from the final rule.

(Response 154) As we stated in the preamble to the proposed rule, although section 204(d)(1) of FSMA refers to ''facilities'' that manufacture, process, pack, or hold food, Congress clearly intended that these traceability recordkeeping requirements would apply to some entities that are not required to register with FDA as ''facilities'' under section 415 of the FD&C Act, such as grocery stores (see 85 FR 59984 at 59995; see also Response 156 regarding application of the rule to farms). Because Congress did not intend that the traceability requirements would apply only to facilities required to register with FDA, it is not necessary to limit the scope of the rule to ''facilities'' as that term is defined in section 415(c)(1) of the FD&C Act. The fact that certain other FSMA regulations and the registration requirements in subpart H apply only to facilities is not relevant, as those regulations were promulgated under different legal authorities than subpart S and were established to address concerns different from enhancing food traceability. As discussed elsewhere in this document, each point in the supply chain is important for effective traceability, and farms, restaurants, and RFEs are all important sources of traceability information. Therefore, under § 1.1300 of the final rule, the subpart S requirements apply not just to ''facilities'' that manufacture, process, pack, or hold FTL foods, but to all ''persons'' who do so. This includes, except where an exemption applies, farms, restaurants, RFEs, and other persons engaged in the manufacture, processing, packing, or holding of FTL foods.

(Comment 155) One comment asks that we define the role of persons who own food but do not manufacture, process, pack, or hold the food.

(Response 155) The final rule covers persons who manufacture, process, pack or hold an FTL food. Therefore, as discussed in the preamble to the proposed rule (see 85 FR 59984 at 60000), persons who own an FTL food but do not manufacture, process, pack, or hold the food are not subject to the rule. As described in Response 465, persons subject to the rule may enter into agreements with other persons to maintain required records on their behalf.

(Comment 156) One comment asserts that FDA does not have authority to regulate farms in general and suggests that we work with farms and farm groups to build electronic recordkeeping capacity on a voluntary basis.

(Response 156) We disagree with the comment. By referencing farms in several instances in section 204(d) of FSMA, Congress clearly contemplated that the additional traceability recordkeeping requirements it directed FDA to establish would apply to farms. For example, section 204(h) states that FDA shall issue an SECG setting forth in plain language the requirements of subpart S ''in order to assist small entities, including farms and small businesses, in complying with the recordkeeping requirements.''

Farms are subject to the requirements in the final rule if they manufacture, process, pack, or hold foods on the FTL. The final rule provides exemptions (in § 1.1305) from the subpart S requirements for certain small producers, including certain produce farms and egg farms. For farms that are not exempted, the specific requirements applicable to them under the final rule would depend on the activities of the farm. All entities that are covered by the rule must maintain a traceability plan, and under § 1.1315(a)(5), for farms that grow or raise an FTL food (with the exception of egg farms), that traceability plan will be required to include a farm map showing the areas in which they grow or raise FTL foods. Farms that harvest or cool covered foods prior to initial packing will be required to keep and provide a streamlined set of KDEs that is set forth in § 1.1325, but they will not be required to adhere to the shipping and receiving KDE requirements for any movement of the food that happens before it is initially packed. Farms that perform initial packing of covered foods will be subject to the requirements in § 1.1330, and will also be required to keep and provide shipping KDEs relating to the shipment of food that happens after the food is initially packed. As discussed in Section V.U.5 of this document, we intend to work with farms and farm groups to help them understand and come into compliance with the subpart S requirements that apply to them.

E. Exemptions (§ 1.1305)

We proposed to establish several exemptions and partial exemptions to the FTL traceability recordkeeping requirements for certain types of foods and certain types of persons who manufacture, process, pack, or hold FTL foods. In response to comments, we have made several changes to the exemptions and added certain exemptions.

1. General

(Comment 157) Some comments note that section 204(d)(6)(E) of FSMA allows FDA, by notice in the **Federal Register**, to identify food commodities for which application of the product traceability requirements is not necessary to protect the public health. The comments suggest that rather than using the proposed waiver, exemption, or modified requirements provisions, we should exempt products through the rulemaking process to clearly identify the exempted commodities and ensure that all steps in the food chain have an equal understanding of what products

are and are not required to comply throughout the supply chain.

(Response 157) In response to comments, we have provided additional exemptions in § 1.1305 of the final rule, such as an exemption for certain raw bivalve molluscan shellfish (see Section V.E.7 of this document) and an exemption for persons who handle FTL foods during or after the time when the food is within the exclusive jurisdiction of the USDA (see Section V.E.8 of this document). We have also provided additional clarifications and descriptions for the commodities on the FTL. For some commodities we have added examples of foods that are and are not considered part of that commodity designation on the FTL. We believe these clarifications and examples will help stakeholders better understand the foods under each commodity that are covered by the rule.

In keeping with section 204(d)(6)(E) of FSMA, the final rule includes provisions under which persons may request an exemption from (or modification of) the subpart S requirements (see §§ 1.1360 through 1.1400). The final rule also includes provisions under which persons may request a waiver of subpart S requirements (see §§ 1.1405 through 1.1450), in accordance with section 204(d)(1)(I) of FSMA. Under these provisions, citizen petitions requesting modified requirements or exemptions would be made public, as would citizen petitions requesting waivers for types of entities. Stakeholders will have an opportunity to submit comments on such citizen petitions. Similarly, these final rule provisions state that should FDA decide on its own initiative to consider adopting modified requirements, granting an exemption, or waiving subpart S requirements, we will publish a notice in the **Federal Register** and provide an opportunity for stakeholders to submit comments. In any of these circumstances, after consideration of any timely submitted comments, we will publish a notice in the **Federal Register** setting forth any modified requirements or exemptions that we ultimately decide to grant for certain foods or types of entities, or any requirements we ultimately decide to waive for certain types of entities, so that all stakeholders will be aware of any changes to covered foods or types of covered entities. Therefore, we do not believe it is necessary to address requests for waivers or exemptions through notice-and-comment rulemaking.

(Comment 158) Some comments assert that small businesses should be exempt from the subpart S requirements, maintaining that they would not be able to comply, including because they lack electronic capabilities, and would be forced to shut down. The comments maintain that the industry is already overburdened, and the proposed requirements are unrealistic and would cause extreme hardship. Some comments state that FDA should use thresholds for exemption from other FSMA rules or those set by the Small Business Administration (SBA). Some comments request that we provide additional flexibilities in the final rule for small businesses. The comments claim that small and medium-sized companies do not have the resources available to comply with the rule compared to large businesses.

(Response 158) We agree with the importance of reducing the burden of the final rule, where possible and appropriate, on businesses that may have fewer resources to apply to complying with the requirements of the regulation, while minimizing the additional health risk caused by exposure to products that would otherwise be covered by the regulation. The final rule provides a full exemption for certain small produce farms (§ 1.1305(a)(1)), specifically farms that are exempt under § 112.4(a) (21 CFR 112.4) in the produce safety regulation, and produce farms with an average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period of no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment. The final rule also fully exempts shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm (see § 1.1305(a)(2)). Another full exemption is provided for certain producers of RACs other than produce or shell eggs (*e.g.,* aquaculture operations) when the average annual sum of the monetary value of their sales of RACs and the market value of the RACs they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (see § 1.1305(a)(3)). In addition to these full exemptions for certain small producers, the final rule also exempts farms whose average annual sum of the monetary value of their sales of RACs and the market value of RACs they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year, from the requirement to provide an electronic sortable spreadsheet containing traceability information FDA may request in certain circumstances (§ 1.1455(c)(3)(iii)(A)).

As discussed below, the final rule also includes other exemptions that would exclude certain foods that farms produce from the coverage of the rule, including, but not limited to, exemptions or partial exemptions for the following: food sold directly to consumers (§ 1.1305(b)); food in farm to institution programs (§ 1.1305(l)); certain foods produced and packaged on a farm (§ 1.1305(c)); foods that receive certain types of processing (§ 1.1305(d)); produce that is rarely consumed raw (§ 1.1305(e)); certain raw bivalve molluscan shellfish (§ 1.1305(f)); and certain commingled RACs (§ 1.1305(h)). The final rule imposes less burdensome requirements on farms than under the proposed rule, including reduced requirements for documentation of growing foods and elimination of proposed requirements for farms to keep and send shipping KDEs for foods that have not yet been initially packed. Furthermore, we will provide education, training, and technical assistance to farmers to help them understand and come into compliance with the new traceability recordkeeping requirements.

The final rule fully exempts small RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (§ 1.1305(i)), and also exempts RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment, from the sortable spreadsheet requirement (§ 1.1455(c)(3)(iii)(B)). The final rule also includes a partial exemption for RFEs and restaurants for food that is purchased directly from a farm (§ 1.1305(j)).

The final rule does not fully exempt from the subpart S requirements any businesses in the middle of the supply chain, such as packers, manufacturers, and distributors. We believe that exempting such firms could result not only in the unavailability of traceability

information at those specific firms, but also in a failure to pass along critical traceability information (such as information relating to the traceability lot code), which would affect subsequent supply chain members and would therefore have a broad impact on the effectiveness of the rule. However, as discussed in Section V.R.3 of this document, the final rule exempts businesses in the middle of the supply chain (*i.e.,* that are neither farms nor restaurants/RFEs) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year, from the sortable spreadsheet requirement (§ 1.1455(c)(3)(iii)(C)).

In accordance with section 204(h) of FSMA, we will be issuing an SECG specifically aimed at assisting affected small businesses in complying with the requirements of this rule. In addition, we may issue other guidance documents to help smaller entities and all persons subject to the FTL recordkeeping requirements understand and meet the requirements applicable to them.

(Comment 159) Some comments argue that the rule should not require businesses to maintain traceability records or create a lot code for any exempt product.

(Response 159) We agree with the comments. When a food is fully exempt from the rule, firms will not be required to maintain subpart S records relating to that food. However, firms that are subject to the subpart J regulation must keep records as required under that subpart. We also note that, as a best practice, we believe that firms should maintain some form of traceability records for all foods that they handle, regardless of whether they are legally required to do so.

(Comment 160) Some comments contend that small dealer operations that sell only to restaurants, farmers markets, or retail operations (as opposed to selling to secondary dealers) should be exempt from the rule as there is only one transaction to trace back in these circumstances. The comments assert that requiring the creation of lot codes for a one-step transaction does not improve the ability to perform traceback or traceforward. The comments further maintain that it is only when a product goes from the primary dealer to a secondary dealer that the requirement for the creation of a lot code should apply.

(Response 160) We understand the word ''dealers'' to mean distributors in the context of the comment, and we decline to exempt from the rule small dealers that do not sell to secondary dealers. Records of sales from dealers to restaurants, farmers markets, and retail operations are necessary to tracing potentially contaminated product and acting quickly to reduce the impact of foodborne outbreaks. However, as discussed in Section V.R.6 of this document, these small dealers may rely on records they already keep (*e.g.,* in the course of business or to comply with other legal requirements, such as the subpart J regulation) to meet applicable requirements under subpart S. Further, dealers will only need to create a traceability lot code if they receive an FTL food that does not already have a traceability lot code because the entity they received it from was exempt from the rule. We also note that small dealers may be exempt from the sortable spreadsheet requirement if they are sufficiently small to be below the $1 million ''ceiling'' in § 1.1455(c)(3)(iii)(C).

(Comment 161) Some comments recommend that we provide additional clarification for each exemption to emphasize that they are only applicable to foods on the FTL. For example, the comments suggest rephrasing the title of proposed § 1.1305(a) to read ''Exemptions for small originators of food on the FTL'' instead of ''Exemptions for small originators.''

(Response 161) We decline to make this change as unnecessary. Under § 1.1300 of the final rule, subpart S applies to persons who manufacture, process, pack, or hold FTL foods. As subpart S does not apply to any foods not on the FTL, we believe it is unnecessary to state that each individual exemption concerns only FTL foods.

(Comment 162) Some comments maintain that the exemptions specified in the proposed rule are too broad and recommend that FDA eliminate exemptions from the rule. The comments suggest that end-to-end traceability is best accomplished by maximizing participation throughout the supply chain and limiting exemptions wherever possible. Some comments recommend that we reconsider all proposed full or partial exemptions that are not expressly required by FSMA to best strike a balance between protecting public health and reducing the burden on small businesses. These comments suggest that in lieu of providing full or partial exemptions, we should provide technical assistance to assist firms in developing traceability systems and work with companies to develop affordable traceability programs. Some comments recommend that if the final rule includes exemptions, we should clarify for the public which entities are exempt from the rule.

(Response 162) We do not agree with the comments that we should eliminate some or all of the proposed exemptions. As some comments note, Congress directed us to establish certain exemptions from the additional traceability recordkeeping requirements; therefore, the final rule must include these exemptions. The several exemptions we proposed on our own initiative reflect our thinking that applying the subpart S requirements to certain persons or foods would not be appropriate for various reasons. For example, in the preamble to the proposed rule (85 FR 59984 at 59995), we discussed the proposed exemption in § 1.1305(a) for certain types of small or very small farms. Given the relatively low volume of food produced by these entities and the fact that subsequent parties in the supply chain will be required to maintain records regarding the food produced by these entities, we considered that covering these small farms would produce little measurable public health benefit. Similarly, in § 1.1305(k), we proposed to exempt transporters from this rule because we found that in most of our investigations of potential foodborne illness outbreaks, it is not necessary to inspect records maintained by food transporters because we generally are able to obtain the tracing information we need from other persons in the food's supply chain (85 FR 59984 at 59999). We continue to believe that the exemptions we proposed on our own initiative are appropriate to maintain, for the reasons described in the proposed rule and as discussed below. Furthermore, as discussed above and below, the final rule includes other exemptions not included in the proposed rule. We intend to provide outreach and assistance to help all firms subject to the rule to come into compliance with the applicable requirements.

Regarding the comments asking that we clarify for the public which particular entities are not subject to the rule, we intend to provide outreach and education to ensure that all affected entities understand the subpart S exemptions. However, it would not be feasible for us to list specific exempt firms by name because we do not have access to the relevant information (*e.g.,* annual sales data) that would allow us to create a comprehensive list of exempt firms. Furthermore, because some

exemptions in § 1.1305 are specific to certain foods, some firms might be covered by the rule but exempt with respect to certain FTL foods they handle. We encourage exempt entities and firms selling exempt foods to provide information about their exempt status to downstream entities in the supply chain.

(Comment 163) Some comments request clarification on whether there are additional regulations in place to ensure the safety of products that are otherwise exempt from this rule. The comments note particular concern regarding foods that receive a kill step and whether there are requirements to ensure that a kill step is appropriately applied. Additionally, the comments question whether, in the case of an outbreak associated with foods that are otherwise exempt from this rule, information on those foods will be available to FDA promptly.

(Response 163) In recent years FDA has established several regulations implementing FSMA that are aimed at ensuring the safety of the food supply. These include regulations on the following: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (80 FR 74354, November 27, 2015) (part 112); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (80 FR 55908, September 17, 2015) (part 117); Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (80 FR 74226, November 27, 2015) (part 1, subpart L); and Sanitary Transportation of Human and Animal Food (81 FR 20092, April 6, 2016)) (21 CFR part 1, subpart O). Other FDA regulations concerning food safety have been adopted in final rules, including the following: Hazard Analysis and Critical Control Point (HAACP) Procedures for the Safe and Sanitary Processing and Importing of Juice (66 FR 6138, January 19, 2001) (21 CFR part 120); Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (60 FR 65096, December 18, 1995) (part 123; see also §§ 1240.3 and 1240.60); Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030, July 9, 2009) (21 CFR part 118); and Manufacture and Processing of Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (38 FR 12716, May 14, 1973) (part 113). Many of these regulations contain provisions related to the application of a ''kill step'' to foods to control for certain hazards. Entities required to comply with these food safety regulations are also subject to FDA inspection and oversight. In addition to these and other final rules we have issued to help ensure food safety, we note that all food remains subject to the adulteration provisions of the FD&C Act.

As previously discussed, in 2004 we adopted the subpart J traceability recordkeeping requirements (see 69 FR 71562), which require persons (with some exceptions, including farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain certain records. The subpart J requirements were designed to allow us to identify the immediate previous sources and immediate subsequent recipients of food, helping to facilitate our ability to quickly notify consumers and/or facilities that might be affected by a foodborne illness outbreak. The subpart J requirements apply to all foods, not just those on the FTL; and in some cases they apply to entities that are not covered by subpart S. Furthermore, in situations where FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, section 414(a) of the FD&C Act requires firms to provide us with access to all relevant records relating to such food (and to any other food that we reasonably believe to be similarly affected). In addition, section 204(f) of FSMA requires farms to provide us with information identifying potential immediate recipients (other than consumers) of foods, in certain situations relating to an active investigation of a foodborne illness outbreak. Therefore, even in the case of an outbreak associated with foods that are exempt from this rule, various mechanisms exist that will help us promptly gain access to information regarding the affected foods.

2. Exemptions for Certain Small Producers

We proposed to exempt from the FTL traceability requirements certain small produce farms, small producers of shell eggs, and other small producers of food, given the relatively low volume of food produced by these small entities and the fact that subsequent persons in the supply chain would have to keep records on the foods produced by these entities.

Under proposed § 1.1305(a)(1), the rule would not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a covered farm under the produce safety regulations in accordance with § 112.4(a) (which concerns farms with no more than $25,000 in annual sales of produce). In proposed § 1.1305(a)(2), we specified that the rule would not apply to shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs produced at that farm. This exemption is consistent with the regulations on shell egg production, storage, and transportation (see § 118.1(a) (21 CFR 118.1(a))). Finally, under proposed § 1.1305(a)(3), the rule would not apply to originators of food with an average annual monetary value of food sold during the previous 3-year period of no more than $25,000 (on a rolling basis), adjusted for inflation using 2019 as the baseline year for calculating the adjustment. We stated that this exemption would apply to, among others, small aquaculture farms and small farms that grow non-produce foods that might be on the FTL in the future.

In response to comments, we are making minor changes and clarifications to these proposed exemptions for certain small producers of FTL foods. These changes are discussed in more detail in the paragraphs below.

(Comment 164) Some comments support the proposed exemptions for small produce and egg farms. The comments state that the proposed exemptions for smaller farms will hopefully encourage participation without imposing a financial burden on them. One comment maintains that the exemption for small farms could lessen the potential for the new traceability requirements to adversely affect farms and producers with sustainable practices. Some comments state they are relieved that small farms that are already covered by local and State tracing regulations would not be subject to increased labor and technology burdens under the rule.

On the other hand, some comments maintain that the subpart S requirements should cover all farms, without exemption or partial exemption. The comments assert that having exemptions would mean that comprehensive and consistent traceability records would not be available to FDA to track foodborne illness, including to small farms that might be considered safer than others. The comments maintain that small farms are less likely to prioritize food safety and less likely to be monitored by FDA and the USDA. The comments therefore assert that a comprehensive food safety system should consider potential food safety hazards at the farm level, including small farms.

(Response 164) We agree with the comments on the importance of adopting comprehensive and consistent recordkeeping requirements to enable us to trace products associated with foodborne illness outbreaks involving FTL foods and act quickly to reduce the impact of these outbreaks. However, we believe it is important to reduce the burden, where appropriate, on farms and other businesses that may have fewer resources to apply to complying with the requirements of the rule, while minimizing any additional health risk that might result from exempting entities from the regulation. When we consider a small business exemption from a regulation, we attempt to determine a small business ''ceiling'' that gives relief to businesses with fewer available resources without inordinately affecting public health. Having carefully considered the risk to consumers posed by FTL foods from small farms, we conclude that the farms below the size ceiling set forth in § 1.1305(a) of the final rule do not contribute significantly to the volume of produce in the marketplace that could become contaminated. Given the relatively low volume of food produced by these entities, and the fact that subsequent parties in the supply chain will be required to maintain records regarding the food produced by these entities, covering these small producers would have little measurable public health benefit.

(Comment 165) Some comments state that the rule violates the small farms and small business protections in FSMA, citing the definition of a small farm in the produce safety regulation and the qualified exemption for certain farms under that rule.

(Response 165) We disagree with the comments. We issued the produce safety regulation in accordance with section 105 of FSMA (which created section 419 of the FD&C Act (21 U.S.C. 350h)), while we are issuing these subpart S requirements in accordance with section 204(d) of FSMA. Section 204(d) of FSMA does not require us to create the same exemptions from the subpart S requirements as are included in the produce safety regulation or any other FSMA regulation, including with respect to how ''small'' entities are defined. We believe that the scope of the exemption for certain small producers in § 1.1305(a) of the final rule is consistent with the purposes of the subpart S requirements as well as with section 204(d)(1)(E) of FSMA, which specifies that the recordkeeping requirements for FTL foods must be scale-appropriate and practicable for facilities of varying sizes and capabilities.

(Comment 166) Several comments ask us to raise the sales ceiling for eligibility for the exemptions for small farms in proposed § 1.1305(a). The comments assert that such increases are appropriate due to the relatively small percentage of farms that would be eligible for the proposed exemptions and the economic burden of compliance with the rule. The comments suggest increasing the ceiling to $1 million or even $3 million in average annual monetary value of sales. Some comments state that while they support the exemption for small farms, they also have concerns about the burden of the rule on mid-size farms, and therefore request an exemption for medium to large farms that sell food to aggregators for redistribution. Some comments recommend matching the ceilings to those in other FSMA regulations and in SBA classifications, including the $250,000 threshold used to extend the compliance date for ''very small businesses'' in the produce safety regulation, the threshold used for ''qualified exempt farms'' that are eligible for modified requirements under the produce safety regulation, and the $1 million threshold used to extend the compliance date for ''very small businesses'' in the regulation on preventive controls for human food. Some comments recommend a non-monetary threshold, specifically one based on full-time equivalent employees (FTEs).

(Response 166) After careful consideration of the comments, we conclude it is appropriate to essentially retain in the final rule the proposed sales ceilings for certain small produce farms, certain egg producers, and certain other small producers of RACs. As discussed below in Section V.F.24 of this document, we have removed the term ''originators'' from this rule, which is why the exemption in § 1.1305(a)(3) is now titled as relating to ''[c]ertain other producers of raw agricultural commodities.'' However, we have made the following slight adjustments and clarifications.

We have added § 1.1305(a)(1)(ii), which states that subpart S does not apply to produce farms when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment. Although this exemption is a subset of produce farms that are exempt under § 1.1305(a)(1)(i) (which exempts farms that are not covered by the produce safety regulation due to their size), we wanted to ensure that our exemption for produce farms was consistent with our exemption for other small producers in § 1.1305(a)(3), while still retaining § 1.1305(a)(1)(i) to provide clarity that any farms that are exempt under § 112.4(a) of the produce safety regulation are exempt from this regulation as well.

We have made minor modifications to the exemption in proposed § 1.1305(a)(3), which are also reflected in the new § 1.1305(a)(1)(ii) (when applicable). We have changed the baseline year for calculating the inflation adjustment from 2019 to 2020 because 2020 coincides with data and estimates of the impacts of the final rule in the FRIA (Ref. 16). And while the exemption in proposed § 1.1305(a)(3) was based on the average annual monetary value of food sold, the final rule exemption is based on the average annual sum of the monetary value of a producer's sales of RACs and the market value of the RACs they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee). This change encompasses two decisions: A decision to look only at RACs, rather than all foods, in calculating the eligibility ceiling; and a decision to consider the value of food that is handled without sale, in addition to the value of sales.

Regarding the first decision, we now use only the value of RACs, rather than all foods, in calculating the eligibility ceiling. This provides greater clarity and creates a standard of eligibility for the exemption that is parallel to the standard in § 1.1305(a)(1), which relates to the value of produce sold (or held without sale) by a produce farm. The word ''originator'' in proposed § 1.1305(a)(3) referred to a producer of RACs, and implied that the ''food sold'' under that provision would be RACs, but the provision was not explicit on that point. For greater clarity in the final rule, and in light of the fact that a producer of RACs might also sell other products that are not RACs (and that we do not intend to be taken into account in calculating eligibility for the exemption), we are stating explicitly in the final rule that the eligibility ceiling is tied to the value of RACs sold (or held without sale, as discussed below).

Regarding the second decision, we have added the market value of RACs manufactured, processed, packed, or held without sale to the calculation of the eligibility ceiling to create an exemption standard that can be used by farms and other producers that hold

food but do not always sell it. We are aware of the complex business relationships that exist at the start of the supply chain, and we therefore wanted to create a standard that encompassed entities that perform services for a fee, rather than engaging directly in the sale of food.

The thresholds in § 1.1305(a) provide appropriate relief to small produce farms, small egg farms, and small producers of other RACs, and are consistent with similar exemptions for small farms in other food safety regulations, such as the produce safety regulation and the shell egg safety regulation (part 118 (21 CFR part 118)). The exemptions for small farms and producers in § 1.1305(a) of the final rule exempt roughly 63 percent of produce farms that would otherwise be subject to the subpart S requirements and roughly 1 percent of covered sales. Also exempted are 98 percent of shell egg producers (roughly 1 percent of covered sales) and 40 percent of aquaculture operations (roughly 3 percent of covered sales) (Ref. 16)). Aquaculture operations are currently the only type of operation affected by § 1.1305(a)(3), because all of the RACs currently on the FTL are either produce, eggs, or seafood (and fishing vessels have a separate exemption in § 1.1305(m)).

We considered other suggestions for sales volume ceilings for eligibility for the small produce farm exemption from the rule, including a threshold tied to the definition of ''very small business'' in the produce safety regulation, $250,000, which was used in that rule to provide an extended compliance date for farms that met that threshold; and various thresholds up to $1 million. Produce farms with no more than $250,000 in annual sales account for nearly 86 percent of covered farms and 6 percent of covered RAC sales in the United States, while produce farms with no more than $1 million in annual sales account for more than 93 percent of covered produce farms and more than 13 percent of covered RAC sales. We conclude that neither of these cutoffs would be appropriate to use for the small produce farm exemption in § 1.1305(a)(1) because they would result in exemption of a significant portion of the covered market from the subpart S recordkeeping requirements, which would inhibit our ability to conduct efficient and thorough tracebacks to protect public health.

For similar reasons, we considered and rejected the possibility of basing eligibility for the small produce farm exemption on FTEs or SBA size standards. Extremely wide variation in revenues earned at any FTE level due to differences in business practices, automation, and other factors make FTEs a less accurate indicator of the true size, viability, and public health impact of businesses than measures based on sales. For produce farms, SBA standards define small businesses as those with no more than $1 million in annual sales, a volume that, if adopted as the ceiling for eligibility for the small produce farm exemption, would have a significant impact on our ability to conduct effective tracebacks and protect public health.

We considered and rejected basing eligibility for the small farm exemption on the definition of a ''qualified exempt'' farm, defined in the produce safety regulation (§ 112.5 (21 CFR 112.5)) as a farm with less than $500,000 rolling annual average in food sales, with more than 50 percent of their food sold to qualified end users (consumers or retailers located in the same State or not more than 275 miles away). While nearly 10 percent of produce production fits into this category, less than 20 percent of all produce farms fall under this definition. Further, some of the farms that fit this definition make nearly $500,000 in annual revenue, produce a relatively large volume of food, and could sell half of their production into large market supply chains. Exempting such farms could have a significant impact on our ability to conduct effective tracebacks and protect public health, while simultaneously providing less relief for the very smallest farms. The exemption in the final rule covers more than 60 percent of produce farms, while an exemption based the produce safety regulation's ''qualified exempt'' threshold would cover less than 20 percent of all produce farms.

(Comment 167) One comment suggests that diversified produce farms may not be eligible for exemption due to the aggregate value of all produce grown on such farms, regardless of the value of FTL foods grown. The comment asserts that the inclusion of non-produce sales in the exemption calculation penalizes diversified farming operations. Additionally, the comment maintains that the proposed rule would require adoption of new traceability practices for either all crops, whether they are covered or not, or just a portion of the crops grown and covered by the rule. The comment asserts that either solution would create incremental expense not experienced by larger-scale farming operations that only grow FTL foods or grow food in such large quantities that they can dedicate resources and develop procedures for those operations that are covered. The comment therefore recommends calculating the small produce farm exemption based only on sales of FTL foods.

(Response 167) We disagree with the comment. We conclude that including all produce sales, rather than just sales of produce on the FTL, in determining eligibility for the small produce farm exemption provides a more accurate measure of a farm's financial ability to meet the traceability recordkeeping requirements under the rule. Consequently, if a diversified farming operation has annual produce sales of more than $25,000, it is more likely to have the resources with which to comply with the applicable subpart S requirements, and it is appropriate that it not be exempt from the rule.

(Comment 168) Some comments assert that the rule will hurt local, regenerative farming that is environmentally friendly. One comment maintains that the rule will reduce options to buy from small farms and force firms to buy from large farms that have a big carbon footprint through scale and shipping and are harmful to the environment.

(Response 168) We disagree that the rule will significantly harm local regenerative farm practices or significantly reduce options to buy from small farms. We note that in addition to the exemption for small produce farms in § 1.1305(a)(1), there are several other exemptions discussed below that may apply to sales of food by and from local, regenerative farms and other smaller farms. Furthermore, as discussed in section V.J of this document, the final rule reduces and streamlines the recordkeeping requirements for covered farms.

(Comment 169) One comment asserts that the proposed requirements will disrupt tracing programs already in place on small, diverse farms.

(Response 169) We disagree. We understand that farms employ a wide variety of tracing programs depending on size, crop mix, season, location, technology, and business models/agreements, and we are adopting requirements that include traceability information that is typically part of existing traceability programs. To the extent that entities with existing traceability programs already generate some or all of the information they are required to maintain under this rule, they may use that information to comply.

(Comment 170) Some comments request that FDA exempt small and midsized farms from ''computerized tracking'' to allow flexibility and that, in

general, FDA should streamline requirements for small farms.

(Response 170) The rule does not require electronic recordkeeping. The only subpart S requirement with an electronic component is the requirement to make available to FDA an electronic sortable spreadsheet in certain circumstances (§ 1.1455(c)(3)). As discussed in more detail in Response 470, the final rule exempts farms from this sortable spreadsheet requirement if they have average annual sales of $250,000 or less (§ 1.1455(c)(3)(iii)(A)). The final rule also includes several full and partial exemptions that may apply to small farms or to certain foods produced on farms, as discussed in Response 158. Moreover, the final rule simplifies the recordkeeping requirements applicable to farms in general, as discussed in Response 156.

(Comment 171) One comment questions how downstream users will be able to identify exempt product, and asks whether an exemption form will be provided to the distributor. The comment questions whether food from an exempt farm is exempt throughout the supply chain. One comment supports the proposed exemption of small shell egg producers but maintains that it should apply throughout the supply chain. Some comments maintain that the requirements for receivers to collect information such as lot code, location identifier and location description of the originator, and the place where the food was packed and cooled would cause difficulty for both the receivers and exempt originators. The comments maintain that receivers of a listed food will require information from the small originator to satisfy their requirements to send information to subsequent receivers. But the comments assert that receivers will have no way of knowing whether the originator is a small originator without receiving this information from the originator, and they argue that taking the steps necessary to demonstrate the application of the exemption would eliminate any benefit from the exemption. Therefore, the comments ask that the rule not require lot codes or record generation for any exempt food.

(Response 171) Farms that qualify for the exemption in § 1.1305(a)(1), (a)(2), or (a)(3) are fully exempt and do not have to keep any records to comply with the rule. However, foods on the FTL produced by exempt farms are not exempt throughout the supply chain, nor are distributors who receive food from exempt farms. Section 1.1330(c) sets forth the records that persons must keep if they initially pack a food received from an exempt farm. Similarly, § 1.1345(b) sets forth the records a person must keep if they receive food from an exempt entity. These requirements are limited to information a person would be reasonably expected to know based on information that is likely provided during the normal course of business. An exempt farm is not expected to provide a traceability lot code; the traceability lot code would be assigned by the initial packer (if they are covered by the rule) or by the person who receives the food from the exempt farm, in accordance with § 1.1345(b)(1).

We anticipate that supply chain partners will be able to communicate about whether or not they are exempt, and we are not placing any requirements on exempt entities regarding the nature of such communications.

(Comment 172) One comment states that FDA should clarify and define ''other originators of food'' in proposed § 1.1305(a)(3). The comment maintains that the term could be interpreted as including all food originators, including shell egg producers that were not exempt because they had more than 3,000 laying hens. One comment states that they understand ''other originators of food'' to include aquaculture.

(Response 172) We have revised the heading for the exemption in § 1.1305(a)(3) to state that it applies to certain other producers of RACs, instead of certain other originators of food. By ''other producers of raw agricultural commodities,'' we mean producers of covered RACs that are not produce or eggs, which are discussed in § 1.1305(a)(1) and (a)(2), respectively. Such other producers of RACs would include producers of seafood and any other non-produce, non-egg RACs that may someday be on the FTL. We have added the phrase ''(*e.g.,* aquaculture operations)'' to help clarify the meaning of ''other producers of raw agricultural commodities.''

3. Exemption for Farms Regarding Food Sold Directly to Consumers

In accordance with section 204(d)(6)(H) and (I) of FSMA, we proposed to exempt farms from the traceability recordkeeping requirements with respect to food produced on the farm (including food that is also packaged on the farm) when the owner, operator, or agent in charge of the farm sells the food directly to a consumer (proposed § 1.1305(b)). These direct-to-consumer sales by farms include applicable sales at farmers' markets, roadside stands, over the internet, and through community-supported agriculture (CSA) programs. The final rule retains this exemption and expands it to include food that is donated directly to a consumer.

(Comment 173) Some comments suggest that we clarify or expand the term ''agent in charge of the farm'' to include all farm employees or other individuals the farm has authorized to make sales on its behalf.

(Response 173) In the context of this exemption, the phrase ''agent in charge of the farm'' may be anyone employed by the farm who is authorized to sell food on behalf of the farm.

(Comment 174) Some comments suggest that farms that share or trade crops with other local farms for the purpose of adding variety to their farm stand or CSA box should be exempt from the rule.

(Response 174) We disagree with the comments. Consistent with section 204(d)(6)(H) and (I) of FSMA, the exemption in § 1.1305(b) is limited to farms that sell or donate the food produced on their own farm directly to a consumer. The value of traceability records in such a circumstance is limited because the food moves directly from the farm that grew it to the consumer. When a farm uses a CSA or a farm stand to sell the food produced on their own farm directly to consumers, the farm will be eligible for the exemption. But when the food was produced on another farm, and was obtained by the farm that runs the CSA or farm stand via sharing, trading, or selling, the exemption does not apply.

However, we note that most CSAs and farm stands will meet the definition of a ''retail food establishment'' under § 1.1310. Therefore, a CSA or farm stand could be eligible for the partial exemption in § 1.1305(j) for RFEs that purchase food directly from the farm that produced the food (see Section V.E.11 of this document). Furthermore, as discussed in Section V.E.10 of this document, an RFE or restaurant will be exempt from the rule under § 1.1305(i) if the average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period was no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment. This may include many CSAs and farm stands.

(Comment 175) Some comments request that all small farms be exempt, not only those that sell food directly to the consumer. The comments assert that only ''hobby''-type farms that do not rely on food sales to make a living can operate with only direct-to-consumer

sales. The comments maintain that even most farms that primarily sell direct to consumers sell some of their products through wholesalers, and that the paperwork for that portion of their sales would be too burdensome.

(Response 175) We understand that the exemption for direct-to-consumer sales in § 1.1305(b) will not fully exempt most farms from the rule because farms that sell some product directly to consumers also sell some of their product through wholesalers. However, as discussed above, the final rule provides a complete exemption for certain small producers (including farms) in § 1.1305(a). There are also other full and partial exemptions that may apply to many small farms. Furthermore, as discussed below, the revised KDEs in the final rule impose less of a burden than the proposed rule did on many farm activities.

4. Inapplicability to Certain Food Produced and Packaged on a Farm

Consistent with section 204(d)(6)(B) of FSMA, we proposed to provide that the FTL traceability recordkeeping requirements would not apply to food produced and packaged on a farm, provided that:

- The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product (proposed § 1.1305(c)(1)); and
- The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged (proposed § 1.1305(c)(2)).

We further proposed that, upon request, FDA would waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm (proposed § 1.1305(c)(2)).

On our own initiative, we have slightly revised the provision concerning waiving the requirement to provide a business phone number to accommodate a religious belief, to align with the text of similar language in § 1.1455(c)(3)(iv) concerning a request for a sortable electronic spreadsheet under certain circumstances. Thus, § 1.1305(c)(2) of the final rule states, in part, that we will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm. We are finalizing the remainder of § 1.1305(c) as proposed. We respond to the comments on proposed § 1.1305(c) in the following paragraphs.

(Comment 176) Some comments express general support for the exemption for foods that are compliant with packaging and labeling requirements. However, some comments maintain that the exemption is too narrow, and some ask that FDA reconsider or delete the restrictions on packaging in this exemption. Some comments assert that the proposed rule requires firms to use plastic sealed packaging to qualify for the exemption for identity-preserved food in proposed § 1.1305(c), in violation of FSMA. One comment contends that FSMA does not require new packaging guidelines, while other comments assert that FSMA specifically exempts certain identity-preserved foods and that there should be no additional requirements on such foods.

Some comments maintain that meeting the packaging requirements would not be feasible for most smaller farms or even mid-size farms. Some comments assert that the requirements only make sense for large, national producers and the exemption does not benefit small, local farms. Some comments maintain that the requirements may cost them business and that it will be difficult to sustain environmentally friendly niche markets. The comments state that some customers do not want food in plastic packaging and that some may even have an allergy to such packaging. Some comments contend that the required packaging is expensive and resource-intensive, and would require investment in expensive equipment and processes. One comment asserts that the requirements will lead to an increase in production costs and to high food prices.

(Response 176) We appreciate the support that some comments expressed for this exemption. Regarding some comments' assertions that § 1.1305(c) imposes packaging requirements that are not feasible for all farms, we note that this provision does not establish packaging requirements for farms; instead, it sets forth an exemption for foods that are packaged and labeled in a certain way. Farms that do not package and label their foods in this way are not in violation of subpart S; they simply are not eligible for this exemption.

Regarding some comments' assertions that the requirements are in violation of FSMA, we conclude that the requirements to meet the exemption in § 1.1305(c) are appropriate and fully consistent with section 204(d)(6)(B) of FSMA, which stipulates that packaging/labeling that qualifies for the exemption should preserve the identity of the farm that grew the product for purposes of traceability and also maintain the integrity of the product and prevent subsequent contamination or alteration of the product. The exemption is written as narrowly as it is to ensure that all of these conditions are met (see Response 178 regarding clamshell packaging).

(Comment 177) One comment requests that FDA clarify the meaning of product ''integrity.'' The comment asserts that Congress was referring to packaging that maintains the food as a distinct unit rather than packaging that prevents exposure to the environment, adding that all produce is packaged in breathable packaging to prevent deterioration. Some comments assert that the consideration should be traceability (*i.e.,* exposure of the product to the environment is irrelevant), and as long as packaging and labeling is identity-preserving, it should be allowed under the exemption, and additional packaging requirements should be kept to a minimum. One comment suggests the exemption be revised to refer to packaging that maintains the integrity of the lot identity of the product and prevents subsequent alteration of the lot identification of the product.

(Response 177) We agree that maintaining the food as a distinct unit and labeling the food so that the farm's identity is preserved to aid in traceability are both important considerations for this exemption. However, they are not the only considerations, and we disagree with the assertion that exposure to the environment is irrelevant. Section 204(d)(6)(B)(i) of FSMA specifies that the packaging must prevent subsequent contamination or alteration of the product. As discussed in Response 178, plastic clamshells and other vented packaging will not necessarily prevent subsequent contamination.

Regarding the comment about lot identity, section 204(d)(6)(B)(i) of FSMA does not require that food be labeled to identify the lot number in order to receive this exemption, and we have not included such a requirement in the final rule. However, we agree that it is a good practice, when possible, for foods to be labeled with information regarding the lot number.

(Comment 178) Some comments suggest that FDA allow the exemption in § 1.1305(c) to apply to foods packed in cardboard and clamshell packing with holes. The comments assert that

the preamble to the proposed rule incorrectly states that vented clamshells do not maintain the integrity of the product they contain. Some comments request information on the contamination risks for food in clamshells or bags with holes when that product is protected by an outer container (cardboard box) and shipped directly to a retailer, and they question how plastic packaging prevents contamination.

(Response 178) As stated in the proposed rule, produce packed or packaged in containers such as clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, or netted bags would not be eligible for this exemption because such packaging does not necessarily maintain the product's integrity and prevent subsequent contamination and alteration. None of the comments presented information or arguments that caused us to revise our understanding of this issue. Although environmental exposure to produce packaged in vented clamshells or bags with holes would be less than when produce is packed without packaging in open crates, vented packaging can subject produce to contamination in many ways, including from condensate in aerosols carried by the air handling system, moisture dripping onto containers, particulates blown through the facility by the air handling system, fingers of handlers during handling of the packages, objects that may be inadvertently inserted through the vents, and pests that can access the produce through the vents. In contrast, sealed plastic packaging that remains sealed throughout the supply chain will prevent contamination that could occur through the vectors described above. Therefore, while plastic clamshells and other vented packaging could maintain identity preserving labeling through the supply chain, such packaging would not necessarily maintain the integrity of the product and prevent subsequent contamination, as required by the statute.

(Comment 179) Some comments assert that the required packaging is environmentally damaging and wasteful, and that the rule creates a bias towards expensive, environmentally damaging packaging. Some comments ask if FDA has considered the environmental impacts of the packaging requirements. Some comments assert that individual item plastic packaging is expensive and wasteful and that some commonly used recyclable packaging will not be permitted under the proposed exemption.

(Response 179) As discussed in Response 176, this provision does not establish a packaging requirement for farms; instead, it sets forth one of several exemptions from the rule applicable to certain foods or supply chain entities. Thus, § 1.1305(c) does not require farms to change how they package their food.

Regarding the comment asking if we have considered the environmental impact of § 1.1305(c), as discussed in the Categorical Exclusion Memorandum (Ref. 24) stating why neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required for this rulemaking (see Section VIII of this document), we think it is very unlikely that a significant number of farms would change their packaging procedures just to avoid the subpart S traceability recordkeeping requirements by making themselves eligible for the exemption in § 1.1305(c). The final rule provides full and partial exemptions for certain farms, as well as a number of exemptions for certain foods produced on farms (see Response 158). In addition, the final rule imposes less burdensome requirements on farms than under the proposed rule, including the elimination of proposed requirements that would have required growers to maintain KDEs regarding the growing of individual lots of food and that would have required the maintenance of shipping and receiving KDEs before the initial packing of a food. Therefore, we anticipate that most farms that are subject to the rule will not conclude that the burden of compliance is so great that they must significantly change their operations for certain foods just to avoid having to keep the required traceability records. We also note that changes to a farm's packaging procedures can themselves be costly and resource-intensive, and might not be feasible for many types of foods. We therefore do not expect the final rule to result in a significant number of farms changing their practices in ways that could cause environmental damage so as to avoid coverage under this rule.

(Comment 180) Many comments support the exemption for products packaged on a farm where the identity of the product is maintained on the packaging all the way to the consumer, as long as the packaging maintains the integrity of the product. Most of these comments also request that these products be exempted throughout the supply chain. The comments maintain that entities downstream in the supply chain from the farm will have no way of knowing some of the traceability information (*e.g.,* the traceability lot code) unless the farm provides the information. The comments assert that this would negate the exemption and could cause firms to avoid buying from these farms. The comments also maintain that buyers will ask non-farm entities to have all of the farm-level information required by the rule if these identity-preserved products are not exempt throughout the supply chain, and claim that having to provide this information would drive some small value-added farm operations out of business. Some comments assert that Congress intended that these identify-preserved farm products would retain their exemption throughout the supply chain. Some comments maintain that distributors and retailers should not have to make decisions about whether the farm-identity information on the packaging and the packaging complies with the exemption criteria in § 1.1305(c).

(Response 180) We agree with the comments that products qualifying for the exemption in § 1.1305(c) are exempt throughout the entire supply chain. This is why the provision states that ''[t]his subpart does not apply to food'' that meets the relevant criteria for the exemption. We believe that products qualifying for this exemption will be relatively easy to identify as they move through the supply chain. This can be accomplished through visual inspection or, if that is not sufficient, through communication with the supplier. Though not required by the rule, we encourage persons selling foods qualifying for this exemption to provide information about their exempt status to downstream entities in the supply chain.

(Comment 181) One comment states that the proposed requirement in § 1.1305(c)(1) that the packaging remain in place until the food reaches the consumer is beyond the scope of FSMA. The comment maintains that some products are labeled but not packaged at all once the store displays them, and these products should still be exempt.

(Response 181) While section 204(d)(6)(B) of FSMA does not specify that the packaging must remain in place until the food reaches the consumer, the provision requires that packaging must maintain the integrity of the product and prevent subsequent contamination or alteration of the product. If the packaging is removed before the product reaches the consumer, the integrity of the product might not be maintained, and contamination or alteration could occur. This is the case even if the food is still labeled with the required information regarding the farm where it was produced and packaged. Therefore, to effectively implement Congress's

intent to exempt only those products whose packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product, § 1.1305(c)(1) of the final rule requires that, to be eligible for this exemption, the packaging of the food must remain in place until the food reaches the consumer.

5. Exemptions and Partial Exemptions for Foods That Will Receive Certain Types of Processing

We proposed to exempt from the FTL traceability recordkeeping requirements produce and shell eggs that receive certain types of processing. Under proposed § 1.1305(d)(1), the requirements would not apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions in § 112.2(b) in the produce safety regulation are met. Under proposed § 1.1305(d)(2), the rule would not apply to shell eggs when all the eggs produced at a particular farm receive a treatment (as defined in § 118.3 (21 CFR 118.3)) in accordance with § 118.1(a)(2) of the shell egg regulation.

In a separate section (proposed § 1.1355), we proposed to specify that if a person applied a kill step to an FTL food, the rule would not apply to the person's subsequent shipping of the food, provided that the person maintained a record of application of the kill step. We further proposed that if a person received an FTL food that had been subjected to a kill step, the rule would not apply to that person's receipt or subsequent transformation and/or shipping of the food.

As discussed in the following paragraphs, we have decided to move these provisions regarding kill steps to the exemptions section of the subpart S regulations. It is set forth in § 1.1305(d) as a partial exemption for food that a person subjects to a kill step, provided that the person maintains a record of the application of the kill step (§ 1.1305(d)(3)(ii)), and as a full exemption for food received that has previously been subjected to a kill step (§ 1.1305(d)(5)). We have also added a partial exemption to § 1.1305(d) for food that will be subjected to a kill step in the future, provided that shippers and receivers of the food enter into written agreements stating that the kill step will be applied by the receiver or an entity in the supply chain (other than an RFE or restaurant) subsequent to the receiver (§ 1.1305(d)(6)).

We received comments that have persuaded us to add a partial exemption for foods that in the future will be changed such that they are no longer on the FTL (§ 1.1305(d)(6)). For example, as discussed in Response 30, fresh spinach is on the FTL but frozen spinach is not on the list. Under the final rule, fresh spinach that is going to be frozen can be exempt from the rule even while it is still fresh, provided that shippers and receivers of the fresh spinach enter into written agreements stating that the spinach will be frozen by the receiver or an entity in the supply chain (other than an RFE or restaurant) subsequent to the receiver. This exemption is included alongside the exemption for food that will receive a kill step in § 1.1305(d)(6) of the final rule. The comments that prompted the addition of this partial exemption are discussed below.

(Comment 182) One comment opposes the commercial processing exemption for produce. The comment asserts that if we maintain the exemption in the final rule, the exemption should not apply until the adequacy of commercial processes are verified and ''cross-scope'' inspection processes are clarified. Other comments request clarification on the types of commercial processing that would be covered under proposed § 1.1305(d)(1).

(Response 182) Under § 1.1305(d)(1) of the final rule, subpart S does not apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in § 112.2(b) in the produce safety regulation are met for the produce. As discussed in the proposed rule (see 85 FR 59984 at 59996), we believe that because of the lesser risk to public health posed by this produce (as reflected in its being exempt from almost all of the requirements of the produce safety regulation), it is not necessary to apply the additional recordkeeping requirements to this food. Section 112.2(b)(1) explains that examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of 21 CFR parts 113, 114, or 120 (parts 113, 114, or 120); treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer, or similar products.

(Comment 183) One comment recommends that we include the kill step exemption with other exemptions in proposed § 1.1305.

(Response 183) We agree with the comment, and because application of a kill step involves certain types of processing, we have moved the expanded kill step provisions to the exemptions and partial exemptions for foods that receive certain types of processing in § 1.1305(d) of the final rule.

(Comment 184) Many comments express support for the proposed kill step exemption. One comment maintains that if an establishment improperly performed the kill step for a food there would be insufficient traceability for those food products.

(Response 184) As discussed above, the final rule retains the proposed rule's approach to foods that receive or have received a kill step, and adds a partial exemption for foods that will receive a kill step in the future. The final rule defines ''kill step'' to mean ''lethality processing that significantly minimizes pathogens in a food'' (§ 1.1310). We think these exemptions and partial exemptions are appropriate because applying a kill step to a food significantly minimizes the presence of pathogens in the food, thus reducing the risk posed by the food and reducing the likelihood that the food would be involved in an outbreak, which in turn reduces the need for further tracing of that food. Application of a kill step generally occurs in accordance with other FDA regulations, such as those concerning preventive controls for human food and LACF, which reduces the likelihood that a kill step would be improperly performed. We note that, if an outbreak were to occur in a food that was fully or partially exempt under these provisions, various mechanisms exist that would help FDA gain access to information regarding the affected foods, as discussed in Response 163.

(Comment 185) Several comments request clarification of the definition of ''kill step'' and the use of the phrase ''significantly minimizes,'' asking whether a log reduction is necessary to significantly minimize pathogens. Several comments ask that we align the definition of kill step with the seafood HACCP, preventive controls for human food, and LACF regulations, or whether food processed under those regulations would be considered kill steps. Several comments ask whether certain processes, such as freezing, individually quick freezing (IQF), drying, ozonated water, or ultraviolet (UV) light, would be considered kill steps. One comment asks whether product formulation, such as a product's pH level, water activity level, or use of certain preservatives could be considered kill steps, particularly for cheese. Several

comments ask whether cooking or shucking molluscan shellfish under the Interstate Shellfish Sanitation Conference (ISSC) Model Ordinance would count as kill steps. Another comment asks us to identify the kill step for products with multiple cooking steps, such as steaming crabs to pick crabmeat, pre-cooking raw tuna before canning, or post-harvest processing of molluscan shellfish. Some comments ask that we provide a list of approved kill steps.

(Response 185) As discussed in Section V.F of this document, in the final rule we are defining ''kill step'' as lethality processing that significantly minimizes pathogens in a food. We added the term ''lethality'' to the proposed definition to clarify that a kill step involves ''lethality processing,'' where the processing is robust (significantly minimizes pathogens in a food) and not something that simply reduces pathogens (*e.g.,* a washing process). It is possible to reduce or minimize pathogens in other ways, such as filtration, but we would not consider that a kill step because it is not a lethality processing. We are not requiring a specific log reduction for a kill step as this depends on many factors, such as the food, the process, the pertinent pathogen, the prevalence and concentration of a pathogen, and other factors. Examples of kill steps include cooking, pasteurization, other heat treatments, high-pressure processing, and irradiation, as long as those processes are conducted in a manner that results in a lethality treatment that significantly minimizes the pertinent pathogen.

Under this definition of ''kill step,'' processes such as freezing, IQF, drying, ozonated water, or UV light generally would not be considered kill steps because those processes usually would not involve a lethality step that significantly minimizes pathogens. Similarly, controlling hazards via a product's pH level, water activity level, use of certain preservatives, or other types of product formulation generally would not be considered kill steps. While those activities may control the growth of the pathogen, they usually would not be applied as kill steps.

Regarding the application of specific other FDA regulations, any LACF that has been processed to commercial sterility in accordance with part 113 will have received a kill step as that term is defined in subpart S. Any lethality step that has been validated to significantly minimize or prevent a pathogen in accordance with the preventive controls regulation would also be considered a kill step. While we anticipate that in many cases a kill step will be performed in a facility that is subject to the preventive controls regulation, the LACF regulation, or both, we recognize that this will not always be the case. (For example, many manufacturing facilities are not subject to the LACF regulation, and a very small manufacturing facility might be exempt from the preventive controls regulation but subject to subpart S.) Any lethality processing that significantly minimizes pathogens in a food will be considered a kill step for the purposes of subpart S, regardless of whether it is performed in a facility that is subject to these other FDA regulations.

The seafood HACCP regulation requires seafood processors to control for certain hazards, and in certain cases, this means processors need to apply a lethality or kill step as a control. The Fish and Fishery Products Hazards and Controls Guidance provides information regarding control of pathogens through techniques such as cooking or pasteurization, with the goal of either eliminating pathogenic bacteria of public health concern or reducing their numbers to acceptable levels. This information could be used to inform a determination of whether or not a specific technique constituted a kill step as that term is defined in subpart S.

Regarding the comment that asked about cooking or shucking molluscan shellfish under the ISSC Model Ordinance, as discussed in Section V.E.7 below, the final rule exempts raw bivalve molluscan shellfish that are covered by the requirements of the NSSP; subject to the requirements of part 123, subpart C, and § 1240.60; or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish.

For products that receive multiple cooking steps, once the food undergoes lethality processing that significantly minimizes pathogens in the food, we will regard the food as having received a kill step. Finally, because whether a process would be considered a kill step depends on the application of the process to a specific food, we decline to provide a list of approved kill steps.

Some manufacturing processes can change the form of a food such that it is no longer on the FTL. In those situations, subpart S would no longer apply to the food under § 1.1305(d)(4) of the final rule, even if the manufacturing process did not constitute a kill step. For example, fresh spinach is on the FTL, but frozen spinach is not. Frozen spinach is therefore not covered by the subpart S requirements, even though freezing is not a kill step.

(Comment 186) Some comments ask for clarity about how the kill step provision would apply to specific commodities such as fresh produce. One comment asks how the kill step exemption would apply to finfish and other seafood since the kill step would not eliminate or reduce fish and other seafood-associated toxins such as histamine or ciguatoxin. One comment asks whether application of a kill step would affect whether a food was covered by the rule or not.

(Response 186) If a kill step is applied to an FTL food, then the food is partially exempt from the subpart S requirements under § 1.1305(d) of the final rule. The person applying the kill step would need to keep receiving records and a record of the application of the kill step, but they would not need to keep transformation records or shipping records related to the food that received the kill step. Subsequent entities in the supply chain would not need to keep records for that food. As discussed in Response 196, an additional partial exemption would be available if it is known in advance that the food will be subjected to a kill step.

As previously stated, we are defining ''kill step'' to mean lethality processing that significantly minimizes pathogens in a food. Histamine and ciguatoxin are not pathogens; they are toxins, and we agree with the comment that toxins are not controlled by the application of lethality processing. Processes such as cooking will constitute a kill step in situations where the relevant hazard relates to pathogens, provided that the cooking is sufficient to constitute lethality processing that significantly minimizes the pathogens in the food. But with respect to a food that is associated with histamine or ciguatoxin as a hazard—which is the case for some of the foods currently on the FTL, as discussed below—cooking would not affect the toxin and would not constitute a kill step. In general, cooking and other lethality treatments do not significantly minimize non-microbiological hazards, nor do they affect the toxins from microbiological hazards that cause foodborne illness through the formation of a heat-stable toxin in food, such as *Staphylococcus aureus* and *Bacillus cereus.*

For each of the commodities on the FTL, there are one or more associated commodity-hazard pairs that drive the commodity risk score and lead to the commodity being included on the FTL (see Refs. 10 and 15). Of the foods currently on the FTL, there are only two commodities with such commodity-hazard pair(s) for which the associated hazards include toxins: Finfish,

histamine-producing species, and Finfish, species potentially contaminated with ciguatoxin. Because the acute chemical toxins are not eliminated by thermal processes, cooking these commodities does not constitute a kill step. But for all of the other commodities currently on the FTL, including seafood products on the FTL that are not in either of these commodities, cooking would be considered a kill step as long as the product is cooked sufficiently to constitute lethality processing that significantly minimizes the pathogens in the food.

As discussed in Section V.T of this document, we plan to periodically review and update the FTL using the procedures set forth in § 1.1465. As a result of this process, it is possible that the commodity-hazard pairs(s) that lead to a commodity being on the FTL could change. In such cases, the determination of whether cooking is considered a kill step would be re-evaluated and could change, depending on whether the associated hazards include an acute chemical toxin or a microbiological hazard that produces a heat-stable toxin in food. Similarly, if new commodities are added to the FTL in the future, we would evaluate the hazards associated with each new commodity to determine whether cooking would be considered a kill step for that commodity. As discussed above, currently the only commodities on the FTL for which cooking (or other lethality processing) is not considered a kill step are Finfish, histamine-producing species, and Finfish, species potentially contaminated with ciguatoxin. This can only change as a result of updates to the FTL that are carried out using the procedures in § 1.1465; and if it does change, we will communicate clearly about which commodities on a revised FTL are in this situation.

As discussed in Responses 27 and 185, some manufacturing processes can change the form of a food such that it is no longer on the FTL. In those situations, subpart S would no longer apply to the food, even if the manufacturing process did not constitute a kill step. For example, canned tuna is in the commodity ''canned seafood,'' which is not on the FTL. Canned tuna has tuna as an ingredient, but not in any of the forms (''fresh'' or ''frozen'') in which tuna appears on the FTL. Canned tuna is therefore not on the FTL and is not covered by the subpart S requirements, even though the canning process does not constitute a kill step for histamine, which is a hazard among the commodity-hazard pairs that lead to Finfish, histamine-producing species (*e.g.,* tuna), being included on the FTL. In many cases, the inquiry into whether or not a process constitutes a kill step will not be relevant, because the same process will have changed the food into a form that is not on the FTL.

(Comment 187) Some comments assert that in addition to the proposed exemption associated with a ''kill step,'' products covered under the LACF and acidified foods (AF) regulations (parts 113 and 114, respectively) should be exempt from other recordkeeping requirements in the proposed rule. The comments state that the processes required in parts 113 and 114 exceed the exemption requirements included in proposed § 1.1305(d). In addition, the comments maintain that those regulations require that the products be marked with a permanent code on their containers and that records be maintained for 3 years. The comments also propose that subpart S be modified to include provisions for identifying foods intended to undergo LACF or AF processes.

(Response 187) As discussed in Response 7, the RRM–FT uses a categorization scheme that classifies FDA-regulated foods into 47 commodity categories. Within each commodity category, the RRM–FT identifies individual commodities. Two of the 47 commodity categories apply to products covered under the LACF and AF regulations: ''Acidified/LACF—Baby (Infant and Junior) Food Products'' and ''Acidified/LACF—NEC.'' These two commodity categories are associated with eight different commodities: baby food; canned broth, chicken or beef; canned fruits and vegetables; canned seafood; cheese sauce (shelf-stable); diet and nutritional drinks (shelf-stable); milk (shelf-stable, not condensed); and soups (canned). None of these commodities had a risk score high enough to be included on the FTL. Therefore, there are currently no products covered under the LACF and AF regulations on the FTL, and such products are therefore not currently subject to the final rule.

We agree it is helpful to identify foods that are intended to undergo processes that would either constitute a kill step or change the food such that it is no longer on the FTL (or both). Therefore, as discussed in Response 196, § 1.1305(d)(6) of the final rule provides a partial exemption for foods that will be subjected to a kill step by an entity other than an RFE, restaurant, or consumer, or that will be changed by an entity other than an RFE, restaurant, or consumer such that the food is no longer on the FTL, provided that shippers and receivers of the food enter into written agreements stating that the food will receive a kill step or be changed such that it is no longer on the FTL. This partial exemption can be used when it is known that an FTL food will ultimately undergo processing under the LACF or AF regulations, and will therefore no longer be on the FTL.

(Comment 188) Some comments state that pasteurized crabmeat should be exempt from subpart S because, in manufacturing the finished product, the crabs must be cooked twice, first to allow removal of the meat from the shell, and then a second time to pasteurize the finished product. The reasons provided in the comment for the requested exemption include that the second ''kill step'' was comparable to the processes that allow for exemption of produce and egg products under proposed § 1.1305(d); that the seafood HACCP regulation requires the maintenance of records for those products for 2 years; that the seafood HACCP regulation requires processors to address all food safety hazards, including hazards introduced from the growing environment; and finally that the crabmeat is separated from the viscera, which eliminates the need for traceback to the harvest environment.

(Response 188) We agree that the cooking or pasteurization of crabmeat products meets the definition of a kill step, provided that it is done in a way that constitutes lethality processing that significantly minimizes pathogens in the food. The exemptions in § 1.1305(d) relating to the application of a kill step are therefore applicable to cooked or pasteurized crabmeat products.

(Comment 189) Some comments request that surimi analogue be considered exempt from the rule. The comments maintain that exemption would be appropriate because the process requires that the finished product be cooked twice during production and the second pasteurization process is comparable to the exemption requirements in § 1.1305(d) for produce and egg products, and the seafood HACCP regulation requires the processor to address all food safety hazards associated with the analogue and to maintain HACCP records for 2 years.

(Response 189) We do not think it is appropriate to exempt surimi analogue from the rule. Surimi analogue is a paste that is usually made from fish. As with any food, if surimi analogue contains an FTL food as an ingredient, it will be on the FTL (provided the FTL ingredient remains in the same form in which it appears on the FTL).

However, the final rule provisions relating to kill steps would apply to surimi analogue just as they do to other foods. Surimi analogue and its FTL ingredients therefore could be eligible for the full and partial exemptions related to kill steps in § 1.1305(d)(3), (d)(5), and (d)(6), if the relevant conditions are met.

(Comment 190) Some comments recommend that seafood that has undergone a cooking process (*e.g.,* cooking, pasteurization, hot smoke) should not be considered ''high risk'' under the rule. The comments maintain that the seafood HACCP requirements and other regulatory controls are sufficient to ensure the safety of these products.

(Response 190) Thermal processes intended to eliminate or significantly minimize pathogens meet the definition of a kill step. This is true of cooking in many contexts. However, as discussed in Response 186, cooking does not significantly minimize toxins such as histamine and ciguatoxin. Cooking a product does not constitute a kill step for foods on the FTL when acute chemical toxins or microbiological hazards that produce heat-stable toxins are determined to be among the commodity-hazard pair(s) that drive the commodity risk score and lead to the commodity being included on the FTL. Of the foods currently on the FTL, there are two commodities with such commodity-hazard pair(s) for which the associated hazards include toxins: Finfish, histamine-producing species, and Finfish, species potentially contaminated with ciguatoxin. Because the acute chemical toxins in these types of finfish are not eliminated by thermal processes, cooking or other thermal processing of these commodities does not constitute a kill step. But for seafood products on the FTL that are not in either of these commodities, cooking or other thermal processing would be considered a kill step as long as the product is cooked sufficiently to constitute lethality processing that significantly minimizes the pathogens in the food.

As discussed in Response 73, smoked finfish (including both hot and cold smoked finfish) is a commodity that was identified for inclusion on the FTL due to its risk score. Therefore, hot smoked finfish is covered by the subpart S requirements, and the hot smoking itself cannot be considered a kill step.

Notwithstanding the fact that other regulations are in place for food safety, Congress instructed FDA to create a list of foods for which additional recordkeeping requirements would be appropriate and necessary to protect the public health, with the goal of improving traceability. While the seafood HACCP regulations are intended to ensure the safety of seafood products, the purpose of this final rule is to improve traceability in the event of a foodborne illness outbreak involving foods on the FTL. The seafood commodities on the FTL are on the list because they have a risk score that meets the threshold for the FTL. Consequently, persons who manufacture, process, pack, or hold seafood products on the FTL must comply with the subpart S requirements, unless an exemption applies.

(Comment 191) Many comments maintain that downstream entities may not know whether a kill step was applied to a particular food and that distributors and retailers may not be able to create different systems for receiving foods on the FTL and foods not on the FTL. But some comments suggest that requiring shippers to communicate to receivers that a food has undergone a kill step would still require recordkeeping, resulting in this not being a true exemption. A few comments request that FDA specify that downstream entities could rely in good faith on the absence of subpart S records as an indication that a kill step was applied. Some comments suggest that FDA exercise enforcement discretion for those downstream entities that rely in good faith on upstream entities to determine whether a product received a kill step. One comment suggests that if the shipper does not provide subpart S records, the receiver should be able to assume the records are not required as long as the receiver does not have affirmative knowledge that the food should be covered by the rule and the shipper has provided a guaranty that it will provide traceability information when required.

A few comments ask us to require the person who applied the kill step to provide a statement to subsequent entities in the supply chain that a kill step had been applied. One comment asks that we require anyone who received a food to which a kill step has been applied to maintain lot-based traceability linking back to the entity that applied the kill step.

(Response 191) As discussed in Response 196, a person who applies a kill step must maintain a record of the kill step, but they are not required to keep records relating to the transformation or subsequent shipping of the food. Under § 1.1305(d)(5), subpart S does not apply to food a person receives that has previously been subjected to a kill step. As discussed above, we think these exemptions are appropriate in light of the reduced risk associated with foods that have received a kill step.

We have not included a requirement for the person applying the kill step to notify downstream entities that a kill step has been applied, and we also decline to require subsequent entities to maintain traceability records for products to which a kill step has been applied. Receivers should not assume (in the absence of other evidence) that just because they receive a product without subpart S records from the shipper of the food that a kill step was applied. Persons covered by the rule are responsible for knowing whether they need to keep subpart S records. In cases where it is not clear whether a kill step has been applied, firms should work with their suppliers to communicate about the status of the product. If entities in a particular supply chain wish to have documentation of a kill step, they can work that out with their supply chain partners. As discussed previously, we encourage persons selling exempt foods to provide information about their exempt status to downstream entities in the supply chain.

(Comment 192) A few comments request that FDA also provide an exemption for foods that will receive a kill step from the consumer. The comments argue that these foods are less likely to result in a foodborne illness outbreak, making additional recordkeeping requirements for traceability unnecessary.

(Response 192) We decline to provide an exemption for FTL foods for which the consumer will apply a kill step. The kill step exemption in the final rule applies only to foods to which a kill step is applied by a commercial entity, and the entity applying the kill step must maintain a record of the application of the kill step. We anticipate that entities applying a kill step will primarily include manufacturers/processors producing food under existing regulations, such as the preventive controls, LACF, and seafood HACCP regulations. Those regulations include additional provisions to ensure that a kill step was applied adequately. Consumers may not apply an adequate kill step in the home or may not follow the cooking instructions; they also might not apply a kill step at all, depending on the nature of the food.

(Comment 193) One comment suggests that the requirement to identify a list of FTL foods to be shipped should not include foods that will receive a kill step.

(Response 193) As discussed in Section V.G of this document, the final rule omits the proposed requirement to maintain a list of FTL foods shipped.

(Comment 194) One comment suggests that we revise the definition of the ''Food Traceability List'' to make clear that if a food on the FTL receives a kill step, it is not covered by the rule.

(Response 194) We decline to revise the definition of ''Food Traceability List'' as suggested. Instead, as discussed above, the final rule provides a complete exemption for food a person receives that has previously been subjected to a kill step, as well as partial exemptions for food a person subjects to a kill step and food that will be subjected to a kill step in the future. We think these exemptions provide an appropriate level of traceability for these foods, while taking into account the reduced risk associated with these foods.

We note that in some cases, the application of a kill step coincides with a food being changed such that it is no longer on the FTL. For example, as discussed in Response 30, fresh spinach is on the FTL because it is part of the commodity ''leafy greens,'' but canned spinach is not on the FTL because it is part of the commodity ''canned fruits and vegetables.'' Moreover, the fact that canned spinach contains spinach as an ingredient does not place it on the FTL, because the spinach is not in the same form (''fresh'') in which it appears on the FTL. The canning process (and related cooking) constitutes a change to the food such that it is no longer on the FTL; consequently, canned spinach is not covered by the rule. It therefore might not be necessary to inquire whether the canned food received a kill step, though we note that the processes associated with making canned spinach under the LACF regulation do constitute a kill step.

(Comment 195) Some comments suggest that we should exempt dietary supplements and dietary ingredients from the rule because dietary ingredient manufacturing involves steps to reduce the presence of microorganisms of public health significance.

(Response 195) We decline to exempt dietary supplements or dietary ingredients from the rule. As discussed in Response 78, dietary supplements are a separate commodity in the Model and they do not have a risk score high enough to merit inclusion on the FTL. However, if a dietary supplement uses an ingredient that is on the FTL, and that ingredient is in the same form in which it appears on the FTL (*e.g.,* ''fresh''), then the dietary supplement would be covered by the rule. For example, some refrigerated dietary supplements contain fresh herbs and are therefore on the FTL and covered by the rule.

(Comment 196) Multiple comments assert that, in addition to providing a partial exemption for foods that receive a kill step, we should also exempt, throughout the supply chain, foods that will receive a kill step in the future. The comments argue that because a kill step will be applied, there is no public health benefit to requiring additional traceability records for those foods. The comments also suggest that receiving and transformation records, including maintaining a lot code, should not be required for foods that will receive a kill step in the future. The comments note that we already allow for an exemption for certain produce and eggs that will receive commercial processing in the future.

(Response 196) We agree with the comments that full traceability records are not necessary for foods that will receive a kill step in the future. Under the final rule, once it becomes known that an FTL food will receive a kill step in the future, the food becomes eligible for the partial exemption in § 1.1305(d)(6), provided that written agreements are in place, as described below, to indicate the intent that the food will be subjected to a kill step. The person who applies the kill step would still need to maintain a record of the kill step, as specified in § 1.1305(d)(3)(ii); however, because of the existence of the written agreement, the person applying the kill step would not need to keep receiving records for the food, as specified in § 1.1305(d)(3)(i). (Furthermore, as discussed in the introduction to Section V.E.5 of this document, the person who applies a kill step is never required to keep transformation or shipping records relating to the food, provided they maintain a record of the kill step.) If the entity applying the kill step does not have a written agreement in place with the shipper of the food, the entity must maintain receiving records for the food, as stated in § 1.1305(d)(3)(i). Once the kill step has been applied, subsequent entities who receive the food would not need to keep subpart S records for the food, as specified in § 1.1305(d)(5).

To ensure that a kill step will be applied, § 1.1305(d)(6) of the final rule requires, for the exemption to apply, that the shipper and receiver of the FTL food enter into a written agreement stating that a kill step will be applied to the FTL food by an entity other than an RFE, restaurant, or consumer. The written agreement can either specify that the receiver will apply a kill step, or that the receiver will only ship the food to another entity that agrees, in writing, that it will either apply a kill step or enter into a similar written agreement with the subsequent receiver stating that a kill step will be applied to the food. The food might move through several steps in the supply chain before it reaches the entity that applies the kill step, and the first shipper might not be aware of who will eventually apply the kill step. However, for each shipping event that is covered by a written agreement between the shipper and the receiver, there must be a shared understanding that the food will eventually be subjected to a kill step by an entity that is not an RFE, restaurant, or consumer. RFEs, restaurants, and consumers are not included because we expect the kill step to be applied under controlled conditions, which may not always be the case in a retail food setting or in the home. As discussed in Response 185, we anticipate that entities applying a kill step will primarily be manufacturers/processors producing food under existing regulations, such as those on preventive controls, LACF, and seafood HACCP, which will help ensure that the kill step is applied adequately.

As specified in § 1.1305(d)(6)(iii), a written agreement under these provisions must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement. We consider electronic signatures to meet the signature requirement of this provision, and another entity (*e.g.,* corporate headquarters) may sign the agreement on behalf of a shipper or receiver provided the agreement is specific to the shipper and receiver. To ensure the agreement reflects the current understanding between the parties, the written agreement must be renewed at least once every 3 years, as set forth in § 1.1305(d)(6)(iv). That provision also specifies that the written agreement must be maintained by both parties for as long as it is in effect.

We are providing flexibility for written agreements to be entered into in a variety of ways, depending on the business practices of the supply chain partners. The written agreement can be a new agreement developed for the purposes of this regulation or it can be written into existing contracts or other documents between the shipper and receiver. The written agreement can be written to cover the FTL food on a per-lot, per-shipment, or other basis (*e.g.,* all products the shipper provides to the receiver will receive a kill step), depending on what makes the most sense for the shipper and receiver.

However, the written agreement must represent the current understanding of the parties. If circumstances change such that the substance of the written agreement is no longer accurate, the agreement must be updated even if the 3 years has not expired. As with all records required under subpart S, written agreements must be provided to FDA upon request in accordance with § 1.1455(c).

This approach aligns with our exemptions in § 1.1305(d)(1) and (2) for produce that is eligible for the commercial processing exemption under § 112.2(b) of the produce safety regulation, and for shell eggs when all eggs produced at a particular farm will receive a treatment. We agree with the comments that it makes sense to add this new partial exemption to broaden the situations in which the recordkeeping burden can be reduced due to advance knowledge that a food will receive a kill step. This new partial exemption is available in situations that are not covered by the two other exemptions in § 1.1305(d), including situations where it does not become known that the food will receive a kill step until after it leaves the farm or other point of origination.

As discussed in Response 194, the partial exemption in § 1.1305(d)(6) is available not only to food that will receive a kill step, but also to food that will be changed such that it is no longer on the FTL.

(Comment 197) One comment requests that FDA expand the kill step exemption to include FTL foods that received a kill step in compliance with the preventive controls for human food regulation in part 117, subpart C (21 CFR part 117, subpart C), or related regulations. The comment argues that this would be consistent with the commercial processing exemption for produce in the proposed rule and would exclude foods that will be prepared under food safety plans that require a kill step, either through processing or validated cooking instructions to the consumer.

(Response 197) As discussed above, we are providing a set of full and partial exemptions relating to foods that receive a kill step. Such kill steps will often, though not always, be applied in facilities that are subject to the preventive controls regulation. We are not exempting FTL foods for which the consumer is expected to apply a kill step, as discussed in Response 192.

6. Exemption for Produce That Is Rarely Consumed Raw

We proposed to exempt from subpart S produce that is listed as rarely consumed raw (RCR) in § 112.2(a)(1) of the produce safety regulation (proposed § 1.1305(e)). We stated that due to the lesser risk to public health posed by such produce (as reflected in its being exempt from the produce safety regulation), it was not necessary to apply the additional recordkeeping requirements to these foods. The final rule maintains this exemption in § 1.1305(e).

(Comment 198) Some comments support exemption of produce that is rarely consumed raw. Some comments also suggest revisiting the RCR list and request that we evaluate a broader range of crops than the commodities found in the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) dataset. One comment suggests exemption of foods that contain an ingredient that is on the FTL if the food is rarely consumed raw (even if the food is not listed on the RCR list in § 112.2(a)(1)), for example, frozen pizza containing an ingredient on the FTL. One comment requests that we apply our exemption for RCR produce to all foods on the FTL that are rarely consumed raw. The comment asserts that this would reduce the number of foods covered by the FTL that have never been associated with a foodborne illness outbreak. The comment maintains that because foods like frozen pizza are usually cooked by the consumer before being consumed, they should not be covered. Other comments maintain that most seafood should not be covered by the rule because it is cooked before consumption.

(Response 198) Produce that is on the RCR list as not covered under the produce safety regulation in § 112.2(a)(1) is exempt from the subpart S requirements under § 1.1305(e). Reevaluation of the RCR list is beyond the scope of this rulemaking. The RCR list is an exhaustive list containing fruits and vegetables that are almost always cooked before being consumed. The list was developed using national food survey data from the NHANES/WWEIA that was conducted in partnership between the U.S. Department of Health and Human Services (HHS) and the USDA. NHANES/WWEIA examines a nationally representative sample of about 5,000 persons each year located across the country. The sample is selected to represent the U.S. population of all ages. More information, data, and other details about how the RCR list was developed are available in the final rule establishing the produce safety regulation (80 FR 74353).

As discussed in Response 192, we are not creating a broader exemption to the subpart S requirements for foods that are expected to receive a consumer kill step. We also decline to create a ''rarely consumed raw'' exemption for non-produce foods. As discussed above, FDA developed an exhaustive list of produce that is designated as RCR in the produce safety regulation, and those products are exempt from the subpart S requirements. However, we have not developed an exhaustive list for other types of foods, such as frozen pizza or specific types of finfish, that are rarely consumed raw, and it would not be feasible to do so at this time. Moreover, although the Agency determined in the produce safety regulation that there was relatively low risk associated with produce that is rarely consumed raw, it does not necessarily follow that this is the case for non-produce items that are rarely consumed raw. Shell eggs are not intended to be consumed raw, and indeed for many years FDA has required that all shell eggs be labeled with safe handling instructions requiring that they be cooked thoroughly (see 21 CFR 101.17(h)). However, subsequent to the issuance of that regulation, shell eggs were nonetheless involved in numerous foodborne illness outbreaks. Furthermore, as discussed above, many types of seafood are associated with hazards that are not addressed by cooking. These are some of the complexities that have led us to decide not to identify and exempt a list of non-produce items that are rarely consumed raw.

The coverage of seafood on the FTL is discussed in several responses in this document. We note that ''Pizza (Frozen)'' is a commodity that was evaluated by the Model, and it did not receive a risk score high enough to be on the FTL. And because all of its ingredients are frozen, a frozen pizza could only be on the FTL if it contained an FTL ingredient that is on the FTL in its frozen form (*e.g.,* finfish).

(Comment 199) Some comments maintain that the majority of seafood products are cooked prior to consumption and are rarely consumed raw (*e.g.,* shrimp, lobster, crab, crayfish), yet the exemption in proposed § 1.1305(e) only addresses produce that is rarely consumed raw. Some comments further maintain that NHANES did not accurately capture consumption patterns of shrimp and the extent to which shrimp is consumed cooked or raw. The comments suggest opening a public comment period for stakeholders to help identify seafood products that are rarely consumed raw

and develop a list similar to that for produce in part 112.

(Response 199) As discussed above, we decline to identify and exempt seafood products that are rarely consumed raw. Under the seafood HACCP regulations, the identification of products that will be cooked before consumption occurs during the individual processor's hazard analysis where hazards and controls are identified. In the absence of an RCR list identifying specific species of seafood that are unlikely to be consumed raw, the Model identified seafood commodities (*e.g.,* several finfish commodities and crustaceans) as having a risk score that meets the criteria for the FTL based on data related to consumption and six other criteria (Ref. 10), which resulted in those foods being included on the FTL. Further, we believe NHANES is currently the best data source available for estimating consumption across the commodities in the RRM–FT, including the commodity ''Crustaceans,'' which includes shrimp. The RRM–FT does not consider consumer cooking because the commodity in the Model is defined as foods available for purchase by the consumer. Therefore, we used data from NHANES regardless of whether the product is consumed cooked or raw by the consumer to score Criterion 6 (Consumption) for ''Crustaceans.''

7. Exemption for Raw Bivalve Molluscan Shellfish

The proposed rule did not include an exemption for molluscan shellfish. However, we received many comments requesting such an exemption. In response to the comments, the final rule includes an exemption for certain raw bivalve molluscan shellfish, as discussed in the following paragraphs.

(Comment 200) One comment maintains that although existing regulations applicable to shellfish are adequate, application of the rule to shellfish could produce potential benefits. On the other hand, several comments ask that we exempt from the rule shellfish that is subject to the NSSP. Several comments compare the existing raw molluscan shellfish safety and traceability requirements to the proposed rule and ask that we exempt raw molluscan shellfish from the rule. One comment maintains that current Louisiana laws and regulations cover most of the proposed requirements for the shellfish industry operating in accordance with the NSSP requirements. Some comments assert that there are conflicts between the proposed rule and the requirements in the seafood HACCP regulation and the NSSP Model Ordinance (recognized by the ISSC), and maintain that the information required by the proposed rule should already be contained in records required by the NSSP. The comments maintain that the current NSSP requirements and local laws regarding traceability and recordkeeping require traceability back to harvesters and harvest waters, adding that processors also must meet the requirements of the NSSP Guide for the Control of Molluscan Shellfish (NSSP Guide) and the seafood HACCP regulation to address food safety hazards associated with raw molluscan shellfish. The comments assert that adding the subpart S requirements would cause financial burdens and further confuse the regulatory environment. One comment asserts that not granting a ''waiver'' for shellfish would establish dual conflicting traceability requirements. One comment maintains that if FDA thinks different traceback information is needed for raw molluscan shellfish, we should use the process for making changes to the NSSP through the ISSC. However, one comment asserts that changes to the NSSP Guide or additional, redundant requirements would cause confusion in both the regulatory community and the shellfish industry. Many of the comments maintain that the proposed traceability requirements would not provide any additional safety benefits regarding raw molluscan shellfish. One comment suggests the use of State-designated harvest areas and NSSP lease numbers as harvest locations. One comment suggests that the rule specifically exempt ''shellfish harvesters and dealers that are regulated pursuant to the National Shellfish Sanitation Program and are listed on the Interstate Certified Shellfish Shippers List published by the U.S. Food and Drug Administration.''

(Response 200) We recognize that the NSSP is a longstanding, well-established Federal-State cooperative program for the sanitary control of shellfish produced and sold for human consumption with broad participation from agencies from shellfish-producing and non-producing States, FDA, the Environmental Protection Agency (EPA), NOAA, foreign governments, and the shellfish industry. Specifically, the NSSP provides a broad framework of raw molluscan shellfish sanitation standards through the NSSP Guide. The NSSP Guide contains within it all relevant federal requirements concerning, among other things, current good manufacturing practice (CGMP), hazard analysis and HACCP plans, recordkeeping, sanitation control procedures, and the restriction of interstate transport of shellfish in an insanitary manner. Importantly, the NSSP Guide also allow products in the program to be traced from harvest to retail. We conclude that applying the requirements of this rule to such molluscan shellfish covered by NSSP would be unnecessary and duplicative in light of those existing controls.

Further, we recognize that under the seafood HACCP regulations, processors of fishery products that meet the definition of ''molluscan shellfish'' in § 123.3(h) (21 CFR 123.3(h)) are required by subpart C of part 123 to maintain records documenting certain required traceability information relating to the shellstock. Additionally, § 1240.60 requires that shipments of molluscan shellstock or containers of shucked molluscan shellfish be accompanied by tags, labels, BOLs, or similar shipping documents that bear certain required traceability information. Therefore, we conclude that applying the requirements of this rule to raw bivalve molluscan shellfish that is subject to the requirements of part 123, subpart C, and § 1240.60 would be unnecessary and duplicative in light of those existing controls.

We also recognize that there are raw bivalve molluscan shellfish that are covered by a final equivalence determination by FDA, meaning that FDA has found that a foreign country has adopted and implemented a system of food safety control measures for raw bivalve molluscan shellfish that provides at least the same level of sanitary protection as comparable food safety measures in the United States (*i.e.,* those applied through the NSSP and those required by subpart C of part 123 and § 1240.60). We therefore conclude that applying the requirements of this rule to raw bivalve molluscan shellfish that are covered by a final equivalence determination by FDA would be unnecessary and duplicative.

Therefore, § 1.1305(f) of the final rule provides that the subpart S requirements do not apply to raw bivalve molluscan shellfish that are covered by the requirements of the NSSP; subject to the requirements of part 123, subpart C, and § 1240.60; or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. This exemption holds throughout the supply chain, including subsequent receivers of raw bivalve molluscan shellfish.

(Comment 201) One comment asserts that the State of Louisiana regulates oyster harvesting, including traceability requirements that require oyster tags to

be kept for 90 days. The comment maintains that the Louisiana recordkeeping requirements (including those concerning commercial trip tickets, oyster tags, and time-temperature logs) help ensure that oysters are tracked from harvest to consumption to protect the public health. The comment asserts that these traceability requirements cover the goals of the proposed rule.

(Response 201) As stated in Response 200, raw bivalve molluscan shellfish covered by the requirements of the NSSP are exempt from subpart S under § 1.1305(f). Through their participation in the NSSP and membership in the ISSC, States such as Louisiana have agreed to adopt the NSSP Model Ordinance into State law and enforce NSSP requirements for the sanitary control of molluscan shellfish.

(Comment 202) One comment recommends that all shellfish harvesters and shellfish farmers be exempt from the requirement to create lot codes and instead, the comment asserts, they should keep records under § 1.337, consistent with existing subpart J requirements. The comment asserts that asking each shellfish harvester and shellfish farmer to register with FDA is duplicative because they already have to be licensed by their State shellfish control authorities.

(Response 202) Under § 1.1305(f), and as stated in Response 200, subpart S does not apply to raw bivalve molluscan shellfish that are covered by the requirements of the NSSP; subject to the requirements of part 123, subpart C, and § 1240.60; or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. However, we decline the recommendation to exempt all shellfish harvesters and shellfish farmers from the requirement to assign traceability lot codes. The FTL contains types of shellfish that are not molluscan shellfish (specifically crustaceans, including, but not limited to, shrimp, crab, lobster, and crayfish) and that are therefore not exempt under § 1.1305(f), and for those types of shellfish, the requirement to assign traceability lot codes is the same as for any other food on the FTL. Shellfish harvesters and shellfish farmers that initially pack a RAC (other than a food obtained from a fishing vessel), perform the first land-based processing of a food obtained from a fishing vessel, or transform a food would be required to assign traceability lot codes in accordance with § 1.1320.

This rule does not establish a requirement for shellfish harvesters and farmers to register with FDA. Food facility registration is addressed in subpart H. We note that subpart H does not apply to farms (see § 1.226(b) (21 CFR 1.226(b)) or to certain fishing vessels (see § 1.226(f)).

(Comment 203) One comment asks if the proposed traceability lot code would be required to travel with oysters after they are shucked. The comment mentions that the shellfish industry commonly commingles shellfish based on grade and order, and maintains that requiring a vessel-specific traceability lot code would be burdensome. One comment asks FDA to clarify if receiver requirements would apply to a shucker of raw molluscan shellfish destined for a restaurant.

(Response 203) As stated in Response 200, subpart S does not apply to raw bivalve molluscan shellfish that are covered by the requirements of the NSSP; subject to the requirements of part 123, subpart C, and § 1240.60; or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. This exemption applies throughout the supply chain, including subsequent receivers, shippers, and transformers of the shellfish. Therefore, a traceability lot code will not be required to travel with oysters (or other raw bivalve molluscan shellfish) after they are shucked, and receiver requirements will not apply to apply to a shucker of raw bivalve molluscan shellfish destined for a restaurant.

Regarding the comment's observation that all shellfish, not specifically oysters, are commonly commingled, we note that not all shellfish are exempt, as discussed in more detail in Response 202 above. Specifically, the FTL also includes crustacean shellfish, which are not exempt under § 1.1305(f). For crustacean shellfish, the requirement to assign traceability lot codes is the same as for any other food on the FTL. As discussed in Section V.E.9 of this document, some seafood will be able to meet the definition of ''commingled raw agricultural commodity'' in this rule and will therefore be eligible for the partial exemption in § 1.1305(h).

8. Exemption for Persons Who Manufacture, Process, Pack, or Hold Certain Foods Subject to USDA Regulation

Although the proposed rule did not include an exemption for foods that are subject to regulation by the USDA, in response to a comment, the final rule specifies that the subpart S requirements do not apply to persons who manufacture, process, pack, or hold FTL foods during or after the time when the food is within the USDA's exclusive jurisdiction, as discussed in the following paragraphs.

(Comment 204) One comment asks whether facilities regulated by the USDA's FSIS are covered by the rule.

(Response 204) Facilities that are exclusively regulated by FSIS are not covered by this rule. See Response 83 for further discussion of § 1.1305(g), which states that the subpart S requirements do not apply to persons who manufacture, process, pack, or hold food on the FTL during or after the time when the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). If FDA and FSIS share joint regulatory oversight of a particular facility, FTL foods produced under exclusive FSIS oversight in that facility would not be covered by the final rule.

The requirements of subpart S apply to FTL foods that have not yet arrived at a facility where they will be exclusively regulated by FSIS. For example, if an FDA-regulated facility sends an FTL food to a facility where it will be exclusively regulated by FSIS, the shipper must maintain the required shipping KDEs and provide the required KDEs to the FSIS facility in accordance with § 1.1340 of the final rule. This will help ensure that the FSIS facility has a record of the shipment of the food in the event a traceback of the food products is necessary. However, neither the FSIS facility nor any subsequent entities in the food's supply chain would be required to keep subpart S records for the food.

9. Partial Exemption for Commingled Raw Agricultural Commodities

In accordance with section 204(d)(6)(D) of FSMA, we proposed to partially exempt certain commingled RACs from subpart S (proposed § 1.1305(f)). For purposes of the partial exemption, and in keeping with Congress's language in section 204(d)(6)(D) of FSMA, we proposed to define ''commingled raw agricultural commodity'' as any commodity that is combined or mixed after harvesting but before processing, except that the term would not include types of fruits and vegetables that are RACs to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 apply (proposed § 1.1305(f)(1)). As a result, the proposed exemption would *not* apply to produce subject to the produce safety regulation. Also in keeping with section 204(d)(6)(D) of FSMA, the proposed rule

stated that the term ''processing'' would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization (proposed § 1.1305(f)(1)). In the preamble to the proposed rule, we stated that for the purposes of this definition of ''commingled raw agricultural commodity,'' a commodity would be regarded as combined or mixed before processing only when the combination or mixing involved food from different farms (see 85 FR 59984 at 59996).

Also, in keeping with section 204(d)(6)(D) of FSMA, proposed § 1.1305(f)(2) specified that, with respect to a commingled RAC that receives the exemption in proposed § 1.1305(f)(1), if a person who manufactures, processes, packs, or holds such commingled RAC is required to register with FDA under section 415 of the FD&C Act in accordance with subpart H with respect to the relevant RAC, such person must maintain records (for 2 years) identifying the immediate previous source of such RAC and the immediate subsequent recipient of such food in accordance with the subpart J traceability requirements in §§ 1.337 and 1.345.

As discussed in the following paragraphs, consistent with changes we are making in response to comments in Section V.E.5 of this document to exempt foods that will be subjected to a kill step (see Response 196), we are expanding the partial exemption for commingled RACs to include RACs that will become commingled in the future, provided that there is a written agreement in place between the shipper and receiver of the RAC, as specified in § 1.1305(h)(2) of the final rule. In response to comments, we have made other minor changes to the proposed partial exemption for commingled RACs and to the definition of ''commingled raw agricultural commodity,'' as discussed in the following paragraphs.

(Comment 205) One comment suggests expanding the proposed definition of ''commingled raw agricultural commodity'' to include bulk and commingled ingredients after they are first combined and subsequently transformed.

(Response 205) We decline to make this change to the proposed definition of ''commingled raw agricultural commodity.'' In section 204(d)(6)(D)(ii)(I) of FSMA, Congress defined ''commingled raw agricultural commodity'' for purposes of this partial exemption as any commodity that is combined or mixed after harvesting but before processing. We incorporated this definition in proposed § 1.1305(f)(1), and we continue to incorporate it in the final rule, although we have moved it to the ''Definitions'' section of subpart S (§ 1.1310). We conclude that it would not be appropriate to broaden the scope of the exemption to include RACs that are commingled *after* processing, as the comment appears to suggest, because this would result in more FTL foods for which subpart S traceability records would not be available in the event of a foodborne illness outbreak involving such a food. However, we note that the partial exemption applies to commingled RACs as they move through the supply chain. Therefore, to the extent that the comment is suggesting that commingled RACs should continue to be exempt after they are shipped by the entity that performed the commingling, this is already part of the stated exemption.

We note that although farms and firms are not required to keep subpart S records for commingled RACs exempted under § 1.1305(h), maintaining traceability records as a best practice can be beneficial in the event that a traceback or recall is required.

(Comment 206) One comment requests that we clarify how the commingled RAC exemption will apply to eggs. The comment asks whether eggs from separate farms under different company management, commingled before packing, are eligible for the exemption. The comment also asks whether, if a processor uses eggs grown on his farm and mixes them with eggs from another farm that are exempted under this commingled RAC exemption, the exemption extends to the processor's mixed eggs.

(Response 206) In the preamble to the proposed rule (85 FR 59984 at 59997), we stated that we would consider commingled shell eggs to be eggs from separate farms under different company management that are physically mixed before packing, while packed eggs that are from a single farm or from separate farms under the same management would not be considered commingled shell eggs. Therefore, if a processor mixes eggs collected on her farm with eggs from another farm under different company management, and she does so before packing the eggs, the eggs so combined would be eligible for the exemption in § 1.1305(h). This is true regardless of whether the eggs from the other farm were already considered to be exempt under this provision.

Although we believe it is likely that most people would understand the phrase ''different farms'' to mean farms under different company management, because there are many different business models for farms, we believe the definition should provide greater clarity on the meaning of ''different farms.'' Therefore, the final rule's definition of ''commingled raw agricultural commodity'' specifies that a commodity is ''combined or mixed'' only when the combination or mixing involves food from different farms under different company management (except with respect to food obtained from a fishing vessel, as discussed in Response 208).

(Comment 207) One comment asks FDA to clarify situations under contract manufacturing with regard to egg production, specifically in-line production (when the henhouse and shell egg processing plant are on the same site) and off-line production (when a shell egg processing plant receives eggs from nearby farms). The comment states that the farms may be under the same ownership as the shell egg processing plant, or the shell egg processing plant may own the laying hens but not the land or the site. The comment maintains that if a farm is operating a shell egg processing plant, the records of contract farms must be sent to the immediate subsequent recipients (retail grocery store or food service company) of eggs, because the eggs in question will have ''originated'' on the contract farms, since the originator is where the eggs are harvested. The comment maintains that in the off-line setting, the shell egg processing plant would have to provide records to immediate subsequent recipients (customers). However, the comment does not believe that this information is relevant or needs to be passed along to the customers, because the processing plant will have those records.

(Response 207) As discussed above, when eggs from different farms under different company management are combined or mixed before they are processed, they are eligible for the partial exemption under § 1.1305(h). Therefore, in the off-line production systems described in the comment, if the eggs come from different farms under different company management and they are combined or mixed at the processing plant before they are processed, they would be eligible for the partial exemption. For the in-line production systems described in the comment, if the eggs being processed are all from the same farm, then they are not eligible for the partial exemption.

For eggs that are not subject to the partial exemption, the requirements of subpart S would apply. As described in Response 271, the final rule does not use the concept of ''origination'' that is

mentioned in the comment. Sections V.J and V.K of this document discuss how the revised KDEs apply to RACs such as eggs. We do not agree that sending traceability information through the supply chain is unnecessary in situations where the processing plant maintains the records. Traceback often begins at RFEs or restaurants, and it is important for those entities to have the relevant traceability records.

(Comment 208) Some comments suggest that the partial exemption for commingled RACs should apply to seafood. The comments maintain that commingling of seafood occurs at different stages after harvesting and before processing. The comments assert that the originating source may not be a farm but a landing source that might range from several docks to fishing vessels. The comments ask whether products produced by factory trawlers and at-sea processing vessels that harvest and process the fish will be eligible for the partial exemption.

(Response 208) The preamble to the proposed rule did not discuss application of the partial exemption for commingled RACs to commingled seafood, and we agree with the comments that we should provide clarity on this matter. We further agree that some seafood will be able to meet the definition of ''commingled raw agricultural commodity'' in this rule and will therefore be eligible for the partial exemption in § 1.1305(h). For seafood that is not obtained from a fishing vessel (*e.g.,* seafood that is farmed in an aquaculture operation), the application of the partial exemption would be similar to what is described above for eggs.

We conclude that we should modify the definition of ''commingled raw agricultural commodity'' as it applies to food obtained from a fishing vessel to reflect the unique circumstances of such food, including the fact that fishing vessels are partially exempt from the rule under § 1.1305(m). Therefore, we have revised the definition of ''commingled raw agricultural commodity'' to specify that for food obtained from a fishing vessel, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. We believe that the requirement that the combination or mixing involve food from different landing vessels and occur after the vessels have landed generally parallels the requirement that the combination or mixing of a RAC not obtained from a fishing vessel must involve food from different farms under different company management. Applying this revised definition of ''commingled raw agricultural commodity'' to the comment concerning products produced by factory trawlers and at-sea processing vessels, we note that the seafood would not be subject to the partial exemption for commingled RACs if the combination or mixing of the seafood occurs before the vessels have landed. We recognize that commingling of seafood often occurs on fishing vessels prior to landing. However, fishing vessels are exempt from subpart S under § 1.1305(m) and therefore are not required by this rule to keep records of any commingling or processing that occurs on the fishing vessel. Under this regulation, the chain of traceability records for food obtained from a fishing vessel does not begin until the vessel lands, as described in Section V.L of this document. Therefore, for food obtained from a fishing vessel, we have defined commingling to mean the combining or mixing of food from different landing vessels that occurs after the vessels have landed. See Response 385 for an explanation of how the first land-based processor of food obtained from a fishing vessel would record KDEs, such as the harvest date range and locations, in situations where the food was caught by different vessels and combined onto a single vessel before coming to land.

(Comment 209) One comment maintains that spices are consolidated/commingled at various steps in the supply chain before processing and therefore should be eligible for the partial exemption for commingled RACs.

(Response 209) ''Spices'' is a commodity that was considered in the Model but that did not receive a high-enough risk score to be included on the FTL; therefore, spices are not currently subject to the rule. If spices were to be added to the FTL in the future, any spices that met the definition of a commingled RAC would be eligible for the partial exemption. We note that herbs are distinct from spices, and herbs are explicitly covered by the produce safety regulation (see § 112.1(b)(1) (21 CFR 112.1(b)(1)). Therefore, herbs—such as fresh herbs, which are currently on the FTL—are not eligible for the partial exemption for commingled RACs.

(Comment 210) Some comments suggest that we establish a partial exemption for commingled RACs (other than fruits and vegetables that are subject to the produce safety regulation) such as grains and oilseeds that are not currently on the FTL but could be added to the list in the future.

(Response 210) We do not think it is necessary to adopt a specific exemption for grains, oilseeds, and other potentially commingled RACs that are not on the FTL but could be added to the FTL in a future update of the list. If a RAC not on the FTL is added to the FTL in the future, and if that RAC is not subject to the produce safety regulation, a mixture or combination of that RAC that met the definition of a commingled RAC would be eligible for the partial exemption at that time.

On our own initiative, we are revising the partial exemption for commingled RACs to extend it to RACs that that will become commingled RACs in the future, provided that there is a written agreement in place between the shipper and receiver of the RAC, as specified in § 1.1305(h)(2) of the final rule. We are making this revision to be consistent with changes we are making to proposed § 1.1305(d) to provide for an exemption for food that will be subjected to a kill step or that will be changed such that the food is no longer on the FTL (see Section V.E.5 of this document). As with food that will become exempt because a kill step will be applied, or because the food will be changed so that it is no longer an FTL food, we conclude that it is not necessary to apply the subpart S requirements to food that will become partially exempt as a commingled RAC, and we think that written agreements can be used to ensure that supply chain partners share the expectation that the RAC will be commingled before it is processed. Therefore, § 1.1305(h)(2)(i)–(ii) of the final rule provides that, except as specified in § 1.1305(h)(3), subpart S does not apply to a RAC that will become a commingled RAC provided that: there is a written agreement between the shipper of the RAC and the receiver stating that the receiver will include the commodity as part of a commingled RAC; or there is a written agreement between the shipper of the RAC and the receiver stating that an entity in the supply chain subsequent to the receiver will include the commodity as part of a commingled RAC and that the receiver will only ship the RAC to another entity that agrees, in writing, it will either include the RAC as part of a commingled RAC or enter into a similar written agreement with the subsequent receiver stating that the RAC will become part of a commingled RAC.

The written agreement must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement (§ 1.1305(h)(2)(iii)), and it must be maintained by both parties for as long as it is in effect and renewed at

least once every 3 years (§ 1.1305(h)(2)(iv)). As discussed in Response 196, we are providing flexibility for written agreements to be entered into in a variety of ways, depending on the business practices of the supply chain partners. The discussion in Response 196 regarding that flexibility in the context of § 1.1305(d)(3) also applies to written agreements under § 1.1305(h)(2).

Because the definition of commingled RAC only applies when the commodity is combined or mixed after harvesting but before processing, the partial exemption in § 1.1305(h)(2) is only available in situations where the RAC is moving through the supply chain without having yet been processed by anyone in the supply chain, and with the intent that it will be combined or mixed before being processed. Once that combining or mixing occurs, the partial exemption in § 1.1305(h)(1) applies.

We did not receive any comments on proposed § 1.1305(f)(2), which specified that with respect to a commingled RAC that receives the exemption in proposed § 1.1305(f)(1), if a person who manufactures, processes, packs, or holds such commingled RAC is required to register with FDA as a food facility with respect to activities concerning the applicable RAC, such person must maintain records (for 2 years) identifying the immediate previous source of such RAC and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345 of subpart J. This language, which is based on section 204(d)(6)(F) of FSMA, has been retained in the final rule as § 1.1305(h)(3). Because we have added the partial exemption for RACs that will become commingled RACs in § 1.1305(h)(2) of the final rule, we have expanded § 1.1305(h)(3) to specify that the requirement for registered facilities to record the immediate previous source and immediate subsequent recipient of the commingled RAC applies with respect to a commingled RAC that receives either of the exemptions in § 1.1305(h)(1) or (h)(2). This will ensure that when a RAC is exempt from the subpart S requirements either because it has already been commingled or because it will be commingled in the future, some amount of traceability records will still be available from entities that are required to register under subpart H.

10. Exemption for Small RFEs and Restaurants

In § 1.1305(g) of the proposed rule, we presented the option of adopting either a full exemption or a partial exemption from the proposed subpart S requirements for RFEs that employ 10 or fewer FTE employees. Option 1 would completely exempt from subpart S RFEs that employ 10 or fewer FTEs (the number of FTEs would be based on the number of such employees at each RFE and not the entire business). Option 2 would only exempt such RFEs from the requirement in proposed § 1.1455(b)(3) to make available to FDA under specified circumstances an electronic sortable spreadsheet containing the information required to be maintained under subpart S (for the foods and date ranges specified in FDA's request).

In response to comments, we are establishing a full exemption from subpart S for certain small RFEs, creating an exemption from the electronic sortable spreadsheet requirement for larger but still relatively small RFEs, and making several other changes regarding the proposed exemption for small RFEs, as discussed in the following paragraphs.

(Comment 211) Some comments voice support for Option 1 in proposed § 1.1305(g), which would provide a full exemption from the rule for RFEs with 10 or fewer FTEs. These comments maintain that requiring small RFEs to comply with the rule would be an undue burden, as many of these entities have few resources; that tracebacks rarely affect small retailers; that complying with the rule would be costly and infeasible for these entities; that there is no need for the regulation to apply to small retailers; and that small retailers in particular should receive a full exemption as many of them have been heavily affected by the COVID–19 pandemic. Some comments maintain that small convenience stores in particular should be eligible for this exemption because they would not be able to comply with the rule due to increased costs associated with equipment, maintenance, and labor.

On the other hand, some comments support Option 2, which would only exempt small RFEs from the sortable spreadsheet requirement in proposed § 1.1455(b)(3). These comments maintain that requirements for small RFEs to comply with the sortable spreadsheet requirements would be unduly burdensome and effectively require the use of electronic records in violation of section 204(d)(1)(C) and (E) of FSMA. In support of Option 2, some comments assert that this option provides the appropriate balance between maintaining a diverse market and achieving widespread adoption of traceability standards, and that small businesses still have the ability to impact public health, particularly in rural communities where they may be the sole source of food. These comments also suggest that compliance with the other subpart S requirements would not require too much effort for these entities, and that records besides the sortable spreadsheet would still be necessary if an outbreak is associated with a small retailer. Further, some comments suggest that with improvements in technology, there is the potential for large businesses to be run with fewer FTEs, which would make more firms eligible for the proposed exemption.

Some comments suggest that FDA consider another option, in which small RFEs would be required to provide to FDA, within 24 hours, records relating to the receipt of a product if they were unable to provide the traceability lot code for the product. The comments suggest that this option would limit the recordkeeping burden on small RFEs while still enabling FDA to readily access traceability information when needed.

(Response 211) We acknowledge that many small RFEs may have limited resources with which to comply with the FTL traceability recordkeeping requirements. In addition, and as stated in the preamble to the proposed rule (85 FR 59984 at 59997), we recognize that because smaller RFEs might handle a lesser volume of food than larger establishments, it is possible that requiring the smaller establishments to comply with subpart S would impose costs that would outweigh the benefits of such compliance. Moreover, because many of the foods sold at small RFEs are nationally distributed and are also sold at larger RFEs, we may be able to obtain relevant information about the source of a foodborne illness outbreak from a larger establishment that sold the same food using the same distributor.

However, we also recognize that in some cases, it might be helpful to traceback efforts for smaller RFEs to have traceability records in place, particularly if the establishments are associated with an outbreak. Keeping small RFEs within the scope of the rule but exempting them from the requirement to provide FDA with an electronic sortable spreadsheet containing requested traceability information would reduce their burden of complying with the subpart S requirements while still providing the Agency with access to tracing information when investigating foodborne illness outbreaks involving listed foods received by such RFEs.

We decline to adopt the approach suggested by comments that would allow small RFEs to provide, within 24 hours, records relating to receipt of a

product if they were unable to provide the traceability lot number for the product. We note that receiving records maintained by RFEs should already contain the traceability lot code, and commenters did not provide a reason why small RFEs might then be unable to provide that information upon request. Therefore, it is unclear why, if small RFEs would already have this information, it would not be appropriate to require them to make this information available to us. Moreover, having access to both the traceability lot code and the KDEs containing information on the food and its handlers is essential to conducting fast and efficient traceback operations. For these reasons, we decline to adopt the suggested alternative requirements.

Having carefully considered the comments regarding the proposed options for exemption of small RFEs, we conclude that it is appropriate to establish a full exemption for certain small RFEs and restaurants (in § 1.1305(i) of the final rule) and an exemption from the electronic sortable spreadsheet requirement for larger but still relatively small RFEs and restaurants (in § 1.1455(c)(3)(iii)(B)). The eligibility ceilings for these exemptions for small RFEs and restaurants are discussed in response to the comments below.

We note that while proposed § 1.1305(g) only mentioned RFEs, the exemptions in §§ 1.1305(i) and 1.1455(c)(3)(iii)(B) of the final rule refer to both RFEs and restaurants. As discussed in Section V.F of this document, we have removed restaurants from the definition of ''retail food establishment'' in the final rule, and we have instead added a separate definition for the term ''restaurant.'' Therefore, in places where the proposed rule only used the term RFE (which encompassed restaurants), we are now using the phrase ''RFEs and restaurants.''

(Comment 212) Some comments support basing the exemption for small RFEs on the number of FTEs, particularly if based, as proposed, on the number of FTEs at each establishment and not the entire business. Some comments request clarification on the methodology used to equate part-time employees to FTEs, while other comments ask that we define or provide a reference for the term ''full-time equivalent employee.'' Other comments assert that a ceiling of fewer than 10 FTEs would cover only a very small portion of the industry and would detract from RFEs focusing on food safety. These comments also suggest that the 10-FTE ceiling seems arbitrary when supply chains are similar across RFEs, regardless of how many FTEs they have. Some comments recommend raising the ceiling so that RFEs with more FTEs would be eligible for the proposed exemption, such as by using the Organization for Economic Cooperation and Development (OECD) ceiling for ''small business'' of fewer than 49 FTEs. Other comments suggest adopting an alternate standard for the RFE exemption, such as one that aligns with FDA's menu labeling regulation, which only covers restaurants and similar RFEs that are part of a chain with 20 or more locations (see 21 CFR 101.11(a)). These comments suggest that using this standard would be easier for industry to understand, as they should already be familiar with it. However, the comments maintain that labeling and food safety regulations may differ in approach and therefore might not be directly applicable to each other.

Some comments suggest other eligibility standards, such as those based on annual sales, volume of product sold, or how many customers an RFE serves. Some comments suggest that an income-based standard would be more appropriate than one based on number of FTEs, as new technologies and automation may reduce the number of employees needed. The comments also claim that use of an income-based standard is a good proxy for volume of food produced as well as an RFE's ability to comply with the rule. Some comments suggest adopting thresholds used elsewhere, such as those used in certain rules issued under FSMA that consider ''very small businesses'' to be those with less than $1 million in annual food sales, or an SBA standard (less than $7.5 million in annual receipts). However, some comments assert that the vast majority of retailers have receipts totaling less than $7.5 million, and that these retailers are responsible for greater than 40 percent of food sales.

Some comments suggest adding an income-based ceiling to the proposed threshold of fewer than 10 FTEs to keep the exemption narrow. Other comments suggest that all RFEs should be exempt; still others simply request that the exemptions for RFEs be size- and risk-appropriate.

(Response 212) We recognize that variation in revenues earned at any FTE level, due to differences in business practices, automation, and other factors, can make the number of FTEs a firm has an unreliable indicator of the true size and viability of the business. Further, the variation in revenues and production capacity at any FTE level make the number of FTEs an unreliable indicator of the public impact of a size-based exemption. We decline the suggestion of some comments that the small RFE eligibility standard be based on the number of customers served, as we believe that this too may not be an accurate indicator of the true size of the business. In addition, we believe that use of the standard from the menu labeling regulation is not appropriate for this rule because doing so would exempt a large portion of the food supply (likely over 99 percent of restaurants) and significantly affect FDA's ability to conduct a traceback in the event of an outbreak.

Having considered the suggestions provided in the comments, we conclude that it is appropriate to adopt an eligibility standard for small RFEs and restaurants that is based on the average annual monetary value of food sold or provided by the business. Annual sales are used in several other regulations issued under FSMA, and we consider them to be a valid indicator of a firm's available resources to comply with the rule as well as the volume of product contributed to the marketplace that could become contaminated. We include the value of food provided to capture food that may be provided as part of a service, but not specifically sold to a consumer. For example, the value of food provided may be included in the price of an overnight stay at a hospital or included in the price of membership of a club that serves food, but not specifically broken out in billing for those services.

Regarding the appropriate limit for annual sales for determining eligibility for exemptions for small RFEs and restaurants, we considered various options, including $100,000, $250,000, $500,000, and $1 million. We estimate that a $1 million threshold would cover 50 percent of RFEs and 6 percent of RFE sales; a $500,000 threshold would cover 36 percent of RFEs and 3 percent of RFE sales; a $250,000 threshold would cover 19 percent of RFEs and 1 percent of RFE sales; and a $100,000 threshold would cover 8 percent of RFEs and less than 1 percent of RFE sales. We do not believe a $500,000 or $1 million ceiling would be appropriate for a full exemption because they would exempt a significant portion of RFEs and restaurants from the requirements to keep records necessary to help ensure effective traceability of FTL foods, significantly affecting our ability to conduct fast, efficient, and thorough traceback investigations. For this same reason, we decline to adopt an eligibility ceiling of $7.5 million (as used in certain SBA regulations).

We conclude that a $250,000 ceiling for annual sales is appropriate for a full exemption for RFEs and restaurants

from the subpart S requirements, as it balances our need to be able to conduct effective traceback with providing relief for small entities that make up a small portion of total RFEs and restaurants. As discussed above, the value of food in the final rule includes the value of food provided to consumers (as well as the value of food sold), to capture the value of food that is provided as part of a service but not specifically sold to a consumer. Therefore, § 1.1305(i) of the final rule provides that subpart S does not apply to RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

However, while we conclude that it would not be appropriate to provide a full exemption to RFEs and restaurants with more than $250,000 in annual sales, we conclude that it would be appropriate to reduce the burden of the rule on establishments that are somewhat larger but still relatively small. Therefore, § 1.1455(c)(3)(iii)(B) of the final rule exempts RFEs and restaurants with food revenues of no more than $1 million from the requirement to provide to FDA in certain circumstances an electronic sortable spreadsheet containing requested traceability information. The electronic sortable spreadsheet requirement and the exemptions from this requirement are discussed in Section V.R of this document.

(Comment 213) Some comments maintain that the rule would overburden small cottage food producers, would be difficult for them to comply with, would cause businesses to close, and would hinder small businesses from starting up. Some comments contend that the rule will create particular difficulties for certain small cottage producers, such as bakers tracking ingredients like eggs. Some comments suggest that if FDA considers exemptions for small RFEs with fewer than 10 FTEs, the Agency should also consider an exemption for small cottage producers. Some comments state that they are very small businesses, some are single-person operations, and some make less than $20,000 per year in revenue. Some comments maintain that their small cottage businesses are already covered by State cottage business laws and that FDA should defer to these State regulations. One of these comments asserts that the burden of ensuring traceability should be on the supplier to keep records of the persons to whom they sell their food.

Some comments suggest that FDA reconsider the small business size thresholds for cottage food producers. Some comments suggest that small cottage producers should be exempt if they make less than $100,000 in annual revenue and are covered by their State cottage business laws; other comments maintain that the rule will be overly burdensome on any business making less than $50,000 in annual revenue.

Some comments assert that cottage food producers with short, local supply chains are not a food safety risk and are easy to trace, while large, conventional producers are the ones that pose a food safety risk. Some comments claim that baked goods are not risky.

(Response 213) FDA agrees with the importance of reducing the burden, where appropriate, on businesses that may have fewer resources to apply to complying with the requirements of the regulation, while minimizing the additional health risk caused by exposure to products that would otherwise be covered by the regulation. As discussed in Response 212, the final rule fully exempts small RFEs and restaurants making no more than $250,000 in annual sales (§ 1.1305(i)), and also exempts RFEs and restaurants with no more than $1 million in annual sales from the requirement to provide an electronic sortable spreadsheet containing traceability information FDA may request in certain circumstances (§ 1.1455(c)(3)(iii)(B)). Because most State cottage food programs set a ceiling for participation at no more than $50,000 in annual sales, we believe most cottage food producers will be fully exempt from this rule.

(Comment 214) Some comments request clarification on whether farms with fewer than 10 FTEs are eligible for the proposed exemption for RFEs in § 1.1305(g). The comments maintain that eligibility should be based on the nature of the supply chain, and that farms that sell directly to consumers but also through short, local supply chains should be exempt. Other comments assert that appropriate treatment of RFEs under subpart S is important for farms because many farms sell their produce to RFEs such as grocery stores.

(Response 214) Section 1.1310 of the final rule defines ''retail food establishment,'' in part, as an establishment that sells food products directly to consumers as its primary function. The definition further states that the term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. Sale of food directly to consumers can include sale of food by a farmer at a roadside stand, farmers' market, or CSA. In addition, the definition states that a ''retail food establishment'' includes certain farm-operated businesses selling food directly to consumers as their primary function, with ''farm-operated business'' meaning a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s). If a farm meets the definition of ''retail food establishment'' in § 1.1310 and meets the criteria for an exemption for RFEs in § 1.1305(i) or § 1.1455(c)(3)(iii)(B), it would be eligible for such exemption. Moreover, as previously discussed, under § 1.1305(b) of the final rule, the subpart S requirements do not apply to a farm with respect to food produced on the farm that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.

(Comment 215) One comment asserts that restaurants and RFEs that only receive food should not have to maintain traceability records. The comment claims that logistics is not a core business function of restaurants or RFEs and that those businesses are not equipped to scan or manually enter data for each delivery. The comment maintains that including these entities in the final rule would result in significant cost, training, and equipment needs.

(Response 215) We do not agree. RFEs and restaurants are often our first point of contact in an outbreak, recall, or other situation requiring fast, efficient traceback. They frequently serve as the first point in the supply chain to provide the traceability information needed by FDA investigators to launch a traceback investigation. Having traceability records at these establishments linking the food they sell to the previous link in the supply chain and ultimately the source of the food is necessary for effective traceback and the protection of public health (Ref. 25). However, as previously stated, we recognize the importance of reducing the burden of the rule, where appropriate, on businesses that may have fewer resources to apply to complying with the rule, while minimizing the additional health risk caused by exposure to products that would otherwise be covered by the regulation. Consequently, as discussed above, the final rule includes several full or partial exemptions from the rule for certain restaurants and RFEs.

(Comment 216) Some comments suggest that the Agency incorporate

additional flexibilities into the rule specifically for the airline catering industry. The comments suggest that one way of doing so would be to amend the definitions of ''retail food establishment'' and ''shipping'' to state that airline caterers are considered RFEs and specify that they do not engage in shipping when they send foods to airline customers for consumption by passengers. Alternatively, the comments suggest that we add a partial exemption to the rule specifying that entities that prepare foods for airlines that are intended for immediate consumption by passengers would not have to maintain transformation, creation, or shipping KDEs, but would only be required to maintain receiving KDEs and traceability program records.

(Response 216) We decline to redefine ''retail food establishment'' to include airline caterers. As previously stated, we proposed to define ''retail food establishment'' as it is defined in the food facility registration regulation (§ 1.227 (21 CFR 1.227)), *i.e.,* an establishment whose primary function is to sell food products directly to consumers from that establishment. Most airline caterers prepare meals and other foods for sale to airlines, rather than directly to consumers. Because airline caterers generally are not RFEs but manufacturers/processors subject to the regulations on preventive controls for human food in part 117, we find no basis for regarding them as RFEs for purposes of the subpart S traceability recordkeeping requirements. For this reason, we also conclude that it would not be appropriate to provide that airline caterers do not engage in ''shipping'' as defined in the rule when they send foods to airlines for consumption by passengers. As discussed in Section V.E of this document, the definition of ''shipping'' states, in part, that shipping does not include the sale or shipment of a food directly to a consumer; however, most airline caterers do not sell food directly to consumers. To the extent an airline caterer meets the definition of an RFE, the traceability recordkeeping requirements for an RFE will apply. Some airline caterers might be eligible for the exemption (discussed in Section V.R.3 of this document) under which entities other than farms, RFEs, or restaurants with no more than $1 million in annual sales would not be required to provide to FDA, under certain circumstances, an electronic sortable spreadsheet containing requested traceability information (§ 1.455(c)(3)(iii)(C)).

(Comment 217) Some comments ask FDA to clarify that RFEs need only keep invoices/receipts, not full traceability logs, to document receipt of FTL foods. The comments assert that it would be an unrealistic and unnecessary burden for small RFEs to keep copies or records establishing where FTL foods were purchased for 180 days.

(Response 217) As discussed in Response 211, the final rule exempts small RFEs and restaurants from the subpart S requirements. With respect to larger RFEs and restaurants that are not exempt from the rule, the rule does not require firms to maintain a ''traceability log'' for their handling of FTL foods. Instead, firms will need to establish and maintain a traceability plan in accordance with § 1.1315, and they will need to keep certain KDEs associated with CTEs, which in the case of RFEs and restaurants generally will be the KDEs associated with receiving in § 1.1345. As with other types of supply chain entities subject to the rule, we anticipate that RFEs and restaurants will be able to rely on records they already use to meet most of their requirements under subpart S. In addition, as discussed in Section V.N of this document, almost all of the receiving KDEs that RFEs and restaurants are required to maintain under § 1.1345 are KDEs that their suppliers will be required to send them under § 1.1340(b).

In general, all subpart S records must be maintained for 2 years (see § 1.1455(d)). However, as discussed below, when an RFE or restaurant purchases food directly from the farm where it was produced, they are only required to maintain a record documenting the name and address of the farm that was the source of the food, and they must maintain that record for only 180 days.

11. Partial Exemption for RFEs and Restaurants Purchasing Food Directly From a Farm

In addition to the full or partial exemption for small RFEs in proposed § 1.1305(g), in accordance with section 204(d)(6)(G) of FSMA, we proposed to adopt a partial exemption from the subpart S requirements for all RFEs when they receive FTL foods directly from a farm. Proposed § 1.1305(h)(1) provided that subpart S would not apply to an RFE with respect to foods on the FTL that are produced on a farm (including foods produced and packaged on the farm) and sold directly to the RFE by the owner, operator, or agent in charge of that farm, except as specified in proposed § 1.1305(h)(2). Under proposed § 1.1305(h)(2), when an RFE purchased an FTL food directly from the owner, operator, or agent in charge of a farm, the RFE would be required to establish and maintain a record documenting the name and address of the farm that was the source of the food. Consistent with section 204(d)(6)(G) of FSMA, RFEs would be required to maintain these farm identification records for 180 days.

Although section 204(d)(6)(G) of FSMA specifies that this limited tracing requirement to document the farm that was the source of the food applies to grocery stores, we proposed to broaden the application of this partial exemption to include all RFEs purchasing food directly from farms.

(Comment 218) Some comments ask whether the partial exemption for RFEs purchasing directly from a farm would include food that first goes through a broker, warehouse, or distribution center that is part of the RFE's network. Some comments maintain that the partial exemption should apply to food purchased by a broker if the food is shipped directly from the farm to the RFE. Some comments assert that the exemption should apply to food shipped directly from the farm to the RFE even when the purchasing entity is the RFE's parent company.

(Response 218) We do not agree with the comments. The intent of the partial exemption is to reduce the number of records required for direct sales of FTL foods from farms to RFEs or restaurants, for which the supply chain is extremely simple, covering a single transaction. This direct connection between a farm and an RFE or restaurant is not present when: (1) an FTL food is shipped to a broker, warehouse, or distribution center before being sent to the RFE, even if such entity is in the same corporate structure as the RFE; or (2) a broker or the RFE's parent company buys the food and arranges for its shipment from the farm to the RFE. Therefore, the exemption does not apply to food purchased by a broker or parent company even if the food is shipped directly from a farm to an RFE or restaurant, even if no third party ever takes physical possession of the food. Similarly, the exemption does not apply to food that is not shipped directly from the farm growing the food to the RFE making the purchase, *e.g.,* food that goes through a broker, a warehouse, or a distribution center, even if these entities are part of the parent company. To make this clear, § 1.1305(j)(1) of the final rule states that except as specified in § 1.1305(j)(2), subpart S does not apply to an RFE or restaurant with respect to a food that is produced on a farm (including food produced and packaged on the farm) and is both sold and shipped directly to the RFE or restaurant by the owner, operator, or

agent in charge of that farm. Section 1.1305(j)(2) provides that when an RFE or restaurant purchases a food directly from a farm in accordance with § 1.1305(j)(1), the RFE or restaurant must maintain a record documenting the name and address of the farm that was the source of the food. Section 1.1305(j)(2) further specifies that the RFE or restaurant must maintain such a record for 180 days, as we had proposed. Throughout § 1.1305(j), and consistent with the rest of the final rule as discussed in Response 285, we refer to both RFEs and restaurants, as opposed to using RFE as an umbrella term that encompasses restaurants, as was done in the proposed rule.

(Comment 219) Some comments request clarification on whether the partial exemption for RFEs that receive FTL foods directly from a farm includes e-commerce sales.

(Response 219) The partial exemption in § 1.1305(j) applies any time food is produced on a farm and then sold and shipped directly to an RFE or restaurant by the owner, operator, or agent in charge of that farm. Whether or not the sale was made online is not relevant as long as the conditions of § 1.1305(j) are met. For example, when a farm sells its food directly to an RFE through the farm's website, the RFE could be eligible for the exemption as long as they bought the food directly from the farm (through the farm's website) and the food was shipped directly to the RFE by the farm.

(Comment 220) Some comments suggest that in addition to requiring RFEs under the partial exemption to maintain the name and address of the farm that sold the food, the RFEs should be required to maintain the lot code and harvest or pack date associated with the food, because the comments assert that this information is the most important to have for traceability purposes.

(Response 220) We decline to make this change because section 204(d)(6)(G) of FSMA requires that if food is sold directly from a farm to a grocery store, the grocery store must not be required to maintain records other than those documenting the farm that was the source of the food. (As previously discussed, we have broadened this partial exemption to apply to all RFEs and restaurants.)

(Comment 221) Some comments request that we expand this partial exemption so that it would also apply to RFEs that purchase wild-caught American shrimp directly from local processors. The comments also suggest that the processors themselves be eligible for the partial exemption.

(Response 221) We decline to make this change. We conclude that it would not be appropriate to expand the partial exemption for RFEs and restaurants purchasing food directly from a farm to apply to RFEs and restaurants that receive food from entities other than farms, such as shrimp processors, or to such other entities themselves. The intent of the partial exemption is to reduce the number of records required when FTL foods are sold and shipped directly from the producing farms to an RFE or restaurant. In such a situation, the supply chain is extremely simple, covering a single transaction. This direct connection between a farm and an RFE or restaurant is not present when the food moves through a processor.

12. Partial Exemption for RFEs and Restaurants Making Certain Purchases From Another RFE or Restaurant

In response to comments expressing concerns about application of the subpart S requirements to certain purchases of food by RFEs from other RFEs, we are adopting a partial exemption as discussed in the following paragraphs.

(Comment 222) Some comments ask that we clarify what RFEs should do if they purchase a listed food from a grocery store or another RFE that does not provide the KDEs required under the proposed rule. One comment asks whether RFEs will be considered to be in compliance with the rule if they keep receipts or invoices for these purchases. Some comments maintain that there is no batch level data available for RFEs that make ''cash and carry'' purchases from other RFEs.

(Response 222) Under the final rule, RFEs and restaurants that receive food (under the definition of ''receiving'' in § 1.1310) are required to keep receiving records under § 1.1345 unless they are exempt. However, we recognize that RFEs, and particularly restaurants, may purchase foods on the FTL on an ad hoc basis to meet immediate operational needs when they run out of an item purchased from a regular supplier. We recognize that it might not be feasible for RFEs or restaurants to keep the full ''receiving'' records of such purchases in accordance with § 1.1345 of the final rule (see Section V.N of this document). It also might not be feasible for the RFE or restaurant that makes the sale to keep and send shipping records under § 1.1340, especially if the sale happens under circumstances where it may seem like the purchaser is a consumer. Therefore, § 1.1305(k)(1) of the final rule provides that, except as specified in § 1.1305(k)(2), subpart S does not apply to either entity when a purchase is made by an RFE or restaurant from another RFE or restaurant, when the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice (*e.g.,* not pursuant to a contractual agreement to purchase food from the seller).

Instead of the receiving KDEs required under § 1.1345, when an RFE or restaurant purchases an FTL food on an ad hoc basis from another RFE or restaurant in accordance with § 1.1305(k)(1), the RFE or restaurant that makes the purchase must maintain a record (such as a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase (§ 1.1305(k)(2)).

We conclude that, in these circumstances, this information would be adequate to enable us to conduct an effective traceback of such a product. As with other subpart S recordkeeping requirements, RFEs and restaurants may keep the required information on such purchases in any records they choose, including paper receipts.

This partial exemption in § 1.1305(k) does not exempt RFEs and restaurants from the subpart S requirements when an RFE or restaurant purchases food from another RFE or restaurant as part of the buyer's usual purchasing practice, as opposed to on an ad hoc basis. For an ad hoc purchase of the sort that would be eligible for this partial exemption, the purchase is generally made through the means utilized by consumers (*e.g.,* through a check-out line), under circumstances where the selling RFE or restaurant might assume that the purchaser is a consumer. When a contractual relationship exists in which one RFE or restaurant serves as a regular commercial supplier for another RFE or restaurant, such purchases would be outside the scope of the partial exemption in § 1.1305(k).

13. Partial Exemption for Farm to School and Farm to Institution Programs

Having consulted with USDA in accordance with section 204(d)(6)(A) of FSMA, we proposed to establish a partial exemption from the subpart S requirements for farm to school and farm to institution programs operated under the auspices of the USDA, State agencies, or local jurisdictions. Proposed § 1.1305(i)(1) would have provided that, except as specified in proposed § 1.1305(i)(2), the subpart S requirements would not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act (Pub. L. 116–94) or Section 4 of the Child Nutrition Act of 1966 (Pub. L. 111–296), or any other entity conducting a farm to school or farm to institution program, with respect to a

food that is produced on a farm (including food produced and packaged on the farm) and sold directly to the school or institution. Under proposed § 1.1305(i)(2), when a school or institution conducting farm to school or farm to institution activities purchases a food directly from a farm in accordance with (i)(1), the school food authority or relevant food procurement entity must establish and maintain a record documenting the name and address of the farm that was the source of the food. Proposed § 1.1305(i)(2) specified that the school food authority or relevant food procurement entity must maintain such records for 180 days, the same retention period that we proposed for records maintained under the partial exemption for RFEs purchasing food directly from a farm in proposed § 1.1305(h).

(Comment 223) Some comments support the partial exemption for entities conducting farm to school or farm to institution programs. Other comments oppose the exemption, maintaining that the exemption would not be protective of public health because these programs move large volumes of food to vulnerable populations. The comments provide examples of food banks that hand out food in parking lots or community centers that they maintain are not designed to allow for safe handling and storage of food.

(Response 223) As discussed in the preamble to the proposed rule, having consulted with the USDA in accordance with section 204(d)(6)(A) of FSMA, we believe it is appropriate to adopt this partial exemption from the subpart S requirements for farm to school and farm to institution programs, to avoid placing undue burdens on these programs. While we disagree with comments suggesting that the partial exemption for farm to school and farm to institution programs is inappropriate, we recognize the potential that food supplied through such programs can play a role in foodborne illness. It is because of this that, rather than fully exempt such programs from the rule, we have established a partial exemption for such programs. Section 1.1305(l)(1) of the final rule states that, except as specified in § 1.1305(l)(2), subpart S does not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution. Under § 1.1305(l)(2), when a school or institution conducting a farm to school or farm to institution program obtains a food from a farm in accordance with § 1.1305(l)(1), the school food authority or relevant food procurement entity must maintain a record (for 180 days) documenting the name and address of the farm that was the source of the food. We believe this partial exemption adequately protects public health while not placing undue burden on such programs, in accordance with section 204(d)(6)(A) of FSMA.

(Comment 224) Some comments recommend expanding the partial exemption in proposed § 1.1305(i) to include food that is donated by a farm to a school or institution. Other comments ask whether the proposed exemption would include food that is sold to schools or institutions through distributors. Other comments suggest that food hubs and other aggregators who work with small farms are a vital link in the farm to institution supply chain, often working with very small farms to aggregate their product into large enough quantities to meet the needs of large institutional kitchens, and should also be exempt; these comments maintain that if the food hubs or aggregators are required to comply, their recordkeeping burden will essentially force the small farms to comply with the requirements as well. Others suggest that if food hubs are required to comply with the proposed requirements, they may cease providing products on the FTL to avoid recordkeeping required by the rule.

(Response 224) We recognize that farm to school and farm to institution programs may receive food through a variety of means, including via sales or donations, and that this food may be received by such institutions either directly or indirectly (*e.g.,* through entities such as brokers, buyers, or school procurement entities). Accordingly, we have revised the partial exemption to specify, in § 1.1305(l)(1), that it applies when food is sold ''or donated'' to a school or institution, and that it does not require that a food be sold ''directly'' from a farm to a school or institution, as had been stated in the proposed rule. To align with this change, we have revised the partial exemption to state, in § 1.1305(l)(2), that a school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food when a school or institution conducting a farm to school or farm to institution program ''obtains a food'' (rather than ''purchases a food directly'') from a farm in accordance with § 1.1305(l)(1).

14. Partial Exemption for Food Obtained from Fishing Vessels

In accordance with section 204(d)(6)(C) of FSMA, we proposed to adopt a partial exemption from the proposed traceability recordkeeping requirements for fishing vessels. Proposed § 1.1305(j)(1) provided that, except as specified in proposed § 1.1305(j)(2), with respect to a food produced through the use of a fishing vessel, subpart S would not apply to the owner, operator, or agent in charge of the fishing vessel. In accordance with section 204(d)(6)(C) of FSMA, we proposed to define ''fishing vessel'' as that term is defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)), *i.e.,* as any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for: (1) fishing or (2) aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing (proposed § 1.1310). Under this partial exemption, activities of fishing vessels such as harvesting, transporting, heading, eviscerating, and freezing fish generally would not be subject to the proposed recordkeeping requirements.

Under the proposed exemption, the owner, operator, or agent in charge of a fishing vessel also would not have to keep tracing records on the sale and shipment of food produced through the use of the vessel, except as provided in proposed § 1.1305(j)(2). In the preamble to the proposed rule, we stated that section 204(d)(6)(C) of FSMA somewhat ambiguously states that the section 204(d) requirements applicable to fishing vessels would be limited to certain requirements for vessels that are required to register with FDA ''until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.'' We stated that although the phrase ''until such time'' could be interpreted as meaning that the owner, operator, or agent in charge of the fishing vessel could be subject to requirements relating to the sale of the relevant food, we believed it was appropriate to exempt the owner, operator, or agent in charge of the fishing vessel from all requirements relating to the relevant food (except as specified in proposed § 1.1305(j)(2)).

In accordance with section 204(d)(6)(C) and (F) of FSMA, proposed § 1.1305(j)(2) specified that if the

owner, operator, or agent in charge of the fishing vessel who receives the exemption in proposed § 1.1305(j)(1) is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the applicable food, in accordance with the requirements of subpart H, that person would be required to maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. This means that fishing vessels that must register with FDA because they process fish on the vessel would be required to comply with the existing subpart J traceability recordkeeping requirements in §§ 1.337 and 1.345, even though many such fishing vessels are currently exempt from those requirements under § 1.327(c) (21 CFR 1.327(c)). Affected fishing vessels would be required to maintain such records for 2 years.

We have made clarifying changes to this partial exemption, as discussed in the following paragraphs.

(Comment 225) Some comments assert that owners, operators, and agents of fishing vessels should not be exempt from the rule. The comments maintain that these entities are best placed to maintain accurate records of the relevant KDEs, that these entities might already be required to keep such records under national/regional catch documentation schemes, and that excluding them risks having inaccurate data later in the supply chain. One comment contends that the exemption would allow unsafe and illegal seafood to enter the supply chain because as supply moves between vessels there is opportunity for laundering of unsafe and illegal catches.

(Response 225) Section 204(d)(6)(C) of FSMA states that with respect to a food that is produced through the use of a fishing vessel, the recordkeeping requirements under this rulemaking shall, until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel, be limited to the requirement that entities who register with FDA under subpart H must maintain records identifying the immediate previous source and the immediate subsequent recipient of such food. As discussed in the preamble to the proposed rule (85 FR 59984 at 59999), we therefore believe it is appropriate to exempt the owner, operator, or agent in charge of the fishing vessel from all requirements relating to the relevant food, except for the requirement to keep certain one-up, one-back records. Section 1.1305(m)(1) of the final rule therefore states that with respect to a food that is obtained from a fishing vessel, subpart S does not apply to the owner, operator, or agent in charge of the fishing vessel, except as specified in § 1.1305(m)(2). Section 1.1305(m)(1) further states that, except as specified in § 1.1305(m)(2), subpart S does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel. This language is meant to clarify the application of the partial exemption in situations where the food is still owned by the owner, operator, or agent in charge of the fishing vessel, but it is being handled by a different entity.

Section 1.1305(m)(2) provides that, with respect to any person who receives the partial exemption in § 1.1305(m)(1), if such person is required to register with FDA under section 415 of the FD&C Act, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years. We note that the proposed rule used both the phrase, ''food obtained from a fishing vessel,'' and the phrase, ''food produced through a fishing vessel.'' In the final rule, for uniformity and clarity, we use only the phrase, ''food obtained from a fishing vessel.''

We believe that the records that the first land-based receiver of an FTL food obtained from a fishing vessel must keep under § 1.1335 of the final rule (discussed in Section V.L of this document) should help ensure adequate traceability of food obtained from fishing vessels. In situations where the first land-based receiver is partially exempt from subpart S under § 1.1305(m), we believe that any records required to be kept under § 1.1305(m)(2), in combination with the records that the first non-exempt receiver will be required to maintain under § 1.1345(b), should help ensure adequate traceability of the food.

Regarding the comment about laundering of unsafe and illegal catches, we agree that this is an important concern, but it is outside the scope of this rulemaking, especially in light of the partial exemption Congress required us to provide for fishing vessels. However, fishing vessels must comply with all of the laws and regulations that apply to them, including any laws and regulations aimed at combating such practices.

(Comment 226) One comment supports the proposed partial exemption for fishing vessels and regards the proposed rule's interpretation of section 204(d)(6)(C) of FSMA to be reasonable and consistent with Congressional intent. Some comments state that although fishing vessels that are not required to register with FDA would be fully exempt, they ask that we adopt an exemption for food sold directly to consumers from fishing vessels, including food sold by fishermen who are specifically licensed to sell their own catch directly to consumers by a ''fresh product license'' or other authority, mirroring the exemption in proposed § 1.1305(b) for farms that sell food directly to consumers, suggesting that section 204(d)(6)(E) of FSMA gives us the authority to exempt entities when application of the subpart S requirements is not necessary to protect the public health.

(Response 226) We appreciate the support for the proposed partial exemption for fishing vessels as being consistent with Congressional intent. We do not think the proposed modification to § 1.1305(b) is necessary. As drafted, § 1.1305(b) exempts farms with respect to food they produce that they sell directly to the consumer. Without this exemption, farms may otherwise be required to keep various subpart S records relating to such food, such as records relating to the harvesting of the food. In contrast, under § 1.1305(m)(1), the owner, operator, or agent in charge of a fishing vessel is already exempt from the subpart S requirements. An additional exemption for this specific circumstance is therefore unnecessary. While it is true that some owners, operators, or agents in charge of fishing vessels may be required to keep records identifying the immediate subsequent recipient of a food in accordance with § 1.345 (see § 1.1305(m)(2)), we note that § 1.345 does not apply to persons who distribute food directly to consumers (see § 1.327). Therefore, even without a modification of § 1.1305(b), it is already the case that under subpart S the owner, operator, or agent in charge of a fishing vessel is not required to keep any records with respect to food obtained from a fishing vessel that such person sells or donates directly to a consumer.

(Comment 227) Some comments state that FDA should treat wild and farmed shellfish production the same. The comments maintain that many individuals participate in both sectors and would be confused by the different requirements. The comments also maintain that most dealers also purchase both wild and farmed shellfish. One comment states that the

rule should regulate shellfish harvesters and shellfish farmers the same as it regulates fishing vessels (*i.e.,* partially exempt).

(Response 227) We note that qualifying raw bivalve molluscan shellfish are exempt from the requirements of the final rule as discussed in Response 200. The exemption applies to both wild-caught and aquacultured raw bivalve molluscan shellfish.

Regarding other shellfish, we are unable to impose the requirements that apply to farmed shellfish on fishing vessels that harvest shellfish because, as discussed in Response 225, Congress required us to create a partial exemption for the owners, operators, and agents in charge of fishing vessels (see section 204(d)(6)(C) of FSMA). And we decline to extend this partial exemption for owners, operators, or agents in charge of fishing vessels to farmed shellfish because, as discussed in Response 97, we think that coverage of farms is important to effective traceability. We acknowledge that an entity that receives both food produced on farms and food obtained from fishing vessels will have to identify as either an initial packer (for food produced on farms) or first land-based receiver (for food obtained from a fishing vessel) for the relevant transactions and comply with the applicable recordkeeping requirements. But we note that although the requirements for initial packer and first land-based receiver are different, the requirements through the rest of the supply chain for food from either type of entity are the same.

(Comment 228) One comment asserts that there should be no new records required for wild-caught domestic shrimp vessels as many of these vessels already must register with FDA as food facilities and keep one-up, one-back traceability records under subpart J.

(Response 228) To the extent that vessels engaged in catching shrimp are ''fishing vessels'' as defined in § 1.1310, they will not be subject to any subpart S requirements unless they are registered food facilities, in which case they would be required to maintain records identifying the immediate previous source and immediate subsequent recipient of the shrimp they catch in accordance with §§ 1.337 and 1.345 of subpart J (see § 1.1305(m), as further explained in Response 225). If the vessel is already keeping subpart J records, those records can be used to comply with § 1.1305(m)(2). As stated in § 1.1455(f), an entity does not need to duplicate existing records that it has if they contain the information required under subpart S.

(Comment 229) One comment asserts that the requirements for first receivers (under proposed § 1.1330) could be read as functionally nullifying the proposed exemption for fishing vessels. The comment suggests that to avoid this, the rule must not require that a traceability lot code be associated with fishing events by fishers, but the first receiver of such food from a fisher might need to assign a traceability lot code. The comment maintains that the GDST standards encourage the assignment of lot codes to fishing events by fishers, but the ISSC's implementation guidelines recognize that this might not be possible for at least several years. Therefore, the comment suggests that FDA encourage lot code assignment at the vessel level as a best practice.

(Response 229) For clarity we have changed the name of the ''first receiver'' of food obtained from a fishing vessel to the ''first land-based receiver,'' which we have defined to mean the person taking possession of a food for the first time on land directly from a fishing vessel (§ 1.1310). Section 1.1335 sets forth the records that a person must keep if they are the first land-based receiver. These requirements have been modified from what the proposed rule would have required for first receivers of food obtained from fishing vessels, and are limited to information that a person would reasonably be expected to know based on information that is likely provided during the normal course of business. The fishing vessel is not expected to provide a traceability lot code; the traceability lot code would be assigned by the first land-based receiver in accordance with § 1.1320(a). If the first land-based receiver is exempt, the traceability lot code would be assigned by the first non-exempt receiver of the food in accordance with § 1.1345(b)(1) (unless that entity is an RFE or restaurant).

(Comment 230) Some comments ask whether the definition of fishing vessel includes boat tenders that catch and offload fish to another fishing vessel. Specifically, the comments ask whether the definition includes tender vessels, carrier vessels, or mother ships. One comment maintains that boat tenders are used in many seafood harvest situations and are an extension of the fishing vessel that is exempt under the proposed rule. The comment also asks FDA to clarify whether the proposed definition of ''first receiver'' includes ''over the dock transfers.''

(Response 230) Any vessel that meets the definition of ''fishing vessel'' in § 1.1310 is subject to the partial exemption in § 1.1305(m). In situations where a tender vessel catches fish and offloads the fish to a carrier vessel or mother ship, all of the vessels involved in the transaction would be partially exempt under § 1.1305(m), as long as they meet the definition of a ''fishing vessel.'' Regarding the comment that asks us to clarify the definition of ''first receiver'' in relation to ''over the dock transfers,'' as discussed in Response 385, the final rule omits the proposed first receiver requirements and includes requirements for the first land-based receiver of food obtained from a fishing vessel. It is unclear what ''over the dock transfer'' means in the context of the subpart S requirements. If a transfer takes place between two fishing vessels, then each fishing vessel would be eligible for the partial exemption in § 1.1305(m), meaning the only records they might be required to keep would be the records described in § 1.1305(m)(2), if applicable. However, if ''over the dock transfer'' refers to a transfer and sale from the owner, operator, or agent in charge of a fishing vessel to a separate land-based entity, then the land-based entity would be the first land-based receiver of the food and would have to keep the records required under § 1.1335.

15. Exemption for Transporters

We proposed to exempt transporters of food from the proposed traceability recordkeeping requirements (proposed § 1.1305(k)). We proposed to define a ''transporter'' as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air (proposed § 1.1310).

(Comment 231) Some comments assert that the proposal to exempt transporters is contrary to language in section 204(d) of FSMA, suggesting that a person who has ''possession, custody, or control'' of food (under the proposed definition of ''transporter'') would also be a person who ''holds'' the food under the statute. Other comments maintain that transporters should not be exempt because although they present a lower risk of contamination, information on when and how food is transported is still important to have. These comments suggest that including transporters in the rule would create added benefits and would facilitate outbreak investigations. Some comments suggest that the Agency should acknowledge that food may become contaminated during transport, referencing the recordkeeping requirements already in place under the sanitary transportation regulation (part 1, subpart O). Some comments request that transporters be exempt from the final rule because they believe that information from

transporters is not necessary for traceability purposes. The comments state that transporters are subject to subpart J, so if certain foods are exempt from this rule, transporters would still have to maintain subpart J records for those foods. Some comments request clarification of requirements for transporters in fish supply chains.

(Response 231) We acknowledge that food can become contaminated during transportation, which is why in the final rule on ''Sanitary Transportation of Human and Animal Food'' (81 FR 20092) we established requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. As the comments state, the sanitary transportation regulation includes recordkeeping requirements for certain entities subject to the regulation, though we note that these recordkeeping requirements focus on ensuring the use of sanitary practices during transportation, not on traceability.

As discussed in the preamble to the proposed rule (85 FR 59984 at 59999), we believe that transporters should be exempt from the subpart S requirements because we find that in most of our investigations of potential foodborne illness outbreaks, it is not necessary to inspect records maintained by food transporters because we generally are able to obtain the tracing information we need from other persons in the food's supply chain. Thus, the final rule maintains this exemption for transporters of food (§ 1.1305(n)). Additionally, we have removed from the final rule the proposed requirements that (1) persons who receive listed foods keep a record of the name of the transporter who delivered the food (proposed § 1.1335(h)) and (2) persons who ship listed foods keep a record of the name of the transporter who transported the food from the shipper (proposed § 1.1350(a)(8)), as discussed in Section V.M of this document.

If necessary, we could review records maintained by transporters of the food in the usual course of business or, when applicable, in accordance with the subpart J regulations. We note that in many cases, the shipper or receiver will have this information as a result of the subpart J requirements.

Regarding the comments suggesting that the proposed exemption for transporters is contrary to the language in the statute, the proposed rule included several full and partial exemptions from the subpart S requirements, including some specified by Congress and some we proposed on our own initiative, including the exemption for transporters. It is within our rulemaking authority to create exemptions beyond what Congress specified. For the reasons stated above, we conclude that exempting transporters is an appropriate exercise of our authority to implement section 204(d) of FSMA.

16. Exemption for Nonprofit Food Establishments

We proposed in § 1.1305(l) that subpart S would not apply to nonprofit food establishments, consistent with their exclusion from the subpart J regulations (see § 1.327(l)). We proposed to define a nonprofit food establishment as in subpart J (§ 1.328 (21 CFR 1.328)), *i.e.,* as a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States (proposed § 1.1310). The definition further stated that the term ''nonprofit food establishment'' includes central food banks, soup kitchens, and nonprofit food delivery services. In addition, to be considered a nonprofit food establishment, we proposed that the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Although we received comments concerned that the definition of ''nonprofit food establishment'' used for this exemption was not broad enough, we are finalizing the exemption as proposed, for the reasons stated below.

(Comment 232) Some comments support the proposed exemption for nonprofit food establishments. Some comments suggest that FDA exempt other nonprofits aside from those that meet the terms of section 501(c)(3) of the Internal Revenue Code, such as food hubs and businesses with section 501(c)(4), (c)(5), or (c)(6) status. The comments maintain that numerous nonprofit food hubs and businesses are organized under other nonprofit statuses and consequently should also be exempt under the final rule. Some comments assert that the language in FSMA means that the rule should only apply to facilities, and that therefore FDA should exempt all nonprofit food establishments in which food is prepared for or served directly to the consumer.

(Response 232) As discussed in the preamble to the proposed rule (85 FR 59984 at 59999), and as finalized in § 1.1305(o), we are exempting nonprofit food establishments from the rule consistent with their exclusion from the subpart J regulation. The definition of ''nonprofit food establishment'' that we proposed and are adopting in § 1.1310 of the final rule is consistent with the definitions used in subpart J (§ 1.328) and the facility registration regulation (§ 1.227), both of which are limited to establishments that meet the terms of 26 U.S.C. 501(c)(3). It is not readily apparent from the comments which entities covered under this rulemaking have section 501(c)(4), (c)(5), or (c)(6) status. Moreover, we are not aware of any particular challenges regarding compliance with subpart S that are faced by entities with section 501(c)(4), (c)(5), or (c)(6) status. Therefore, we conclude that it is not necessary to revise the definition of nonprofit food establishment for the purposes of the subpart S requirements.

However, we note that the rule includes procedures for requesting a waiver of one or more of the subpart S requirements for an individual entity or a type of entity on the grounds that having to meet the requirements would result in an economic hardship, due to the unique circumstances of the individual entity or type of entity (see §§ 1.1405 through 1.1450, as discussed in Section V.Q of this document). Establishments with status under a different section of section 501(c) might wish to submit a request for a waiver if they believe that application of the subpart S requirements to them would result in an unusual economic hardship, and that the conditions set forth in § 1.1405 are met.

As discussed in Response 154, we do not agree that Congress's use of the word ''facility'' prevents subpart S from applying to entities that provide food to consumers.

(Comment 233) One comment requests clarification on whether shippers who supply food to exempt nonprofits would have to follow the requirements of the rule, maintaining that to do so would not have any public health benefit because the nonprofit would not be required to maintain records under the rule.

(Response 233) The exemption for nonprofit food establishments in § 1.1305(o) applies only to the nonprofit food establishment and not to any other entities within the supply chain that supply food to them. We do not agree that there would be no benefit to requiring shippers who supply food to nonprofits to maintain records, as we continue to believe that having entities maintain records up to receipt by the nonprofit is appropriate to help ensure the traceability of potentially contaminated food. However, we note that the definition of shipping in § 1.1310 does not include the donation

of surplus food. Therefore, if a shipper is donating surplus food to a nonprofit food establishment (or other entity), they would not be required to keep records of the shipment of the donated food.

(Comment 234) One comment requests clarification on how the requirements would apply to participants in the ''food recovery system,'' especially nonprofit organizations, maintaining that onerous requirements might drive people away from participating in food recovery efforts.

(Response 234) If an organization participating in the ''food recovery system'' meets the definition of ''nonprofit food establishment'' in § 1.1310 of the final rule, it would be exempt from the rule. The comment did not provide information as to what kinds of entities, other than nonprofit organizations, might be involved in the food recovery system, and we are unable to determine whether there are other entities involved in food recovery that would otherwise be exempt from this rule. However, such entities might be eligible for exemptions or partial exemptions under other provisions of the final rule. Also, as discussed in Section V.Q of this document, the rule includes procedures for requesting a waiver of one or more of the subpart S requirements for an individual entity or a type of entity on the grounds that having to meet the requirements would result in an economic hardship, due to the unique circumstances of the individual entity or type of entity (see §§ 1.1405 through 1.1450).

17. Exemption for Persons Who Manufacture, Process, Pack, or Hold Food for Personal Consumption

We proposed that subpart S would not apply to persons who manufacture, process, pack, or hold food for personal consumption (proposed § 1.1305(m)). In the preamble to the proposed rule, we noted that whether a food is for personal consumption depends on many factors, but we would consider food prepared in a private home and transported for other than business purposes (*e.g.,* to a ''potluck'' dinner with friends) to qualify for this exemption (see 85 FR 59984 at 59999, citing 69 FR 71562 at 71579). We received no comments on this provision and we are finalizing the exemption as proposed in § 1.1305(p) of the final rule.

18. Exemption for Certain Persons Who Hold Food on Behalf of Individual Consumers

We proposed (in § 1.1305(n)) that subpart S would not apply to persons who hold food on behalf of specific individual consumers, provided that such persons are not parties to the transaction involving the food they hold and are not in the business of distributing food. The preamble to the proposed rule stated that the proposed exemption would cover persons such as a hotel concierge, reception desk staff in an apartment building, and staff at an office complex who receive and store a food on the FTL on behalf of the consumer but are not parties to the purchase of the food they hold and are not in the business of distributing food (see 85 FR 59984 at 59999). We received no comments on this provision and are finalizing the exemption as proposed under § 1.1305(q) of the final rule.

19. Exemption for Food for Research or Evaluation

As discussed in the following paragraphs, we received comments that have prompted us to add an exemption from the subpart S requirements for food used in research or evaluation.

(Comment 235) Some comments suggest we establish an additional exemption for food for research and development purposes. Some commenters request a full exemption and others note that it should be similar in scope to the exemption for food for research and development purposes under the FSVP regulation (see 21 CFR 1.501(c)). These comments assert that food for research and development purposes poses a low risk to public health, is subject to the one-up, one-back requirements of subpart J, and is not intended for retail sale or otherwise distributed to the public.

(Response 235) We agree with the comments that food for research or evaluation generally should be exempt, provided that certain conditions similar to those in the FSVP regulation are met. We conclude that the risk of a foodborne illness outbreak arising from use of food in research or evaluation is low. Therefore, § 1.1305(r) of the final rule provides that subpart S does not apply to food for research or evaluation use, provided such food (1) is not intended for retail sale and is not sold or distributed to the public; and (2) is accompanied by the statement ''Food for research or evaluation use.''

20. Other Requests for Exemption

We received several comments requesting that we exempt other persons or foods from the subpart S requirements. We discuss these comments in the following paragraphs.

a. Certain Foods

(Comment 236) Some comments assert that the rule is unnecessary for tracing of seafood. Some comments maintain that there are existing traceability requirements for certain seafood species and request that such seafood be exempted from the rule.

(Response 236) We do not agree that the rule is unnecessary for tracing of seafood. Based on the data in the Model, the risk scores for certain seafood commodities result in those foods being placed on to the FTL and covered by the final rule. Except with respect to raw bivalve molluscan shellfish (discussed in Section V.E.7 of this document), we are not aware of existing traceability requirements applicable to seafood that will ensure a comparable level of traceability as outlined in the final rule.

(Comment 237) One comment suggests that shrimp processors that have gained certification through a third-party inspection should be exempt from additional traceability requirements.

(Response 237) We disagree with the comment. The certification to which the comment refers generally concerns compliance with applicable manufacturing/processing regulations, such as those concerning HACCP or CGMP, which do not necessarily address traceability. Therefore, we do not believe it would be appropriate to exempt shrimp processors that obtain such certification from the subpart S requirements.

(Comment 238) One comment suggests that a blue crab processor or dock that holds either a Marine Stewardship Council (MSC) or Gulf United for Lasting Fisheries-Responsible Fisheries Management (G.U.L.F.-RFM) sustainability certification should be exempt from the rule. The comment asserts that any processor or dock that sells processed or live crab product using one of these certifications is required to have undergone a chain of custody inspection and demonstrate the capability to trace the product back to its origin. The comment maintains that under these certifications, crab transport crates are labeled with the fisherman's license and name, and that, combined with trip tickets, this allows crabs to be tracked from vessel to dealer and often to processor.

(Response 238) The comment did not provide specific information about the traceability aspects of these programs, and we do not have information to establish that they have sufficient traceability requirements to ensure the effective and efficient tracing of food through the supply chain. However, any

existing records kept under these programs that contain information required by subpart S can be used for compliance with the final rule. Duplicate records would not need to be kept, which would reduce the burden on entities with those certifications.

b. Food Hubs

(Comment 239) Some comments request that FDA exempt food hubs from the regulation due to the additional burden the regulation would pose and the role that food hubs have played during the COVID–19 pandemic.

(Response 239) We decline to establish an exemption for food hubs. The term ''food hub'' covers a wide range of business models and functions. Food hubs that pack and hold RACs are covered by the ''farm'' definition in the final rule if the farms that grow, harvest, and/or raise the majority of the RACs packed and/or held by the food hub own, or jointly own, a majority interest in the food hub. Some food hubs may conduct activities that transform RACs into processed food. Some food hubs have a farm-to-business/institution/retail model (*e.g.,* selling to food cooperatives, grocery stores, institutional foodservice companies, and restaurants), while others have a farm-to-consumer model (*i.e.,* selling directly to the consumer, such as through a CSA program), and some are hybrids that sell to both businesses and consumers. Some food hubs provide value added services such as fresh-cut operations. Given the diverse range of activities conducted by food hubs, we conclude that it is not appropriate to create a blanket exemption for all food hubs. However, depending on the activities they conduct, individual food hubs might meet the criteria for one or more of the exemptions provided in the final rule.

c. Third-Party Cold Storage Facilities

(Comment 240) Some comments request that certain facilities be exempt from the final rule under section 204(d)(6)(E) of FSMA, which allows FDA to provide modified requirements or an exemption from subpart S for a food or type of facility when the Agency determines that additional records are not necessary to protect public health. These comments assert that we should grant exemptions for third-party cold storage facilities where the customers, including manufacturers, maintain ownership of the food and are responsible for the records, provided the food continues to be owned by the entity that shipped the food to the third-party facility. The comments assert that additional records are not needed to protect public health in this situation and would create a significant burden for the third-party cold storage facilities.

(Response 240) We decline to establish an exemption for third-party cold storage facilities. In general, we believe it is necessary for effective traceability to require entities that physically hold an FTL food at a location, including third-party cold storage facilities, to keep records to facilitate traceback and traceforward to other entities in the food's supply chain. As discussed in Section V.F of this document, the definition of ''holding'' in § 1.1310 of the final rule states that holding facilities could include cold storage facilities. However, as discussed in Section V.R of this document, such storage facilities may enter into an agreement with another party, such as the owner of the FTL food, to keep records on behalf of the storage facility.

d. Third-Party Logistics Providers

(Comment 241) One comment asserts that third-party logistics providers should not be covered by the rule because agreements between such providers and food companies might need to be very complex, which could lead some providers to decide not to receive or ship FTL foods. The comment maintains that this could hurt small businesses who rely on third-party logistics providers to grow their businesses.

(Response 241) We decline to establish an exemption for third-party logistics providers. Regardless of agreements in place between third-party logistics providers and food companies, if the third-party logistics provider is an entity that manufactures, processes, packs, or holds a food on the FTL, subpart S records are needed to ensure traceability is maintained and unbroken between supply chain partners. As discussed in Response 259, persons who do not physically possess food are not engaged in ''holding'' within the meaning of this final rule. Thus, if a third-party logistics provider does not take physical possession of the food, it would not be subject to the rule.

e. Small Wholesalers

(Comment 242) Some comments ask whether there is an exemption for very small wholesalers. The comments note that while there is an exemption for small retailers, there is no mention of wholesalers. The comments ask that if small and very small wholesale operations are covered by the rule, FDA should provide further guidance as to how these firms can comply in a way that aligns with their fiscal limitations.

(Response 242) While we understand the concerns of small wholesalers about the potential financial impact of compliance with the rule, we also recognize that it is necessary to ensure that essential traceability information is kept and passed forward along the entire supply chain. We conclude that if small wholesalers were exempt from the rule, there might be significant gaps in the tracing information available at critical points throughout the distribution chain. Small RFEs and restaurants are at the end of the distribution chain, while small producers are typically at the beginning of the distribution chain, which means that the exemptions in § 1.1305(a) and (i) do not create gaps in the distribution chain. An exemption for small wholesalers, however, would create a gap in the middle of the distribution chain. Therefore, we decline to adopt a full exemption for small wholesalers (or for any small entities not at either end of the supply chain). However, as discussed in Response 470, the final rule provides some relief to small wholesalers and other small entities in the middle of the supply chain by exempting them from the requirement to provide an electronic sortable spreadsheet containing requested tracing information under certain circumstances.

As previously stated, in accordance with section 204(h) of FSMA, we will be issuing an SECG specifically aimed at assisting affected small businesses in complying with the requirements of this rule. In addition, we may issue other materials to help smaller entities and all persons subject to the FTL recordkeeping requirements understand and meet the requirements applicable to them.

f. Intracompany Shipments

(Comment 243) Some comments suggest that intracompany shipments should be exempt from the rule, maintaining that keeping records of such shipments is not necessary to protect public health and would create a significant burden. Some comments suggest that FDA revise the definitions of ''shipping'' and ''receiving'' to expressly exclude shipments between shippers and receivers that are under the ownership or operational control of a single company. These comments maintain that data related to internal movement of food products between locations under the same ownership would fail to add value, cause delays in providing critical traceability information to FDA, and be overly burdensome. Noting that we proposed to define ''receiving'' as an event in a

food's supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported from another defined location, the comments assert that intracompany movements do not involve a ''customer'' because the typical industry understanding of ''customer'' means the purchaser of the food. The comments also maintain that companies already have appropriate internal controls and recordkeeping requirements in place for traceability of food that moves within a company. In addition, the comments assert that each CTE will trigger voluminous records and that exempting intracompany movement of FTL foods will significantly reduce the burden of the rule.

(Response 243) We decline to exempt intracompany shipments from the subpart S requirements. We conclude that effective traceability requires that records be kept when a product changes physical location, regardless of whether the shipper and receiver are under the ownership or operational control of the same company as in intracompany shipment (as the comments have described that term). Therefore, as discussed more fully in Section V.F of this document, we have revised the definition of ''shipping'' to specify that it includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm; we have added a similar clarification to the definition of ''receiving.'' However, we note that movement of a product within a particular location of a firm (*i.e.,* at a particular street address) does not constitute ''shipping'' or ''receiving'' under the final rule.

g. Cross-Docking

(Comment 244) Some comments suggest that we provide an exemption for cross-docking activities and describe cross-docking as when a pallet of food products is sent from a firm through a distribution center or cross-docker and then sent on to the next point in the supply chain. The comments maintain that during cross-docking, a product passes over a loading dock from one transporter to another without being held at the cross-docking facility for an appreciable amount of time, and the product is held under procedures that maintain essential transportation conditions, such as temperature. The comments maintain that the food is not entered into the inventory of the distribution center or cross-docker, and that the shipping records for such food are primarily paper invoices. The comments assert that shipping and receiving requirements should not apply to food that is shipped in this way and request clarity regarding the common logistical practice of ''cross-docking'' and whether it is covered under subpart S.

(Response 244) We do not think it is necessary to exempt cross-docking activities from the subpart S requirements. The final rule defines shipping to mean an event in a food's supply chain in which a food is arranged for transport (*e.g.,* by truck or ship) from one location to another location. Records must be kept regarding both locations, *i.e.,* the location where the shipping event began and the location where it ended (*i.e.,* where the food was received). It is not necessary to have records of the route the food took, including any instances where it may have been moved from one carrier to another. Thus, in a cross-docking situation where food is arranged for transport from point A to point B, but it is briefly placed on a loading dock at point X in order to be transferred from one truck to another truck, we would not consider the food to have been shipped to point X (or to have been received at point X). Thus, no records would need to be kept regarding point X; the required shipping and receiving records would reflect that the food was shipped from point A and received at point B. A full discussion of the requirements applicable to the shipping (under § 1.1340) and receiving (under § 1.1345) of FTL foods is set forth in Sections V.M and V.N, respectively, of this document.

We recognize that questions might arise in situations where food is arranged for transport from point A to point B, with an understanding that there will be an intermediary step during which the food is held at point X for a period of time. To determine whether the food was received at point X (and then subsequently shipped to point B), we would consider factors such as how long the food was held at point X, whether it was held there under temperature-controlled conditions that differ from transportation conditions, and whether it was taken into inventory at point X.

F. Definitions (§ 1.1310)

We proposed to codify definitions of several terms we use in the subpart S traceability recordkeeping regulation (proposed § 1.1310). As discussed in the following paragraphs, we have revised several of the proposed definitions in response to comments we received, and we have added and deleted definitions in accordance with other changes to the proposed requirements we are making in the final rule.

(Comment 245) Several comments request that we ensure that definitions of terms used in the subpart S are consistent with the definitions of those terms in other FSMA regulations.

(Response 245) We agree that the definitions should be aligned as much as possible. In most cases, the definitions used in the final rule are identical to the definitions in other FDA regulations, including other FSMA regulations. To the extent there are minor differences in certain definitions, we discuss them in response to the comments below.

1. Category

We proposed to define ''category'' to mean a code or term used to classify a food product in accordance with a recognized industry or regulatory classification scheme, or a classification scheme a person develops for their own use. We did not receive any comments on the definition of ''category.'' The term ''category'' is not included in the final rule as it was a component of the definition of ''traceability product description,'' which we have also deleted (see Response 299 regarding deletion of the term ''traceability product description'').

2. Commingled Raw Agricultural Commodity

Although the proposed rule included a definition of ''commingled raw agricultural commodity'' within the text of the partial exemption for commingled RACs (proposed § 1.1305(f)), we have revised the definition and moved it to the definitions section of the final rule (§ 1.1310). In accordance with section 204(d)(6)(D) of FSMA, we proposed to define ''commingled raw agricultural commodity'' as any commodity that is combined or mixed after harvesting but before processing, except that the term ''commingled raw agricultural commodity'' does not include types of fruits and vegetables that are RACs to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 apply. We further stated that for the purpose of this definition, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different farms; in addition, the term ''processing'' would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

As discussed in Response 206, we have revised the definition of

''commingled raw agricultural commodity'' to specify that a commodity is ''combined or mixed'' only when the combination or mixing involves food from different farms under different company management, consistent with the statement in the preamble to the proposed rule that we would not consider packed eggs that are from a single farm or separate farms under the same management to be commingled shell eggs (see 85 FR 59984 at 59997). In addition, as discussed in Response 208, we have revised the definition of ''commingled raw agricultural commodity'' to specify that, for food obtained from a fishing vessel, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. We are finalizing the remainder of the definition of ''commingled raw agricultural commodity'' as proposed.

3. Cooling

We proposed to define ''cooling'' to mean active temperature reduction of a food using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process, either before or after packing. We have modified the definition of ''cooling'' for clarity as explained below.

(Comment 246) One comment asks FDA to confirm that re-cooling is considered part of cooling under the rule.

(Response 246) We recognize that cooling of food can take place at multiple points along the supply chain. To more precisely specify the entities required (under § 1.1325 of the final rule) to keep certain records of cooling that occurs before a RAC is initially packed, we have revised the definition to refer to active temperature reduction of a RAC, rather than a ''food.'' Under this revised definition, re-cooling would be considered ''cooling'' if the food in question was still a RAC, and if the other elements of the definition were met. In addition, we have clarified that ''cooling'' does not include icing of seafood, because seafood is generally iced to maintain product quality during holding rather than to reduce the temperature of the food.

4. Creating

We proposed to define ''creating'' to mean making or producing a food on the FTL (*e.g.,* through manufacturing or processing) using only ingredient(s) that are not on the FTL. The definition further stated that ''creating'' does not include originating or transforming a food. As explained below, we have removed this term from the final rule.

(Comment 247) As part of requests for FDA to align the final rule with industry traceability standards, some comments request that the Agency use the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 19987 and 19988 standard term of ''commissioning'' instead of the proposed ''growing'' and ''creating'' terms. Other comments assert that the terms ''creating'' and ''transforming'' are confusing, as they are essentially the same thing.

(Response 247) We agree that the term ''creating'' appears to have caused some confusion, based on comments. In the final rule, we have removed the term ''creating'' and merged the concept and definition of ''creating'' with the concept and definition of ''transformation.'' Thus, the final rule defines ''transformation'' in part as an event in a food's supply chain that involves manufacturing/processing a food or changing a food (*e.g.,* by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the FTL. This definition encompasses both ''transformation'' and ''creating'' as those terms were defined in the proposed rule. While we appreciate the value of industry standards for traceability, we decline to use the term ''commissioning'' in the final rule, as we believe it is not needed. We believe that the concept of ''transformation'' as defined in the final rule is widely used in industry and, because it streamlines two concepts into one, should reduce potential confusion. We also do not believe it would be appropriate to combine the ''growing'' activity (there was no proposed definition of ''growing'') into the ''transformation'' definition because we conclude it is more consistent with the framework of the FTL traceability rule to focus the concept of ''transformation'' primarily on manufacturing/processing and related activities.

5. Critical Tracking Event

We proposed to define ''critical tracking event'' to mean an event in the supply chain of a food involving the growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food. We did not receive any comments on the definition of ''critical tracking event.'' In the final rule, we have modified the definition of ''critical tracking event'' to align with other changes to the proposed codified provisions. In response to comments, the CTEs in the final rule consist of harvesting, cooling (before initial packing), initial packing of RACs other than food obtained from a fishing vessel, first land-based receiving of food obtained from a fishing vessel, shipping, receiving, and transformation (see Sections V.H through V.O of this document for a discussion of changes to the CTEs). As a result of these changes, we define ''critical tracking event'' in the final rule as an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a RAC other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

6. Farm

We proposed to define ''farm'' as it is defined in § 1.328. The definition further stated that, for producers of shell eggs, ''farm'' means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3. We have retained this definition in the final rule.

(Comment 248) One comment asks whether oyster leaseholders are considered farms.

(Response 248) The definition of ''farm'' in § 1.328 states that, among other things, a farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. Therefore, if an oyster leasehold is used for the raising of seafood, it is a farm for the purposes of this rule.

(Comment 249) One comment requests that FDA clearly state that aquaculture operations are farms, and asks that we require that growing area coordinates or the equivalent be maintained for aquaculture farms, not just harvest information.

(Response 249) As discussed above, operations devoted to the raising of seafood, such as aquaculture operations, are farms. As discussed in Response 328, the final rule requires that aquaculture farms maintain a farm map showing the areas in which they raise FTL foods, and the map must show the location and name of each container (*e.g.,* pond, pool, tank, cage) in which the seafood is raised, including geographic coordinates and any other information needed to identify the location of each container (see § 1.1315(a)(5) and (a)(5)(ii)). As discussed in Section V.J of this document, persons who harvest an aquacultured food are required to keep (among other KDEs) information

identifying where the food was harvested (see § 1.1325(a)(1)(vi)). Similarly, as discussed in Section V.K of this document, persons who initially pack an aquacultured food must also keep this information (see § 1.1330(a)(6)).

(Comment 250) Several comments request that we update the definition of ''farm'' in this rulemaking or update it elsewhere before finalizing the rule. These comments suggest that there is a need for a revised and clear definition of ''farm'' that is consistent across all the FSMA rulemakings. One comment maintains that the question of how to handle intracompany shipments is complicated by the fact that the definition of farm in § 1.328 does not clearly define whether an operation is one farm or multiple farms.

(Response 250) We agree that, to the extent possible, the definition of ''farm'' in the subpart S food traceability regulation should be consistent with other FDA regulations, including other FSMA rules. The final rule defines ''farm'' to mean farm as defined in § 1.328, except that for producers of shell eggs, ''farm'' means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3. By referencing the farm definition in § 1.328, we are aligning our definition not only with subpart J (which is where § 1.328 appears), but also with several regulations that have adopted the identical farm definition, including the food facility registration regulation (see § 1.227), the produce safety regulation (see § 112.3), and the preventive controls for human food regulation (see 21 CFR 117.3). We think it is appropriate for the farm definition in the food traceability regulation to include additional language about egg farms so that our rule is also aligned with the definition of ''farm'' in the egg safety regulation (see § 118.3).

As discussed in the January 2018 document, ''Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs,'' FDA intends to initiate a future rulemaking related to farm activities, which may change the farm definition that is used in those three FSMA regulations (which is identical to the farm definition used in this final rule). If the definition of ''farm'' in § 1.328 is revised through that separate rulemaking, those revisions will be incorporated into the subpart S food traceability regulation, because our definition of ''farm'' directly references § 1.328.

7. First Land-Based Receiver

We are adding a definition of ''first land-based receiver'' to the final rule to clarify the scope of changes we have made concerning recordkeeping requirements for the first land-based receiver of food obtained from a fishing vessel (see Section V.L of this document). For the purposes of subpart S, ''first land-based receiver'' means the person taking possession of a food for the first time on land directly from a fishing vessel.

8. First Receiver

We proposed to define ''first receiver'' as the first person (other than a farm) who purchases and takes physical possession of a food on the FTL that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested. Because we have deleted from the rule the proposed requirements applicable to the first receiver of an FTL food (see Section V.K of this document), we are also deleting the definition for ''first receiver.''

(Comment 251) One comment asks that we include a definition of a ''first shipper'' to allow the first receiver to know what data must be sent with each shipment.

(Response 251) Because we have deleted the proposed requirements that would have applied to first receivers, there is no need to define ''first shipper.''

(Comment 252) One comment asks that the first receiver definition be amended to include fresh produce packinghouses because they maintain many of the first receiver KDEs linked to a lot code assigned by the packinghouse at the time of packing. The comment contends that growers are comfortable with packers maintaining this information on their behalf.

(Response 252) As previously stated, the final rule deletes the proposed requirements for first receivers, so there is no need to revise the definition as suggested. However, in response to comments, we have replaced the requirements for first receivers with requirements for persons who either (1) perform the initial packing of a RAC other than a food obtained from a fishing vessel or (2) are the first land-based receiver of a food obtained from a fishing vessel (see Sections V.J and V.K of this document). As discussed below, ''initial packing'' is defined as packing a RAC (other than a food obtained from a fishing vessel) for the first time. Under § 1.1330 of the final rule, an entity (such as a produce packinghouse) that initially packs a RAC not obtained from a fishing vessel must assign a traceability lot code and maintain harvest and (when applicable) cooling KDEs, among others, linked to the traceability lot code.

(Comment 253) One comment requests that we clarify situations when an RFE might meet the definition of a ''first receiver,'' such as when an RFE purchases from a vendor that received food from a farm.

(Response 253) As previously stated, we have deleted the proposed requirements for first receivers of FTL foods. We have replaced the first receiver concept with the concepts of initial packing (for RACs not obtained from a fishing vessel) and first land-based receiving (for food obtained from a fishing vessel). We think it is unlikely that an RFE or restaurant would engage in the initial packing of a food. We also do not think that most RFEs or restaurants would be the first land-based receiver of a food obtained from a fishing vessel, although there are situations where this might be the case. In most circumstances we anticipate that the only CTE performed by an RFE or restaurant would be receiving.

(Comment 254) One comment expresses concern that the inclusion of ownership in the proposed definition of ''first receiver'' would create confusion with FDA's definition of ''secondary activities farm'' in the produce safety regulation.

(Response 254) Because the final rule does not include requirements for first receivers, this should eliminate any possible confusion of the term ''first receiver'' with definitions of terms in other regulations. We also note that the definitions of ''initial packing'' and ''first land-based receiver'' (which define the events that replaced the first receiver CTE) do not include ownership of the food as part of the definition.

(Comment 255) One comment requests that FDA define ''non-farm entity,'' which is a phrase we used in the preamble to the proposed rule to explain the proposed definition of ''first receiver.''

(Response 255) Because the final rule does not include requirements for ''first receivers,'' there is no need to clarify the meaning of ''non-farm entity.''

9. Fishing Vessel

We proposed to define ''fishing vessel'' as any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to,

preparation, supply, storage, refrigeration, transportation, or processing. On our own initiative, we have added text at the end of the definition stating that the definition is as set forth in the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1802(18), which is the definition for ''fishing vessel'' specified in section 204(d)(6)(C) of FSMA.

(Comment 256) One comment requests that we revise the definition of ''fishing vessel'' to include aquaculture farm vessels or trucks, because shellfish farms do not use boats to access their farms. The comment maintains that the Magnuson-Stevens Act definition of ''fishing vessel'' does not apply to aquaculture.

(Response 256) We decline to make this change. Section 204(d)(6)(C) of FSMA requires a partial exemption for ''fishing vessel'' as that term is defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act. If a conveyance used on an aquaculture farm does not meet this definition, it would not be considered a ''fishing vessel'' for the purposes of subpart S.

10. Food Traceability List

We proposed to define ''Food Traceability List'' to mean the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of FSMA. The definition further stated that the term ''Food Traceability List'' includes both the foods specifically listed and foods that contain specifically listed foods as ingredients. We did not receive any comments on the proposed definition, but we received several comments asking whether certain foods were on the FTL, some of which indicated confusion with how the FTL was defined. We are revising the definition in the final rule for clarity, consistent with determinations we have made regarding the description of foods on the FTL (see Response 27). Therefore, the final rule defines ''Food Traceability List'' as the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of FSMA, and further states that the term ''Food Traceability List'' includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (*e.g.,* fresh) in which it appears on the list.

11. Growing Area Coordinates

We proposed to define ''growing area coordinates'' as the geographical coordinates (under the global positioning system (GPS) or latitude/longitude) for the entry point of the physical location where the food was grown and harvested.

(Comment 257) One comment requests that the final rule emphasize that the term ''growing area coordinates'' applies to where a food was both grown and harvested.

(Response 257) Because growing area coordinates was one of the KDEs we proposed to require for the CTE of growing an FTL food, and the final rule deletes the proposed CTE for growing of foods (see Section V.J of this document), we are also deleting the definition of ''growing area coordinates.'' As discussed in Section V.G of this document, the final rule instead requires certain farms to keep, as part of their traceability plan, a farm map showing the location and name of each field (or other growing area) in which an FTL food is grown, including geographic coordinates and any other information needed to identify the location of each field or growing area. As discussed in Section V.J of this document, harvesters of produce covered by the rule also will be required to keep, among other KDEs, the name of the field or growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name. Similar requirements apply to aquacultured food, as discussed in Section V.J.

12. Harvesting

We proposed to define ''harvesting'' to mean activities of farms and farm mixed-type facilities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. The definition further stated that ''harvesting'' is limited to activities performed on RACs, or on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, on a farm. The proposed definition went on to state that ''harvesting'' does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act, and provided examples of harvesting, including cutting (or otherwise separating) the edible portion of the RAC from the crop plant and removing or trimming part of the RAC (*e.g.,* foliage, husks, roots, or stems). Additional examples of harvesting in the proposed definition included collecting eggs, taking of fish and other seafood in aquaculture operations, milking, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing RACs grown on a farm.

(Comment 258) Several comments state that the proposed definition of ''harvesting'' does not include ''cooling,'' unlike the definition of ''harvesting'' in other FSMA regulations. The comments ask that we include ''cooling'' in the definition of ''harvesting'' to make the definition consistent with the other FSMA regulations.

(Response 258) We agree that it is important to maintain consistency in definitions, when possible, in situations where the same term is defined in multiple FDA regulations. Because of this, we have aligned many of the subpart S definitions with § 1.227, which is a provision with which many other FSMA rules have also aligned their definitions. We are therefore revising the definition of ''harvesting'' in the final rule so that it is the same as the definition in § 1.227. We had proposed not to include ''cooling'' in the definition because the rule includes KDEs related to cooling and we believed it would be helpful to distinguish cooling from harvesting. However, to maintain consistency across FDA regulations, the final rule includes cooling in ''harvesting,'' while maintaining separate KDEs for the two different events of harvesting and cooling. As discussed above, the final rule continues to include a definition of ''cooling,'' to clarify the application of the KDEs that relate to cooling. When a person performs ''cooling'' as defined in the final rule and that person does not otherwise perform any activities associated with harvesting, they would not be required to maintain the harvesting KDEs in § 1.1325(a). If applicable, such a person would be required to maintain the cooling KDEs in § 1.1325(b).

In accordance with finalizing the definition of ''harvesting'' as it appears in § 1.227, we are removing from the proposed definition a few of the additional examples of harvesting that we had proposed to include, specifically ''collecting eggs, taking of fish and other seafood in aquaculture operations, [and] milking.'' We continue to consider these activities to be harvesting activities, even though we are removing them from the definition for the sake of consistency. Other than the removal of these additional examples and the

addition of ''cooling'' to the list of additional examples, the remainder of the proposed definition of ''harvesting'' was already identical to the definition in § 1.227.

13. Holding

We proposed to define ''holding'' to mean storage of food and also include activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). The definition further stated that ''holding'' also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets) but does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act. The proposed definition notes that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(Comment 259) One comment asks that we confirm that the definition of ''holding'' requires physical possession of food and expresses support for that definition.

(Response 259) We confirm that the definition of ''holding'' requires physical possession of the food. However, to ensure that ''holding'' is defined consistently in FDA regulations, we are not adding this clarification to the text of the definition. The final rule maintains the same definition of ''holding'' that we proposed with one edit (explained below), which makes the definition in the final rule identical to that in § 1.227 and consistent with other FDA regulations, including the FSMA regulations.

(Comment 260) Some comments assert that the ''exemption'' of brokers and importers who do not physically possess FTL foods will complicate successful implementation of the rule. The comments do not believe that most importers also hold food, and they maintain that, in FSMA's FSVP provisions, Congress recognized the need to hold importers accountable for the safety of the foods they import, regardless of whether they take physical possession of the food. The comments maintain that importers should retain and share with key partners essential traceability data to enable FDA to access the lot number and necessary information at the point of sale. The comments also state that, in the sanitary transportation regulation, freight brokers are identified as a type of ''shipper'' that is subject to that regulation. The comments assert that because other FSMA regulations recognize the role that importers and brokers play in food safety, importers and brokers should not be excluded from the subpart S requirements.

A few comments urge FDA to ensure that brokers and importers help facilitate compliance for other entities in the supply chain. The comments acknowledge that brokers may not hold the food and therefore would not be covered by the rule, but the comments maintain that such brokers may still possess relevant information for traceability. The comments also question whether excluding such brokers from the rule would place an unfair burden on manufacturers to ensure that information is shared across the supply chain if the broker is the entity that moves the food.

(Response 260) Section 204(d)(1) of FSMA directs FDA to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods for which we have determined that the additional requirements are appropriate and necessary to protect the public health. As discussed in the preamble to the proposed rule (85 FR 59984 at 60000), we believe that persons who do not physically possess food are not engaged in holding of food within the meaning of the rule. This means, for example, that a person who coordinates the import of a FTL food but never takes physical possession of the food would not be subject to the rule, while a person who imports a listed food and physically possesses the food would be subject to the rule unless an exemption applies. Similarly, food brokers who negotiate sales of food from producers to wholesalers, retail stores, and others but never physically possess the food would not be subject to the rule. Although, as noted by the comments, brokers and importers that do not physically possess food are subject to other FSMA regulations, the inapplicability of the subpart S requirements to such firms does not constitute a conflict, as the different regulations serve different food safety purposes and are based on different statutory authorities. Given the many different business models and persons that may be involved within a supply chain, we encourage all supply chain partners to work together to provide the required information to each other to ensure end-to-end traceability.

We also note that entities that are covered by the rule may designate entities that are not covered, such as importers or brokers who do not hold the food, to maintain traceability records on behalf of the covered entity (see § 1.1455(b)). However, the covered entity would remain responsible for ensuring that the subpart S requirements are met for the FTL foods that they manufacture, process, pack, or hold.

(Comment 261) One comment notes that the proposed definition of ''holding'' omits the word ''could'' from the statement in the definition of ''holding'' in the preventive controls regulation that ''[h]olding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.'' The comment asks if the omission was intended to convey a different meaning.

(Response 261) We did not intend to convey a different meaning of ''holding'' from that in the preventive controls regulation. To ensure that we are defining ''holding'' consistently, the final rule specifies that holding facilities ''could include'' warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(Comment 262) One comment requests that we replace the example of ''drying/dehydrating hay or alfalfa'' in the definition of ''holding'' with an example that is relevant to the current list of FTL foods.

(Response 262) We disagree with the comment that we should delete the example of drying/dehydrating hay or alfalfa from the definition of ''holding'' in the final rule. As noted above, we believe it is important to maintain consistency with definitions that are common across various FDA regulations (including the FSMA regulations); therefore, we are finalizing the definition of ''holding'' as it appears in § 1.227.

(Comment 263) One comment asks whether the definition of holding includes holding of live animals, such as lobsters in a lobster pond.

(Response 263) Crustaceans such as lobsters are included on the FTL and are therefore covered by the final rule. Because ''holding'' means storage of food, including activities performed incidental to storage of a food, holding crustaceans such as lobsters in ponds or other containers is ''holding'' under the final rule.

(Comment 264) One comment requests that we clarify the difference between drying alfalfa and drying raisins, and asks why drying alfalfa is considered a harvesting activity while drying raisins is considered a manufacturing/processing activity.

(Response 264) We regard the drying of hay and alfalfa as a holding activity (rather than a ''harvesting'' activity as

the comment asserts) because the drying is done to effectuate the safe storage of hay/alfalfa and is not a process that transforms the hay/alfalfa into a distinct commodity. The drying of grapes into raisins is considered a manufacturing/processing activity because the process transforms the grapes (a RAC) into a distinct commodity (raisins), which is not a RAC.

14. Initial Packing

We are adding a definition of ''initial packing'' to clarify the scope of the CTE for the initial packing of a food, as discussed in Section V.K of this document. The final rule defines ''initial packing'' to mean packing a RAC (other than a food obtained from a fishing vessel) for the first time.

15. Key Data Element

We proposed to define ''key data element'' to mean information associated with a CTE for which a record must be established and maintained in accordance with this subpart. We did not receive any comments on this definition. On our own initiative, we are revising the definition to specify that a KDE is information associated with a CTE for which a record must be maintained ''and/or provided'' in accordance with subpart S, to reflect that certain KDEs must be provided to other supply chain entities as well as maintained. Also on our own initiative, we removed ''established and'' in the phrase ''for which a record must be established and maintained in accordance with this subpart,'' because in some situations an entity might receive the relevant record from a supply chain partner (*e.g.,* the shipper), rather than establish a new record.

16. Kill Step

We proposed to define ''kill step'' to mean processing that significantly minimizes pathogens in a food. We did not receive any comments on this definition, but we received questions about what constitutes a kill step, some of which indicated confusion about how to apply the definition. As discussed in Section V.B of this document, we have added the word ''lethality'' before ''processing'' in the definition to clarify that the processing must be robust and not something that simply reduces pathogens (*e.g.,* a washing process).

17. Location Description

We proposed to define ''location description'' to mean a complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code for domestic facilities and comparable information for foreign facilities, including country; except that for fishing vessels, ''location description'' means the name of the fishing vessel that caught the seafood, the country in which the fishing vessel's license (if any) was issued, and a point of contact for the fishing vessel.

(Comment 265) Several comments state that requiring both a ''physical location name'' and a ''physical location description'' is confusing. The comments maintain that a physical location description typically means a complete physical address and other key contact information; another comment states that ''location description'' should be defined as the business name, phone number, and physical address. Some comments request that we clarify which KDEs are required for a location description; several other comments suggest that we allow flexibility in how an entity's location is communicated.

(Response 265) We agree that the proposed definition of ''location description'' was somewhat unclear. To address this, we have deleted ''physical location name'' from the definition and removed the word ''primary'' preceding ''phone number'' as it was not adding clarity. We also removed the phrase ''complete physical address'' from the beginning of the definition because it was redundant with the information that followed. The revised definition also specifies that the key contact information should be for the location where a food is handled (as opposed to the address of the corporate headquarters of a brand owner or parent company), because that is the information that is most useful during a traceback investigation. The final rule therefore defines ''location description'' to mean key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country.

We are providing flexibility in allowing a physical location address or geographic coordinates. However, there is only so much flexibility we can allow in the location description because it is important for the location description to be a complete set of information to allow us to quickly identify, during an outbreak of foodborne illness, the physical location of the entity that handled the FTL food, as well as to have an accurate phone number that will allow us to contact that location quickly.

(Comment 266) One comment maintains that, for fishing vessels, location description is not a KDE used by other traceability programs and should be changed to vessel flag state. Another comment says that location description is a confusing term with respect to fishing vessels because it could include the vessel identification number, license number, name of vessel, and country in which the vessel is licensed. The comment also asks why a point of contact is needed and suggests that this KDE be optional for fishing vessels.

(Response 266) The final rule omits from the definition of ''location description'' the proposed text on what the definition meant specifically for fishing vessels. Instead, § 1.1335 of the final rule specifies that if a person is the first land-based receiver of a food that was obtained from a fishing vessel, the only location description record the person must maintain is the location description for itself, which also serves as the traceability lot code source for the food, since the first land-based receiver must assign a traceability lot code to the food (see Section V.H of this document). We have removed requirements to maintain records related to the identity of the fishing vessel, such as the country of license of the vessel and a point of contact for the vessel (which we had proposed as part of the location description) and the vessel identification number (which we had proposed as part of the location identifier), to simplify the requirements of the final rule, as we have determined that this information is not essential for traceability under subpart S. However, the first land-based receiver of a food obtained from a fishing vessel must maintain a record of the harvest date range and location for the trip during which the food was harvested because it may be important to know where the fish was caught for traceability purposes in the event of an outbreak of foodborne illness.

18. Location Identifier

We proposed to define ''location identifier'' to mean a unique identification code that an entity assigns to the physical location name identified in the corresponding location description, except that for fishing vessels, location identifier would mean the vessel identification number or license number (both if available) for the fishing vessel. To avoid potential confusion regarding this term, we have deleted it from the rule, as discussed in response to the comments below.

(Comment 267) Several comments maintain that including both a location description and location identifier for an entity is redundant and that use of the term ''identifier'' is confusing, offers more detail than is necessary, and could be difficult to obtain, while other comments suggest that either location description or location identifier but not both should be required. One comment maintains that having both a location description and a location identifier could be confusing to FDA during an investigation. One comment suggests allowing for flexibility for the location identifier, with options to provide a name and physical location or a unique identifier, potentially using the last 5 to 6 digits of the FDA registration number. However, one comment suggests that FDA facility registration numbers should not be used as a location identifier. One comment suggests that FDA assign location identifiers for all establishments that produce, transform, package, or label foods covered by this rule. Finally, some comments state that location identifiers are not commonly used in business at all or are not commonly used to refer to the physical location of production; instead, the comments maintain that a location identifier often refers to a commercial location such as headquarters, sales, or customer service locations.

(Response 267) We recognize that the proposed requirements to keep both a ''location description'' and a ''location identifier'' for an entity were confusing to many commenters. Therefore, we have removed the requirement to keep a ''location identifier'' and deleted the definition of ''location identifier'' from the final rule. We conclude that the information specified in the definition of ''location description'' is adequate to identify where an entity is physically located, and comments indicate that some covered entities do not currently use location identifiers. Businesses that use location identifiers, such as to differentiate between intracompany locations (*e.g.,* store numbers), may choose to include that information as part of their location description. This could be done either by adding it to the required information or by using it as a shorthand for some or all of the required information, provided that a glossary or key is maintained (and, if necessary, shared) to indicate the complete physical address and other required information relating to the specific location.

(Comment 268) Several comments recommend expanding the definition of ''location identifier'' to include the GS1 Global Location Number (GLN). According to comments, the GLN has wide global acceptance and is endorsed by the FAO. Comments suggest adopting the GLN as the location identifier, maintaining that the GLN better identifies fishing vessels and that it would be useful for identifying packing and cooling locations. On the other hand, one comment supports the definition of ''location identifier'' for fishing vessels as proposed.

(Response 268) We have deleted the proposed requirement to maintain a location identifier (including, where applicable, a fishing vessel identifier) for all CTEs. Consequently, we have also deleted the definition of ''location identifier.'' However, businesses that use GLNs may choose to include that information as part of their location description. This could be done either by adding it to the required information or by using it as a shorthand for some or all of the required information, provided that a glossary or key is maintained (and, if necessary, shared) to indicate the complete physical address and other required information relating to the specific location.

19. Lot

We proposed to define ''lot'' to mean the food produced during a period of time at a single physical location and identified by a specific code. The proposed definition further stated that a lot may also be referred to as a batch or production run. As discussed below, we are deleting this definition to avoid possible confusion with the term ''traceability lot.''

(Comment 269) Several comments express confusion about the difference between ''lot'' and ''traceability lot,'' maintaining that the need for two terms was unclear. (As discussed below, we proposed to define ''traceability lot'' as a lot of food that has been originated, transformed, or created.) Some comments recommend that FDA should define ''lot'' by using current industry terminology to better align with currently used processes and standards, and remove new terms that are causing confusion, such as ''traceability lot.''

(Response 269) We agree there was potential for confusion between the terms ''lot'' and ''traceability lot.'' We have deleted the definition of ''lot'' from the final rule. Because the rule is focused on keeping and providing to subsequent supply chain entities the traceability lot code, which applies to a ''traceability lot'' of an FTL food, we conclude that it is not necessary to have an additional definition for ''lot.'' Regarding consensus terminology, we have reviewed traceability standards and initiatives both domestically and internationally and we are not aware of a consensus definition of ''lot.'' For the purposes of subpart S, we think the important thing is to have a shared understanding of the term ''traceability lot,'' the definition of which is discussed below. Businesses may choose to assign additional lot codes that are internal to their operations, but such practices are beyond the scope of this rule and therefore do not require a definition of ''lot.''

20. Manufacturing/Processing

We proposed to define ''manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. The proposed definition further stated that examples of manufacturing/processing activities include baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. Finally, the proposed definition noted that, for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. We did not receive any comments on this definition and are finalizing it as proposed, which is identical to the definition in § 1.227.

21. Mixed-Type Facility

We proposed to define ''mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The definition further states that an example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. We did not receive any comments on the definition of ''mixed-type facility'' and are finalizing it as proposed, which is identical to the definition in § 1.227.

22. Nonprofit Food Establishment

We proposed to define ''nonprofit food establishment'' to mean a charitable entity that prepares or serves food directly to the consumer or

otherwise provides food or meals for consumption by humans or animals in the United States. The definition further stated that the term includes central food banks, soup kitchens, and nonprofit food delivery services and notes that to be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code.

(Comment 270) One comment asks whether hospitals and nursing homes are considered nonprofit food establishments.

(Response 270) Hospitals and nursing homes are nonprofit food establishments under the rule (and thus would be exempt from subpart S under § 1.1305(o)) if they meet the definition of ''nonprofit food establishment'' that we proposed and are finalizing, *i.e.,* they are a charitable entity that prepares or serves food directly to consumers or otherwise provides food or meals for consumption by humans or animals in the United States, and they meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code. Hospitals and nursing homes that are not nonprofit food establishments might be eligible for other exemptions or partial exemptions, such as the exemption for small RFEs and restaurants in § 1.1305(i).

23. Originating

We proposed to define ''originating'' as an event in a food's supply chain involving the growing, raising, or catching of a food (typically on a farm, a ranch, or at sea), or the harvesting of a non-produce commodity. As explained below, we have removed this term from the final rule.

(Comment 271) One comment asks that we replace ''growing'' with ''harvesting'' in the definition of ''originating.'' The comment maintains that traceability lot codes normally are not assigned to food before it is harvested.

(Response 271) We agree that traceability lot codes usually are not assigned to a food until after it is harvested, and we have made several changes to the rule to reflect this, including adoption of requirements applicable to the initial packer of a food not obtained from a fishing vessel and the first land-based receiver of a food obtained from a fishing vessel (see §§ 1.1330 and 1.1335). As a result of these and other changes, the final rule no longer includes requirements concerning originators or originating of foods, and we are deleting the definition of ''originating.''

24. Originator

We proposed to define ''originator'' to mean a person who grows, raises, or catches a food, or harvests a non-produce commodity. We did not receive any comments on this definition. Consistent with the deletion of the term ''originating,'' we are deleting the definition of ''originator'' from the rule.

25. Packing

We proposed to define ''packing'' to mean placing food into a container other than packaging the food, including re-packing and activities performed incidental to packing or re-packing a food (*e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but not including activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. The proposed definition was identical to the definition in § 1.227. We are finalizing the definition of ''packing'' as proposed, except that we are deleting the reference to the definition of ''raw agricultural commodity'' in section 201(r) of the FD&C because we are adding a definition of ''raw agricultural commodity'' to the rule, stating that the term means ''raw agricultural commodity'' as defined in section 201(r) of the FD&C Act. We note that, in general, packing means putting a product into a container that is distributed in commerce (*e.g.,* packing clamshell containers into a cardboard box for shipment), and does not include placing a product into a temporary container to move it, such as from a field to a packinghouse.

(Comment 272) Some comments state that the proposed definition of ''packing'' conflicts with practices used for seafood, especially molluscan shellfish. The comments maintain that activities such as sorting and culling are associated with harvesting for seafood, particularly molluscan shellfish. The comments ask that we revise the definition of ''packing'' to focus on activities associated with the first receiver KDEs to be more consistent with the seafood HACCP regulation.

(Response 272) We understand that industries handling different FTL foods sometimes use the same terms differently. The definition of ''packing'' we proposed is used in other FDA regulations, and we are finalizing it as proposed (except for the small edit described above, which matches other FSMA regulations that also define ''raw agricultural commodity'' separately) for consistency with those regulations. In response to comments, the final rule deletes proposed requirements associated with the first receiver of an FTL food; KDEs related to packing will need to be kept when an entity performs the initial packing of a RAC (other than a food obtained from a fishing vessel) (see Section V.K of this document). As the comment mentions molluscan shellfish, we note that the final rule includes an exemption for certain raw bivalve molluscan shellfish (§ 1.1305(f)).

26. Person

We proposed to define ''person'' as it is defined in section 201(e) of the FD&C Act, *i.e.,* as including an individual, partnership, corporation, and association. We are finalizing the definition of ''person'' as proposed.

(Comment 273) Some comments request that we reconsider using ''person'' to describe both people and companies. One comment asks how ''person'' applies to multi-location corporations.

(Response 273) We decline to revise the definition of ''person,'' which is a term and definition used in the subpart J regulation and throughout the FD&C Act. Because persons who manufacture, process, pack, or hold FTL foods under § 1.1300 of the final rule could include both individuals and companies, it is appropriate that the definition include individuals along with partnerships, corporations, and associations. Multi-location corporations might have different corporate structures and practices, and the final rule includes flexibility to account for this fact. For example, a multi-location corporation may choose to maintain all of the required records associated with its various branches in a central location, as long as such records can be provided to FDA within 24 hours of request for official review (see § 1.1455(c)(2)). We also note that, as discussed in Response 276, the final rule specifies that ''shipping'' includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

27. Physical Location Name

We proposed to define ''physical location name'' to mean the word(s) used to identify the specific physical site of a business entity where a particular critical tracking event occurs. The definition further stated that a physical location name might be the same as an entity's business name if the entity has only one physical location. We did not receive any comments on

this definition, but we received comments about the proposed definition of ''location description,'' which included the phrase ''physical location name.'' As discussed previously, we have deleted ''physical location name'' as a component of ''location description'' and are therefore deleting the definition of ''physical location name'' from the rule.

28. Point of Contact

We proposed to define ''point of contact'' as an individual having familiarity with an entity's procedures for traceability, including their name, telephone number, and, if available, their email address and Fax number. As explained below, we have made changes to the definition of ''point of contact'' in response to comments.

(Comment 274) Many comments express concern about proposed provisions requiring the identification of a point of contact. Some comments maintain that, with employee turnover rates, requiring an individual's name for the point of contact would increase costs and paperwork burden, introduce an opportunity for updating errors, and create privacy issues in sharing the information. Some comments maintain that requiring names and phone numbers of points of contact to be passed through the entire chain puts individuals at unnecessary risk for the compromise of their privacy, and could potentially make them an information target for a criminal organization and raise liability concerns if such an individual is targeted for information after a data breach of information stored by a downstream entity. Some comments acknowledge the importance of maintaining a record of the point of contact but maintain that this information is not currently communicated within most of the produce industry, and the comments request guidance on feasible options to demonstrate compliance with this requirement. Many comments oppose the proposed requirements to provide a point of contact for the lot code generator, stating that sharing this information may disclose confidential information about a firm's suppliers. Some comments ask that we provide additional justification to explain the benefit of including a point of contact requirement, asserting that it is unnecessary to have the name of the individual responsible for a covered entity's traceback program for FDA to perform an efficient traceback. Other comments ask that we provide more flexibility to allow firms to determine the best way to provide information on the designated point of contact. These comments recommend changing the definition of ''point of contact'' to allow for reference to a job title or a more general reference to a responsible individual, rather than stating an individual's name.

(Response 274) We appreciate the comments' concerns about the privacy of individuals serving as a firm's point of contact. To address these privacy concerns, we have deleted proposed requirements for firms to provide point of contact information to other entities in the supply chain. In the final rule, the only requirements regarding a point of contact are in the traceability plan (which is not shared with other entities in the supply chain) (§ 1.1315(a)(4)) and in the procedures for requesting a waiver for an individual entity (§ 1.1415(a)).

To further address the concerns raised in the comments, we have revised the definition of ''point of contact'' to mean an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and phone number. We conclude that providing a job title in place of (or in addition to) an individual's name allows firms to provide essential point of contact information without infringing on the privacy of employees and provides flexibility for firms to decide how best to identify the individual or individuals who have familiarity with the firm's procedures for traceability.

On our own initiative, we have removed the proposed requirement to provide the email address and Fax number for the point of contact. The proposed requirement was to provide these pieces of information ''if available,'' and we determined that neither was necessary. When reaching out to a point of contact, we will generally do so by phone, and at that point we can get any other contact information that is needed.

(Comment 275) Several comments recommend that the rule provide flexibility in the number of points of contact a firm can provide to fulfill a point of contact requirement, noting that some covered entities may have an entire team of people tasked with this responsibility.

(Response 275) We agree with the comments. As stated above, we are revising the definition of ''point of contact'' to allow for the use of job titles in place of (or in addition to) an individual's name. As noted in Response 450, we have deleted as unnecessary the use of ''(s)'' (indicating pluralization of terms as applicable) from all provisions in which we had proposed to include it (except with respect to the definition of ''retail food establishment,'' where we have retained it so that the definition is the same as in other FDA regulations).

29. Produce

We proposed to define ''produce'' as it is defined in § 112.3 in the produce safety regulation. We did not receive any comments on this definition and are finalizing it as proposed.

30. Product Description

We are deleting the proposed definition of ''traceability product description'' and replacing it with a definition of ''product description.'' The final rule defines ''product description'' to mean a description of a food product, which includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. The definition further states that for seafood, the product name may include the species and/or acceptable market name. We discuss comments on the proposed definition of ''traceability product description''—which are relevant to the definition of ''product description''—in Response 299.

31. Raw Agricultural Commodity

For clarity in understanding certain provisions of subpart S that include the term ''raw agricultural commodity,'' we are adding a definition of the term identical to that found in other FDA regulations, including the produce safety regulation. Thus, ''raw agricultural commodity'' means ''raw agricultural commodity'' as defined in section 201(r) of the FD&C Act.

32. Receiving

We proposed to define ''receiving'' as an event in a food's supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported (*e.g.,* by truck or ship) from another defined location. As discussed below, we are making several changes to the definition of ''receiving'' in response to comments.

(Comment 276) One comment supports specifying that ''receiving'' only involves receipt of food by a ''customer'' other than a consumer. On the other hand, several comments recommend changing ''customer'' to ''received by a different facility'' in the receiving definition. The comments maintain that the proposed rule's inclusion of ''customer'' in the definition of ''receiving'' makes it unclear whether the rule applies to shipments among different locations under a single corporate umbrella. One comment supports requiring records of intracompany movements under the

rule. The comment describes shipments of foods on the FTL from a retailer's distribution center to the retailer's stores, which the comment asserts might be excluded under the proposed rule because the ownership of the food does not change and the receiver is not a ''customer.'' The comment claims that this would create a serious gap in traceability. To avoid this potential, the comment recommends revising the definition of ''receiving'' to clarify that product movement is between distinct or noncontiguous physical locations, regardless of ownership.

Conversely, several comments request that FDA exempt from the final rule intracompany shipments of food, such as shipments between manufacturers and internal warehouses and shipments between manufacturers and third-party warehouses under the same company's control. The comments assert that intracompany shipments do not provide necessary traceback information because the records do not contain either the supplier or the customer of the food. Further, the comments state that additional recordkeeping is not needed for intracompany movements because they would already be captured in a company's one-up, one-back records because, according to the comments, subpart J has a relevant exemption that is narrowly focused on vertically integrated companies. A few of the comments request that food transported between facilities owned or controlled by the same company be excluded from maintaining shipping and receiving records, provided a record is maintained of all locations where the product was stored or produced. The comments argue that recordkeeping would be challenging due to the frequency of intracompany movement of food, would require entities to maintain redundant records, and would force companies to maintain electronic recordkeeping. Another comment asserts that a new traceability lot code should not be required when an ingredient is transferred from one site to another within the same company. One comment recommends that the final rule exclude movements between entities that are ''under the ownership or operational control of a single legal entity which may establish and maintain traceability records in conformance with common, integrated, written procedures,'' to be consistent with the sanitary transportation of human and animal food regulation exemption for intracompany food shipments.

(Response 276) We decline to exempt intracompany shipments from the final rule. We generally agree with the comments that are concerned that failure to record certain intracompany movements of food could create the potential for gaps in traceability, and we have revised the definition of ''receiving'' to address this concern. First, we have deleted the reference to ''customer'' so that receiving is now defined as an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (*e.g.,* by truck or ship) from another location. Second, we have added to the definition a statement that receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm. Under the revised definition, the example provided in the comment of movement of an FTL food between a retailer's distribution center to the retailer's stores would be considered a receiving event at the stores. If this were not the case, FDA would not be able to determine precisely which traceability lot codes were available for purchase at an RFE during a timeframe of interest. We would need to rely on receiving records at the distribution center and the firm's inventory practices, which might significantly expand the number of suspect traceability lot codes to be traced, increasing investigation time and reducing effectiveness.

Contamination of foods may occur at any point in the supply chain, including warehouses. Therefore, records of intracompany movements between warehouses are important for traceability and may help identify where contamination occurred. Relying on a firm's business practices, as some comments propose, rather than the KDEs required by the final rule may reduce traceback effectiveness and increase investigation time.

Movement of a food within a single location (at a particular street address) of a firm does not constitute receiving. Examples of movements within a location that would not be considered receiving events include the following: (1) moving received foods from the loading dock to the warehouse; (2) moving ingredients from storage to processing; and (3) moving foods from processing to the warehouse or shipping dock. Intracompany movements of ingredients would not require a new traceability lot code (§ 1.1320 describes the situations in which a traceability lot code must be assigned).

The final rule does not prescribe how firms should maintain records, only what information should be maintained. Electronic records of intracompany shipments are not required. Further, firms do not need to duplicate existing records, if those records contain some or all of the required information (§ 1.1455(f)); in addition, firms do not need to keep all of the required information in a single set of records (§ 1.1455(g)).

Finally, the goals of the food traceability regulation are different from the goals of the sanitary transportation regulation. Knowing where food has been is important for traceability. Therefore, we are not providing an exemption for intracompany food shipments.

(Comment 277) Comments in favor of excluding cross-docking from the rule argue in favor of including the word ''customer'' in the definition of ''receiving'' so as to exclude the cross-docking facility, which is not a ''customer.''

(Response 277) We have removed the word ''customer'' from the definition of ''receiving'' (see Response 276). We discuss handling of cross-docking under the final rule in Section V.E.20.g of this document and Response 244.

(Comment 278) One comment seeks clarification on whether the term ''receiving'' would apply to transporting RACs from the orchard or field to the packinghouse, because the grower often maintains ownership of the food and therefore there is no ''customer.''

(Response 278) While the term ''receiving'' as defined in subpart S could include movement of RACs from an orchard or field to a packinghouse at a different physical address, we have excluded such movements from the receiving CTE in the final rule. As discussed in Section V.N.3 of this document, § 1.1345(c) of the final rule specifies that § 1.1345 (concerning records to kept when receiving a food) does not apply to receipt of a food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

(Comment 279) One comment asks that we not consider receipt of a product at a third-party warehouse under the control of a given manufacturer to be a ''receiving'' event, maintaining that a requirement that the third-party warehouse assign a new traceability lot code when receiving an FTL food would not lead to efficient tracing.

(Response 279) We do not agree that receipt of an FTL food by a third-party warehouse should not be a ''receiving'' event. We conclude that having the third-party warehouse keep a record of its receipt of the food is necessary to ensure adequate traceability of the food.

However, we agree that the third-party warehouse should not assign a new traceability lot code to the food. The third-party warehouse's receipt of the food at its physical site would constitute ''receiving'' and would therefore be subject to the requirements in § 1.1345. However, a firm that receives an FTL food and only holds it at a location (and perhaps subsequently ships it from that location) generally may not give the food a new traceability lot code. The circumstances in which a firm may assign a traceability lot code are limited (see § 1.1320), and a firm may not assign a traceability lot code solely due to its receipt of a food unless it receives a food that has no traceability lot code from an entity that is exempt from the rule (see § 1.1345(b)(1)).

33. Reference Document

In partial response to comments about the proposed definition of ''reference record,'' which is discussed below, we are deleting that term from the rule and we are adding a definition of ''reference document.'' The final rule defines ''reference document'' to mean a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE in the supply chain of a food. The definition further states that a reference document may be established by a person or obtained from another person. The definition also states that reference document types may include, but are not limited to, BOLs, POs, ASNs, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.

34. Reference Document Number

Consistent with the change from ''reference record'' to ''reference document,'' we are deleting the proposed definition of ''reference record number'' as described below, and adding a definition of ''reference document number'' to mean the identification number assigned to a specific reference document. The proposed definition of ''reference record number'' had included similar language and had also provided the examples of a PO number, BOL number, or work order number. We have deleted these examples from the definition of ''reference document number'' because examples of reference documents are provided in the definition of ''reference document.'' We note that, in addition to being KDEs for certain CTEs, reference document numbers might be used in an electronic sortable spreadsheet requested by FDA in accordance with § 1.1455(c)(3) to indicate the particular reference documents that contain information included in the spreadsheet.

35. Reference Record

We proposed to define ''reference record'' as a record used to identify an event in the supply chain of a food, such as a shipping, receiving, growing, creating, or transformation event. The proposed definition further stated that types of reference records include, but are not limited to, BOLs, POs, ASNs, work orders, invoices, batch logs, production logs, and receipts.

As discussed above, in the final rule we are replacing the term ''reference record'' with ''reference document.'' We are also changing the definition in response to comments, as discussed below.

(Comment 280) One comment suggests adding ''movement documents'' to the definition's list of types of reference records to provide flexibility to allow companies to use existing records to meet the requirements of the rule.

(Response 280) We decline to make this change because we are not certain that ''movement document'' is a widely used term in the food industry. However, the list of types of reference documents in the definition of ''reference document'' is non-exclusive, and firms may use a movement document or any other type of document as a reference document under the rule.

(Comment 281) One comment states that the proposed definition of ''reference record'' may preclude commonly used data exchange standards from GS1, including the Global Data Synchronization Network (GDSN), Electronic Product Code Information Services (EPCIS), and Electronic Data Interchange (EDI). The comment asserts in this regard that section 204(d) of FSMA requires FDA to adopt approaches that are ''practicable'' and ''reasonably available and appropriate.''

(Response 281) We do not agree that the definition of ''reference document'' (previously ''reference record'') precludes the use of GS1-related documents as reference documents. As previously stated, the definition's listing of types of documents that can serve as reference documents is not exhaustive. Moreover, in changing from the term ''reference record'' to ''reference document,'' we have revised the definition to make clear that a reference document may be a business transaction document, record, or message, and may be in electronic or paper form; the definition also specifies that a person subject to the rule may establish a reference document or use one that has been provided to them by someone else. As discussed in Section V.R of this document, the final rule neither prescribes nor excludes the use of specific technologies for maintaining required records or providing required information to subsequent recipients.

36. Reference Record Number

We proposed to define ''reference record number'' as the identification number assigned to a reference record, such as a PO number, BOL number, or work order number. We received no comments on the definition but have replaced the term ''reference record number'' with ''reference document number'' in the final rule, and have revised the definition as described above.

37. Restaurant

We are adding a definition of ''restaurant'' as it is defined in the food facility registration regulation (§ 1.227). The definition states that ''restaurant'' means a facility that prepares and sells food directly to consumers for immediate consumption. The definition further states that ''restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. The definition also specifies that the following are restaurants: (1) entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens; and (2) pet shelters, kennels, and veterinary facilities in which food is provided to animals.

See our responses to the comments on the proposed definition of ''retail food establishment'' for an explanation of the addition of a definition for ''restaurant.''

38. Retail Food Establishment

We proposed to define ''retail food establishment'' as it is defined in the food facility registration regulation (§ 1.227), *i.e.,* as an establishment that sells food products directly to consumers as its primary function. The definition further specified the following:

- The term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers;

• an RFE's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers;

• the term ''consumers'' does not include businesses;

• a ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations; and

• a ''retail food establishment'' also includes certain farm-operated businesses selling food directly to consumers as their primary function.

The proposed definition of ''retail food establishment'' further specified that the sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers in the following circumstances:

• at a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

• through a CSA program. CSA program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

• at other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

The proposed definition further stated that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers in the same circumstances specified with respect to sale of food directly to consumers from an establishment located on a farm.

The proposed definition further stated that for the purposes of the definition, ''farm-operated business'' means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

We are finalizing the definition of ''retail food establishment'' without change.

(Comment 282) One comment asks if retail chains with in-store food production meet the definition of an RFE under subpart S.

(Response 282) If a retail chain store sells food products directly to consumers as its primary function, then it meets the definition of ''retail food establishment.'' We are aware that many RFEs, such as grocery stores, have in-store food production. As discussed in Section V.O.3 of this document, § 1.1350(c) of the final rule provides that the recordkeeping requirements for the transformation of foods do not apply to RFEs and restaurants with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers).

(Comment 283) One comment asks whether CSA programs are included in the definition of ''retail food establishment.''

(Response 283) The definition of ''retail food establishment'' specifies that a ''retail food establishment'' includes certain farm-operated businesses selling food directly to consumers as their primary function. The definition of ''retail food establishment'' further specifies that the sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers through a CSA program, and that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers through a CSA. The definition further states that a CSA program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season.

(Comment 284) One comment asks whether the definition of ''retail food establishment'' includes distribution centers.

(Response 284) If a distribution center sells food products directly to consumers as its primary function and otherwise meets the above-stated definition of ''retail food establishment,'' it would be an RFE for purposes of the subpart S requirements. However, we believe it is likely that many distribution centers would not meet this definition because most function to distribute food to wholesale or retail locations as a primary function, rather than sell food directly to consumers.

(Comment 285) Many comments request clarification about whether restaurants are included in the definition of ''retail food establishment.'' Several comments recommend including restaurants, online food retailers, and meal kit delivery companies in the definition of ''retail food establishment,'' noting that we said in the preamble to the proposed rule that we consider those operations to be RFEs. The comments also note that the FDA Food Code includes restaurants in the definition of ''food establishment,'' and maintain that including restaurants in the definition of ''retail food establishment'' would be consistent with the retail model code. Some comments assert that issues have arisen in successfully tracing product in the ''last mile,'' which includes many types of retail operations, and therefore maintain that it is critical to include such operations in the definition of ''retail food establishment.''

(Response 285) We agree that it is important for restaurants to be covered by subpart S, and we recognize that many commenters were confused by the fact that restaurants were not mentioned in the codified of the proposed rule. However, we decline to add restaurants to the definition of a ''retail food establishment.'' We note that ''restaurant'' is a term that is defined separately from ''retail food establishment'' in the food facility registration regulation (see § 1.227), and that it is also independently defined in subpart J (see § 1.328). Therefore, to be consistent with other FDA regulations, we are adding a definition of restaurant to § 1.1310 (as described above), and we are maintaining the proposed definition of ''retail food establishment.'' We think this will achieve the clarity that commenters sought regarding the application of subpart S to restaurants. The final rule applies relevant provisions such as exemptions and CTE requirements to both RFEs and restaurants in exactly the same manner, using the phrase ''retail food establishments and restaurants.''

As noted in the comment, the definition of ''food establishment'' in the FDA Food Code is different from the definition of ''retail food establishment'' used in § 1.227. We are considering how to address this difference, but in the meantime we conclude that it is appropriate to align subpart S with the existing definitions of ''retail food establishment'' and ''restaurant'' in other FDA regulations.

Regarding the request to add online food retailers and meal kit delivery companies to the definition of ''retail food establishment,'' we have concluded that this revision is not necessary. We note that the definition already explicitly addresses sales from establishments located on farms and sales by farm-operated businesses on direct-to-consumer sales platforms, including door-to-door sales and mail,

catalog, and internet order, including online farmers' markets and online grocery delivery (see above and at § 1.1310). More generally, facilities that sell food directly to consumers via the internet or mail-order may be RFEs, provided they meet the other criteria of the ''retail food establishment'' definition in § 1.227 (see Ref. 26).

39. Shipping

We proposed to define ''shipping'' as an event in a food's supply chain in which a food is arranged for transport (*e.g.,* by truck or ship) from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver. The definition further stated that shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. As explained below, we have changed the definition of ''shipping'' in the final rule.

(Comment 286) A comment requests that we clarify the definition of shipping and revise it to include the idea that it is movement of food from a defined location to a customer, similar to the proposed definition of ''receiving.''

(Response 286) We decline to make this change. As stated in Response 276, we have deleted the reference to a ''customer'' in the definition of ''receiving'' because it caused confusion with respect to the application of the receiving CTE requirements to intracompany shipments. Consequently, we conclude that it would not be appropriate to add a similar reference to a ''customer'' in the ''shipping'' definition. We also revised the definition of ''shipping'' to reflect changes we are making to CTE requirements, including deletion of the proposed requirements for the first receivers of FTL foods. Thus, the revised definition specifies that ''shipping'' means an event in a food's supply chain in which a food is arranged for transport (*e.g.,* by truck or ship) from one location to another location. Finally, consistent with another change we made to the definition of ''receiving'' concerning intracompany shipments, we have revised the definition of ''shipping'' to specify that it includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

(Comment 287) One comment asks that we clarify whether retailers who donate food need to capture traceability information.

(Response 287) The definition of ''shipping'' in § 1.1310 specifically states that shipping does not include the donation of surplus food. Therefore, retailers who donate food do not need to document any traceability information relating to the donation. However, they may need to document information relating to their receipt of the food, unless another exemption applies.

(Comment 288) One comment seeks clarification that shipping CTE requirements do not apply to RACs shipped from the field or orchard to the packinghouse.

(Response 288) As discussed in Section V.M.3 of this document, the shipping CTE requirements do not apply to shipment of a RAC that occurs before the RAC is initially packed (see § 1.1340(c)).

(Comment 289) Some comments ask that we use consumer data and reviews to help us conduct outbreak investigations. One comment suggests that all food industry and regulated partners be required to submit customer loyalty information and/or credit card information to assist in the notification of customers who have purchased products involved in outbreak investigations. One comment expresses concern that we have substantially downplayed the utility of consumer-specific data. The comment asserts that tracking lot numbers purchased by individual consumers is not currently practical but asks that we encourage industry, both conventional and e-commerce, to capture and voluntarily submit consumer-specific data, such as customer loyalty or credit card information. The comment asks that firms that currently maintain this information not be inadvertently penalized or disproportionately targeted because they have this information.

(Response 289) As stated in the preamble to the proposed rule (85 FR 59984 at 59992), we support efforts by retailers to identify and provide us with anonymized consumer purchase data during our investigations into foodborne illness outbreaks. We agree that such information can be very helpful in narrowing the scope of an investigation and more quickly identifying the source of contamination. We do not target or penalize firms that maintain this information; rather, we encourage firms to make available any relevant consumer data they might have. However, as stated in the preamble to the proposed rule (85 FR 59984 at 60003), we believe that it would be too burdensome to require retail facilities to keep traceability records of sales to consumers, and we conclude that it not essential that we have access to such records to effectively respond to threats to public health posed by outbreaks. Therefore, the final rule does not require records of sales to consumers. A sale of an FTL food to a consumer does not constitute a shipping event (even if the sale involves transport of the food, as with sales made over the internet), because the definition of ''shipping'' in § 1.1310 specifies that shipping does not include the sale or shipment of a food directly to a consumer.

40. Traceability Lot

We proposed to define ''traceability lot'' as a lot of food that has been originated, transformed, or created. As explained below, we have revised the definition of ''traceability lot'' to align with changes we have made to the proposed CTE requirements.

(Comment 290) Some comments suggest that the definition of ''traceability lot'' is easily confused with the definition of ''lot.'' The comments express concern that the recordkeeping requirements will be overly burdensome if FDA is not specific about the expectations for maintaining records based on a lot or traceability lot of an FTL food.

(Response 290) We recognize that proposing separate definitions for ''lot'' and ''traceability lot'' caused confusion among many commenters. We have therefore deleted the definition of ''lot'' from the rule and changed the definition of ''traceability lot'' to refer to either a batch or lot of food. We have also revised the definition to align with changes to the rule regarding when a traceability lot code must be assigned (see § 1.1320). The revised definition states that a traceability lot is a batch or lot of food that has been initially packed (for RACs other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

(Comment 291) One comment asks how many fish from multiple fishing vessels can be used in one finished-product lot. Several comments request guidance on how a lot should be created to encourage uniformity across industry.

(Response 291) The rule places no limits on how much of an FTL food can be put into a lot, or how many different sources (including different fishing vessels) the food can be from. (See Section V.E.9 of this document for a discussion of commingling RACs, including RACs obtained from fishing vessels.) We believe industry should have the flexibility to determine how to create traceability lots in a manner that works best for their operations. This approach is consistent with the approach to the creation of lots under the regulation on preventive controls for human food.

41. Traceability Lot Code

We proposed to define ''traceability lot code'' as a descriptor, often alphanumeric, used to identify a traceability lot.

(Comment 292) Several comments suggest that the term ''traceability lot code'' be replaced by another phrase to indicate its special status and avoid use of the word ''lot,'' maintaining that the concept of ''lot'' already has varied usage and might cause confusion. One comment suggests using the term ''traceability code'' instead of ''traceability lot code.''

(Response 292) We disagree with the comments. The traceability lot code, assigned to a traceability lot of a food on the FTL, is the key to the subpart S traceability framework because it is the piece of information to which the other KDEs for a traceability event are linked. While we are providing flexibility for industry to determine how to create traceability lots in a way that work best for their operations, we think that the concept of a ''lot'' is well understood within industry (as is the concept of lot-based traceability), and we want our terminology to communicate that the traceability lot code is assigned to a specific lot (*i.e.,* the traceability lot) of the food. Therefore, we believe it is important to retain the reference to a ''lot'' in the definition. In addition, to improve a traceability lot code's ability to help identify a particular FTL product, and in response to comments suggesting that the traceability lot code be globally unique (see Response 507), we have revised the definition of ''traceability lot code'' to state that it is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source (*i.e.,* the place where the traceability lot code was assigned to a food).

(Comment 293) One comment requests that we clarify that a lot code, batch code, or production code for a food on the FTL can be the traceability lot code if it meets the definition of a traceability lot code.

(Response 293) We agree that a lot code, batch code, or other production code for an FTL food could be used as a traceability lot code if it meets the definition of ''traceability lot code'' stated above.

(Comment 294) One comment suggests that the definition of ''traceability lot code'' account for the activity of harvesting, as lots are identified when a product is harvested.

(Response 294) We decline to make this revision. We acknowledge that lots are sometimes identified at the point of harvesting; however, we received several comments stating that RACs are most often assigned lot codes at initial packing. Therefore, § 1.1320 of the final rule requires that a traceability lot code be assigned when a person initially packs a RAC other than a food obtained from a fishing vessel, performs the first land-based receiving of a food obtained from a fishing vessel, or transforms a food. Under the final rule, lot-based recordkeeping is not required at harvest or at any point before the initial packing (or first land-based receiving) of a RAC. This topic is further discussed in Section V.J of this document.

(Comment 295) One comment recommends that we consider FDA Establishment Identifier numbers, Food Facility Registration Numbers, or DUNS numbers as alternatives to traceability lot codes under the subpart S requirements.

(Response 295) As previously stated, a traceability lot code is a descriptor that must uniquely identify a traceability lot within the records of the traceability lot code source. If a firm chooses to create traceability lot codes incorporating numbers assigned by FDA or DUNS, they may do so, provided the resulting code meets the definition of a ''traceability lot code,'' including that the code uniquely identifies a particular lot within the firm's tracing records.

42. Traceability Lot Code Generator

We proposed to define ''traceability lot code generator'' as the person who assigns a traceability lot code to a product. We received several comments expressing confusion about the concept of a ''generator'' of a traceability lot code and concern about providing information identifying the traceability lot code generator to customers (see Response 412). As explained below, for clarity in the final rule, we have replaced the term ''traceability lot code generator'' with the term ''traceability lot code source.''

(Comment 296) Several comments maintain that the proposed rule puts too much emphasis on the traceability lot code generator and suggest that there is confusion around capturing information about the ''person'' that assigned the traceability lot code to a product.

(Response 296) We agree that, with respect to the assignment of traceability lot codes, the focus for traceability should be on the place where the code was assigned, rather than the specific individual or entity who assigned the code. Because the traceability lot code is an integral component of the subpart S traceability requirements, it is important to document the physical location where the traceability lot code for an FTL food was assigned. During outbreak situations, this will allow FDA to more quickly identify this location and prioritize where we need to collect tracing data, which in turn will help us more quickly identify the origin of contaminated food. Therefore, we conclude that it is appropriate to replace the term ''traceability lot code generator'' with ''traceability lot code source,'' which we define as the place where a food was assigned a traceability lot code. Unless the relevant entity is exempt from the rule, the traceability lot code source will be the place where the food was initially packed (for RACs not obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

(Comment 297) One comment requests clarity about who is considered the traceability lot code generator in situations of contract manufacturing. Specifically, the comment asks whether the contract manufacturer or the entity that initiated the contract should be regarded as the traceability lot code generator.

(Response 297) As discussed above, in the final rule we have replaced the term ''traceability lot code generator'' with the term ''traceability lot code source.'' If the contract manufacturer made the FTL product at their facility, that facility would be the traceability lot code source for the food, consistent with the definition of ''traceability lot code source'' stated above (which refers to the ''place'' where a traceability lot code was assigned).

(Comment 298) Some comments maintain that for businesses that use random number generators to assign lot codes, a requirement to name the individual who assigned a traceability lot code would be superfluous.

(Response 298) As previously stated, we agree that it is unnecessary to keep a record of the identity of the individual who assigned a traceability lot code to the food. Instead, firms must document the place where the traceability lot code was assigned, *i.e.,* the traceability lot code source.

43. Traceability Lot Code Source

As stated above, we are replacing the term ''traceability lot code generator'' with the term ''traceability lot code source.'' The final rule defines ''traceability lot code source'' to mean the place where a food was assigned a traceability lot code. Unless the relevant entity is exempt from the rule, this will be the place where the food was initially packed (for RACs not obtained from a fishing vessel), first processed on land

(for food obtained from a fishing vessel), or transformed.

44. Traceability Lot Code Source Reference

We are adding a definition of ''traceability lot code source reference.'' The final rule defines ''traceability lot code source reference'' to mean an alternative method for providing FDA with access to the location description for the traceability lot code source as required under subpart S. The definition goes on to state that examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source. If a firm uses a web address as the traceability lot code source reference, the associated website may employ reasonable security measures, such as only being accessible to a government email address, provided FDA has access to the information at no cost and without delay. We are adding this definition and provisions concerning the use of traceability lot code source references in response to comments expressing concern about data privacy associated with the provision of information on the traceability lot code generator (now the traceability lot code source) (see Section V.M of this document).

45. Traceability Product Description

We proposed to define ''traceability product description'' as a description of a food product typically used commercially for purchasing, stocking, or selling, and as including the category code or term, category name, and trade description. The definition further stated that for single-ingredient products, the trade description includes the brand name, commodity, variety, packaging size, and packaging style; for multiple-ingredient food products, the trade description includes the brand name, product name, packaging size, and packaging style. As previously stated, we are deleting the term ''traceability product description'' and replacing it with the term ''product description.'' In response to the comments on the proposed definition of ''traceability product description,'' we made changes that are incorporated into the definition of ''product description'' in the final rule.

(Comment 299) Several comments urge FDA to simplify the requirements for the traceability product description. The comments suggest that the traceability product description is unnecessary for tracing, contains information not currently used, and is redundant and irrelevant to food traceability. One comment suggests that category code or term and category name (which are part of the proposed definition of ''traceability product description'') should be optional. This comment recommends that much of the information under a traceability product description be required only as applicable.

(Response 299) We agree that not all of the information included in the proposed definition of ''traceability product description'' is needed, and we have simplified the definition of ''product description'' in the final rule. As discussed below, we have removed the requirement for information on ''category'' as part of the product description and we have removed the distinction between information needed for single-ingredient products and multi-ingredient products. To address differences between these types of products, the definition of ''product description'' in the final rule specifies that the product name includes the brand name, commodity, and variety ''if applicable'' (because, for example, a multi-ingredient product might not have a commodity or variety name).

Although we have simplified the information required under a product description, we do not agree that information fully describing an FTL product is irrelevant to tracing, because it provides information we need to be able to conduct traceback investigations and accurately identify the source of contaminated food. Therefore, the final rule includes requirements to keep a record of the product description as one of the KDEs for several traceability events. The final rule uses the term ''product description'' rather than ''traceability product description'' to eliminate potential confusion regarding the use of a new term. The final rule defines ''product description'' to mean a description of a food product and to include the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. The definition further states that for seafood, the product name may include the species and/or acceptable market name.

(Comment 300) Some comments recommend adding the GS1 Global Trade Item Number (GTIN) to the traceability product description and seek clarification of the concept of ''category'' as a component of the description.

(Response 300) Having reconsidered the components of the proposed definition of ''traceability product description,'' we conclude that it is not necessary to include a product's category code/term or category name as part of a product description. Regarding the suggestion to add a GTIN to the product description, we do not believe that would be appropriate because GTINs are not universally used in the food industry. However, a firm that uses GTINs may choose to include that information as part of their product description. This could be done either by adding it to the required information, or by using it as a shorthand for some or all of the required information, provided that a glossary or key is maintained (and, if necessary, shared) to indicate the full product description that corresponds to the GTIN.

46. Traceability Product Identifier

We proposed to define ''traceability product identifier'' as a unique identification code (such as an alphanumeric code) that an entity assigns to designate a specific type of food product. As explained below, we are deleting this definition from the final rule.

(Comment 301) One comment requests examples of the traceability product identifier and asks if we meant numbers such as a GTIN or an Internal Item Number. The comment asserts that the need for uniqueness would be a concern, particularly to prevent duplication with traceability product identifiers assigned by other covered entities.

(Response 301) The final rule does not include a definition of ''traceability product identifier'' because we have deleted the proposed requirements to establish a product identifier for an FTL food for certain CTEs. In the proposed rule, we included a traceability product identifier, along with the traceability product description, as important descriptive information for FTL foods to help us during tracebacks, because different firms often use different names for the same product (*e.g.,* ''Maradol papayas'' instead of ''papayas''). However, in response to comments requesting that we simplify the KDEs, we conclude that it is not necessary to require firms to keep a product identifier for a food to ensure that there is adequate information for efficient traceability (see Section V.M.1 of this document).

(Comment 302) One comment asks that we revise the definition of traceability product identifier to allow covered entities to describe the relationship between different packaging configurations of the same product. The comment maintains that current industry standards enable firms to declare a relationship between

consumer-ready packaging and higher levels of packaging used to transport the consumer-ready packages through the supply chain to RFEs. The comment asserts that this ability to determine the parent/child relationship between product identifiers is important for tracking the movement of products.

(Response 302) As previously stated, we have deleted the proposed requirements to keep a record of the traceability product identifier for FTL foods. However, if the product hierarchy described in the comment is an important component of a firm's traceability records, the firm may wish to include product identifier information as part of the product descriptions it keeps for FTL foods the firm handles.

(Comment 303) One comment maintains that for molluscan shellfish the unique product identifier would be the same as the product description.

(Response 303) As stated in Response 301, we have deleted the definition of traceability product identifier as well as all of the proposed requirements to keep a record of a product identifier. We also note that, as discussed in Section V.E.7 of this document, the final rule exempts certain raw bivalve molluscan shellfish from the subpart S requirements.

47. Transformation

We proposed to define ''transformation'' as an event in a food's supply chain that involves changing a food on the FTL, its package, and/or its label (regarding the traceability lot code or traceability product identifier), such as by combining ingredients or processing a food (*e.g.,* by cutting, cooking, commingling, repacking, or repackaging). The definition further stated that transformation does not include the initial packing of a single-ingredient food or creating a food. In the final rule, we have combined the proposed CTEs of ''transformation'' and ''creating'' into a single ''transformation'' CTE and revised the definition of ''transformation'' accordingly, as discussed in response to the following comments.

(Comment 304) One comment maintains that the proposed definition of ''transformation'' is well defined and aligns with current industry practices. However, several comments recommend that we recognize that creation and transformation are essentially the same and that any differentiation is based solely on whether the foods used are on the FTL. These comments maintain that, with respect to the requirements for traceability lot code assignment and linkage, having to differentiate between creation and transformation could become complex for processors that have multiple manufacturing steps within their facilities that result in different products. These comments assert that current industry traceability standards designate all such activities as ''transformation.''

(Response 304) We conclude that it is appropriate to use the term ''transformation'' to cover both the activities we described in the proposed definition of that term as well as the activities described in the proposed definition of ''creating'' (see Section V.O of this document). Therefore, the final rule defines ''transformation'' as an event in a food's supply chain that involves manufacturing/processing a food or changing a food (*e.g.,* by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the FTL. The definition further states that transformation does not include the initial packing of a food or activities preceding that event (*e.g.,* harvesting, cooling). We conclude that this revised definition of ''transformation'' more closely aligns with current industry practices while helping to ensure that firms understand the recordkeeping requirements applicable to transformation activities.

(Comment 305) Several comments state that farms often repack produce from within the same lot and request that such repacking be excluded from the definition of ''transformation.'' The comments further ask that FDA clarify that repacking only takes place at ''facilities'' and not at ''farms.''

(Response 305) We decline to make the changes requested by the comments. Repacking whole fresh produce within one traceability lot is considered transformation under subpart S. Repacking whole fresh produce may introduce contamination, whether the repacking is done at a facility or a farm. (Though as previously stated, transformation does not include the initial packing of a RAC.) At the repacking stage, the traceability lot code can be changed or the traceability lot code of the original lot can be retained, but a new traceability lot code source would be required to identify the repacker, and the KDEs identified in § 1.1350 would need to be maintained.

(Comment 306) One comment asks FDA to reconsider treating repackaging of molluscan shellfish as a transformation event. The comment suggests that repackaging could involve dividing a traceability lot into smaller traceability lots. The comment asserts that applying transformation recordkeeping requirements to repackaging would impose a significant recordkeeping burden and impair traceability by introducing potential errors.

(Response 306) We decline to revise the definition of ''transformation'' as requested. We consider repackaging (and repacking) to be transformation events under subpart S because repackaging and repacking may introduce contamination, and because in many situations they have the potential to impede traceability by dividing one lot into several lots, or by commingling lots. Regarding the repackaging of molluscan shellfish (most of which are likely exempt from the rule under § 1.1305(f)), a traceability lot code could have been assigned by the initial packer or first land-based receiver of the shellfish at one facility and then again during repacking at another facility, in accordance with § 1.1320 of the final rule. At the repacking stage, the traceability lot code can be changed or the traceability lot code of the original lot can be retained (assuming there has been no commingling of lots), but a new traceability lot code source would be required to identify the repacker. If the second facility was not identified as the traceability lot code source for the repackaged product, an investigator might initially miss a potentially important node in a traceback investigation.

(Comment 307) One comment asks whether transformation KDEs are required following the breaking of a master case of product into smaller units, which the comment maintains is a common practice during foodservice distribution.

(Response 307) We understand that the breaking of a master case into smaller units is a common practice during food distribution. The breaking of a master case during foodservice distribution does not necessarily constitute transformation. If, as part of the breaking of the master case, the product is repacked or repackaged, then this would constitute transformation, as described in Response 305. However, if a distributor or other entity is simply breaking a master case (*e.g.,* a pallet containing 20 individual cases) into separate shipments (*e.g.,* 4 shipments of 5 cases each), this would not constitute transformation. In this instance, the distributor would only need to follow the requirements for shipping and receiving under §§ 1.1340 and 1.1345, respectively. Because no transformation event has occurred, the distributor would not keep transformation records under § 1.1350, nor would they assign a traceability lot code or become the traceability lot code source. If the pallet

contained cases associated with different traceability lot codes, the shipping records would use those traceability lot codes to indicate which traceability lots were shipped to which location.

(Comment 308) One comment expresses concern that changing a food label is within the definition of ''transformation.'' The comment supports a narrow interpretation of the changes to food labels that are regarded as transformation and maintains that changing the brand on a label should not be considered transformation.

(Response 308) We disagree with the comment. The final rule specifies that the brand name (if any) is a component of the product description of an FTL food, and changing a brand name on labeling would be transformation under the rule. We believe that including ''relabeling'' in the definition of ''transformation'' is consistent with current practice in much of the industry, for example for entities following the Produce Traceability Initiative (PTI) or GS1 GTIN standards.

48. Transporter

We proposed to define ''transporter'' as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air. We did not receive any comments on this definition and are finalizing it as proposed.

49. Vessel Identification Number

We proposed to define ''vessel identification number'' to mean the number assigned to a fishing vessel by the International Maritime Organization, or by any entity or organization, for the purpose of uniquely identifying the vessel. As discussed in Response 388, we are deleting proposed requirements to record the vessel identification number at certain CTEs, so we are deleting the definition of ''vessel identification number'' from the rule.

(Comment 309) One comment maintains that for molluscan shellfish, the rule should use the aquaculture lease number instead of the vessel identification number. The comment further states that aquaculture farms and wild harvesters of molluscan shellfish do not use boats, and that the harvest area or lease number would provide more useful information.

(Response 309) As discussed in Section V.E.7 of this document, the final rule exempts from subpart S raw bivalve molluscan shellfish that are covered by the requirements of the NSSP, subject to the requirements of part 123, subpart C, and § 1240.60, or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. For molluscan shellfish that are subject to subpart S, the final rule has no requirements to maintain a record of the vessel identification number.

(Comment 310) One comment agrees with the proposed definition of ''vessel identification number.'' One comment asks for clarification whether vessel identification numbers assigned by agencies other than the International Maritime Organization meet the requirements of the rule.

(Response 310) As stated above, because the final rule contains no requirements for the maintenance of vessel identification numbers, we are deleting the definition of ''vessel identification number'' from the rule.

50. You

We proposed to define ''you'' to mean a person subject to subpart S under § 1.1300. We did not receive any comments on this definition and have finalized it as proposed.

51. Comments Requesting Additional Definitions

We received comments requesting that the rule include definitions for additional terms. We decline to add these definitions, for the reasons set forth below.

(Comment 311) One comment asks that we provide additional clarity around use of the term ''broker'' in the rule. The comment maintains that use of the term ''broker'' is confusing because food brokers and customs brokers serve different functions.

(Response 311) Because the final rule does not include the word ''broker,'' there is no need to specify a definition of the term. The preamble to the proposed rule (85 FR 59984 at 60000) only mentioned brokers in the context of saying that food brokers who negotiate sales of food from producers to wholesalers, retail stores, and others but never physically possess the food would not be subject to the rule. This was just one example of how a person who does not take physical possession of an FTL food is not engaged in the holding of the food and therefore would not be subject to the rule.

(Comment 312) One comment requests that we include a definition of ''facility'' that is consistent with the definition of ''facility'' in other FSMA rules.

(Response 312) We decline to define the term ''facility'' in the final rule. As discussed in Section V.D of this document, although section 204(d)(1) of FSMA refers to ''facilities'' that manufacture, process, pack, or hold food, the final rule is phrased in terms of ''persons'' that manufacture, process, pack, or hold food, to avoid possible confusion with other uses of the term ''facilities'' in other FDA food regulations. Because the final rule does not include requirements that apply specifically to ''facilities,'' we conclude that it is not necessary to include a definition of ''facility'' in the rule.

(Comment 313) Several comments ask for a definition and clarification on the meaning and application of ''fresh-cut'' regarding activities that are considered part of harvesting, such as trimming, field coring, and washing, as compared to activities that are considered to take place after harvesting. The comments request that we clarify how processing activities that result in ''fresh-cut'' produce differ from those that are part of traditional harvesting, such as trimming and cutting.

(Response 313) Because the subpart S regulations do not refer to ''fresh-cut'' produce, there is no need to add a definition of ''fresh-cut'' to the rule. In the RRM–FT, we define fresh cut commodities based on FDA's ''Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry'' (*https://www.fda.gov/media/117526/download*), which states that ''fresh-cut produce'' means any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field. In addition, a description of the foods on the FTL is available on the FDA website to aid stakeholders in determining whether a specific food is covered.

(Comment 314) Several comments request that we define the terms ''owner,'' ''operator,'' and ''agent in charge'' or address these terms in guidance. One comment suggests that the rule define ''agent in charge'' as a person who is employed by or contracted by an entity, has responsibility for traceability recordkeeping, and is not necessarily the owner.

(Response 314) We decline these requests. The phrase ''owner, operator, or agent in charge'' is statutory language (in section 204(d)(6)(C) and (d)(6)(I)(ii) of FSMA) used in subpart S only in certain exemptions related to farms (§ 1.1305(b) and (j)) and fishing vessels (§ 1.1305(m)). Because this phrase ''owner, operator, or agent in charge'' is used frequently in the produce safety regulation, which applies to farms, and the term ''operator'' is used throughout FDA's ''Fish and Fishery Products Hazards and Controls Guidance'' (Ref. 23), we believe that the meaning of these terms is generally understood by

relevant covered entities. Therefore, we conclude that it is not necessary to add definitions of these terms to the rule.

(Comment 315) Some comments request that we add a definition of ''smoked'' to the rule.

(Response 315) We decline this request because the word ''smoked'' does not appear in the subpart S regulations. In the RRM–FT, we define smoked finfish based on FDA's ''Fish and Fishery Products Hazards and Controls Guidance,'' which has the same definition for ''smoked or smoke-flavored fishery products'' as that in the seafood HACCP regulation (§ 123.3(s)). We believe that relevant covered entities understand the term ''smoked.'' In addition, a description of the foods on the FTL is available on the FDA website to aid stakeholders in determining whether a specific food is covered.

(Comment 316) Several comments request that we define ''sprouts'' in the final rule.

(Response 316) We decline to define ''sprouts'' in the final rule. The produce safety regulation (part 112), which includes a sprout-specific section (subpart M), does not define the term ''sprouts.'' However, subpart M makes a distinction between soil- or substrate-grown sprouts harvested without their roots, and all other sprouts (see 21 CFR 112.141). Therefore, we believe that sprout growers will understand the use of the term ''sprouts'' in this final rule. We have clarified in the final rule that the sprout-specific provisions of § 1.1330(b) do not apply to soil- or substrate-grown sprouts harvested without their roots.

G. Traceability Plan (§ 1.1315)

In the provisions of proposed subpart S that are under the heading ''Traceability Program Records,'' we proposed to require entities subject to the rule to keep traceability program records for the FTL foods they handle (proposed § 1.1315), and we specified when entities must assign traceability lot codes to FTL foods (proposed § 1.1320). Proposed § 1.1315 stated that covered entities must establish and maintain records related to their traceability program. These records would include a description of the reference records in which the required information is maintained, an explanation of where on the records the required information appears, and if, applicable, a description of how reference records for different tracing events for a food are linked (proposed § 1.1315(a)(1)). We also proposed that required entities must establish and maintain a list of foods on the FTL that they ship, including the traceability product identifier and traceability product description for each food, and a description of how the entity establishes and assigns traceability lot codes to foods on the FTL they originate, transform, or create, as well as any additional information necessary to understand the data provided within any of the records required under subpart S, such as internal or external coding systems, glossaries, and abbreviations (proposed § 1.1315(a)(2) through (4)). We proposed that these traceability program records be retained for 2 years after their use is discontinued (proposed § 1.1315(b)).

To better capture the intent of this section and to align our approach with other FSMA regulations, we have revised § 1.1315 to set forth the requirements for a firm's ''traceability plan.'' Rather than describe the reference records that a firm uses to document required information, revised § 1.1315(a)(1) requires firms to describe their procedures for maintaining FTL records; and rather than maintaining a list of FTL foods shipped, revised § 1.1315(a)(2) requires firms to describe their procedures for identifying FTL foods they handle. In alignment with other changes we are making concerning requirements applicable to farms, revised § 1.1315(a)(5) requires persons who grow or raise an FTL food (other than eggs) to maintain a farm map as part of their traceability plan. These and other changes to proposed § 1.1315 are discussed in response to the comments set forth below.

1. General

(Comment 317) One comment asks that we require firms have a product tracing plan. The comment refers to the 2012 IFT Final Report (Ref. 1), which includes a recommendation that FDA require that each member of the food supply chain develop, document, and exercise a product tracing plan containing the following elements: identified CTEs and KDEs; identification of how information is recorded and linked; identified authorized points of contact; metrics for trace data reporting response times; and frequency of trace plan exercises and review. One comment recommends that the subtitle of ''Traceability Program Records'' (encompassing proposed §§ 1.1315 and 1.1320) should be renamed because, according to the comment, that terminology does not align with language used in other FSMA regulations, such as those for allergen control or supply chain verification.

(Response 317) We agree with the comments that it is appropriate for entities to have a traceability plan for the FTL foods they handle. As stated in the preamble to the proposed rule (85 FR 59984 at 60004), we believe it is important that firms be able to provide information on how they conduct their required traceability operations to help us understand the records we review in an outbreak investigation. To make this clear in the final rule, we have revised the subtitle ''Traceability Program Records'' to ''Traceability Plan,'' and we have revised § 1.1315(a) to state that if an entity is subject to the subpart S requirements, it must establish and maintain a traceability plan containing, as discussed below, a description of the procedures the firm uses to maintain its traceability records (including the format and location of the records), a description of the procedures used to identify foods on the FTL that the firm handles, a description of how the entity assigns traceability lot codes, a statement identifying a point of contact for questions regarding the traceability plan and records, and, if the entity grows or raises foods on the FTL (other than eggs), a farm map. In addition, the final rule requires entities to update their traceability plans as needed to ensure that the information provided reflects the entity's current practices and to ensure compliance with subpart S (see Section V.F.8 of this document). The previous plan must be retained for 2 years after any updates (§ 1.1315(b)).

(Comment 318) Several comments ask if the proposed traceability program records requirements would apply to each SKU, ingredient, or commodity.

(Response 318) As stated in Response 317, § 1.1315(a) of the final rule requires covered entities to establish and maintain a traceability plan containing information relating to their traceability procedures. Persons subject to subpart S are not required to have a separate plan for each food on the FTL they handle; instead, they can have a single plan that covers all FTL foods they handle, provided that the plan describes, among other things, the procedures used to maintain the records required to be kept for all such foods.

(Comment 319) One comment asks how the requirement to establish and maintain traceability program records would be applied to foreign exporters and establishments.

(Response 319) The subpart S requirements apply to all entities, domestic and foreign, that manufacture, process, pack, or hold foods on the FTL (unless an exemption applies). Thus, foreign exporters and other firms that manufacture, process, pack, or hold FTL foods will be required to maintain a traceability plan under § 1.1315 of the final rule.

2. Description of Procedures Used To Maintain Records

(Comment 320) Several comments request clarity on the requirement in proposed § 1.1315(a)(1) to maintain a description of the reference records in which information required under subpart S is maintained. One comment supports the flexibility FDA provided in allowing covered entities to use whatever reference record suits their operations (*e.g.,* BOLs, ASNs) rather than requiring that information be maintained in a particular record.

(Response 320) As stated in section V.F.33 of this document, elsewhere in the final rule we have replaced the term ''reference record'' with ''reference document,'' which the final rule defines as a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE in the supply chain of a food. In addition, to address confusion about the meaning (in proposed § 1.1315(a)(1)) of a ''description of the reference records'' in which a firm keeps information required under the rule, we conclude that the focus of a firm's traceability plan should be on the *procedures* it uses to maintain records required under subpart S. Therefore, we have deleted from § 1.1305(a)(1) the proposed requirement to describe the reference records a firm uses; instead, § 1.1305(a)(1) requires that an entity's traceability plan include a description of the procedures the entity uses to maintain the records it is required to keep under subpart S, including the format and location of these records. Under § 1.1305(a)(1), firms will not need to identify each reference document it has used to record the KDEs of each CTE for each FTL food it handles, but rather to describe the general recordkeeping procedures it follows in meeting its subpart S requirements, including the format in which it keeps these records and where they are stored. Information on the format and location can include, for example, a description of the electronic system of FTL records that contains the KDEs, if that is the firm's practice. As another example, information on the format and location may include a description of the firm's receipt and storage of business documents as FTL records, or practice of scanning or data entry from such records that contain the KDEs, if that is the firm's practice.

(Comment 321) One comment requests that the final rule clarify how reference records for different CTEs are linked and whether records must be linked electronically. The comment suggests that linking be defined as the ability of a covered entity to use information on one record to identify additional relevant records. Another comment opposes the proposed requirement to describe how the reference records used for different tracing events are linked because two firms might assign different lot codes to a product shipment that are not connected by records to the incoming product.

(Response 321) As stated in Response 320, we are deleting the proposed requirement to describe reference records used and to describe how reference records for different tracing events are linked. The final rule does not require that the traceability plan include a description of how reference documents for different CTEs for an FTL food are linked. However, the provisions applicable to each CTE require entities to link the required KDEs for the event (including the traceability lot code) to the particular traceability lot. Because the traceability lot code is documented at each CTE, these requirements will enable FDA to effectively trace a specific traceability lot across multiple CTEs.

Although the final rule does not define ''linking,'' we agree with the comment that linking can involve connecting information about a CTE that appears on one record with another record that contains other KDEs for that event or with a record that contains KDEs for the next event in the supply chain. For all CTEs, the final rule requires firms to maintain records containing and linking certain KDEs to a particular traceability lot. KDEs for a CTE could be ''linked'' in different ways, including by being listed together in single row of an electronic sortable spreadsheet, stored together as a record in a database, shared to a subsequent recipient as an electronic message, or printed on the same commercial document (*e.g.,* BOL). KDEs may also be linked together using a common identifier on multiple records, such as the traceability lot code or the reference document number (*e.g.,* a PO number attached to a buyer's PO; a supplier's BOL that connects to a customer's invoice).

3. Description of Procedures Used To Identify Foods on the Food Traceability List

(Comment 322) Several comments ask that we delete the proposed requirement to maintain a list of foods on the FTL that a firm ships, asserting that meeting the requirement would require substantial time and resources because products and circumstances change often, which would necessitate frequent updating of the list. The comments also maintain that the list would become outdated almost immediately and would not be helpful to FDA in protecting public health. The comments further state that the list would include foods subject to a kill step and shipments of ingredients and semi-finished foods, all of which would require a burdensome case-by-case review. The comments maintain that in the event of a food safety investigation, firms can generate automated reports to gather current information about products, such as a list of finished goods that contain a specific ingredient. Some comments assert that when FDA conducts a traceforward it has already identified a food or foods it is investigating, making it unnecessary for firms to keep a list. Some comments maintain that most firms keep shipping records for all their products, and they ask that if the final rule includes this listing requirement, firms should be allowed to include FTL foods within their existing records, rather than create a separate list. One comment maintains that although they see the usefulness in having a master list of all the FTL foods shipped, they do not understand why this is essential for facilitating foodborne illness investigations because all shippers will be required to maintain and send the KDEs associated with FTL foods. The comment contends that it is unrealistic for entities that only receive and ship foods to establish this master list because they must rely on information provided by the previous shipper.

Some comments ask that we exempt food service distributors, including fresh produce distribution centers, from the requirement to keep a list of FTL foods shipped. The comments maintain that the requirement would burden small specialty food distributors and ingredient distributors because distributors ship large volumes of product from many different firms daily. Another comment maintains that this requirement would impose a burden on fresh produce distribution centers because of the large number of listed products and the need to frequently change the list; one comment estimated that based on current practices, the FTL list could change, on average, every 3 minutes. The comments also maintain that requiring the traceability identifier and traceability product description as part of the list of FTL foods shipped would further increase the burden on distributors because they would have to maintain a list of each individual supplier for each covered product they ship. The comments assert that

maintaining the list would provide little traceability value and would be less relevant to distributors because they do not create or transform food.

(Response 322) We agree with the comments that the requirement to keep a list of FTL foods shipped could be burdensome and is not necessary to ensure adequate traceability of these foods. Therefore, we are deleting the proposed requirement from the final rule. Instead, § 1.1315(a)(2) of the final rule specifies that an entity's traceability plan must include a description of the procedures the entity uses to identify foods on the FTL that it manufactures, processes, packs, or holds. We conclude that this requirement will help us understand how a firm identifies which of the foods it handles require records under subpart S.

(Comment 323) Several comments ask that we clarify how frequently an entity must update the list of foods on the FTL that it ships.

(Response 323) Because we are deleting the proposed requirement to maintain a list of FTL foods shipped, there is no need to specify how frequently the list should be updated.

4. Description of How Traceability Lot Codes Are Assigned

(Comment 324) Some comments request additional guidance on the creation and assignment of traceability lot codes, including more information about the entity that creates the code and whether the code will be maintained throughout the supply chain, how to identify foods with a traceability lot code, and how to communicate the traceability lot code to subsequent recipients. The comments also recommend that we adopt a specific format or system for use in creating and assigning traceability lot codes. Some comments suggest that compliance and enforcement will be difficult to attain if the rule allows companies to choose how they wish to assign traceability lot codes.

(Response 324) We decline to specify a particular method or system by which firms must assign traceability lot codes, because we think it is appropriate for firms to have the flexibility to choose the approach that best suits their needs. Several food industry-supported traceability initiatives offer best practices and standards for uniquely identifying a food using a combination of a globally unique product identifier, firm-assigned internal lot code, and standard date code. This information, taken together, could be used as a traceability lot code, provided it meets the definition of ''traceability lot code'' in § 1.1310 of the final rule. Because traceability lot codes are central to subpart S, and because we are providing flexibility regarding how a firm chooses to assign such codes, § 1.1315(a)(3) requires that, for firms that assign traceability lot codes, their traceability plan must include a description of how they assign them.

Although the rule allows for flexibility in the structure and format of traceability lot codes, § 1.1320 of the final rule limits the circumstances under which traceability lot codes may be assigned. As discussed in Section V.H of this document, § 1.1320(a) of the final rule specifies that firms must assign a traceability lot code when they initially pack a RAC other than a food obtained from a fishing vessel, perform the first land-based receiving of a food obtained from a fishing vessel, or transform a food. Under § 1.1320(b), except as specified otherwise in subpart S (see Sections V.H and V.N of this document), firms must not establish a new traceability lot code when they conduct other activities (*e.g.,* shipping) for an FTL food.

5. Statement Identifying a Point of Contact

(Comment 325) One comment suggests that the final rule include a requirement that entities have a ''qualified individual'' who can perform the recordkeeping activities required under the rule. The comment maintains that some businesses subject to the rule that create or transform FTL foods do not use lot coding systems and rely on the date the product was produced or a ''best by'' date. The comment maintains that for such businesses, building their first lot code will pose a significant challenge. But the comment notes that, unlike other FSMA regulations (*e.g.,* FSVP, preventive controls for human food), the traceability rule has no requirement to designate a specific employee and level of expertise to be responsible for a firm's traceability system. The comment asserts that the rule constitutes the first time specific traceability information will be required by a regulation, which presents a difficult educational challenge because some firms already collect more information than will be required under the final rule, though possibly in different formats, while others will be starting completely from scratch. The comment also maintains that, more than any other FSMA rule, the compliance of downstream entities in the supply chain is predicated on the understanding and ability of previous entities in the supply chain to implement the rule, because downstream entities must be able to collect correct and compliant information to meet their own responsibilities. The comment questions how this will occur without a developed and standardized curriculum to ensure effective implementation of the requirements.

(Response 325) We do not agree that it is necessary to codify in the regulation a requirement that persons subject to the final rule have a ''qualified individual'' with a specified level of expertise who has studied a standardized curriculum. We do not believe it is necessary to establish qualifications for individuals who conduct traceability operations to ensure compliance with the subpart S recordkeeping requirements, and developing a standardized curriculum would be impractical because individual firms vary widely in their approaches to traceability recordkeeping. However, we have revised § 1.1315(a) to specify (in § 1.1315(a)(4)) that an entity's traceability plan must include a statement identifying a point of contact for questions regarding the entity's traceability plan and records. As previously stated, the rule defines ''point of contact'' as an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number. Thus, an entity subject to subpart S must have someone available as a point of contact who is familiar with the firm's traceability plan and traceability records. This means that firms will have to employ or obtain the services of at least one person who understands how the firm conducts its internal traceability procedures, including how traceability information is received and/or provided to its supply chain partners. We conclude that this requirement to identify a point of contact will help ensure that traceability information for FTL foods is made available to FDA and other supply chain entities on a timely basis.

(Comment 326) Several comments suggest that FDA can obtain information necessary for traceback by contacting a firm's facility registration contact. The comments suggest that FDA could communicate this expectation to industry either through guidance in support of this rule, guidance in support of facility registration renewal, or as part of the facility registration process. The comments maintain that contacting the facility registration contact would obviate the need for firms in the supply chain to provide point of contact information to customers, since FDA already has access to facility registration information.

(Response 326) We decline to specify that a firm's point of contact for

purposes of the subpart S requirements must be its facility registration contact. Although facility registration data may provide information on points of contact for some firms subject to subpart S, not every covered entity is required to register with FDA as a food facility. For example, farms, RFEs, and restaurants are not required to register with the Agency. Furthermore, a firm's facility registration contact might not have knowledge of the firm's traceability program and therefore would not be best positioned to respond to questions about the program. As stated in Response 274, we have addressed concerns about the privacy of points of contact by revising the definition of ''point of contact'' so that firms may provide the job title (instead of the name) of their point of contact.

6. Farm Map

In response to comments we received about the proposed requirement (in § 1.1325(a)) that those who grow FTL foods maintain records linking the traceability lot code of the food to the growing area coordinates for the food, we are deleting that requirement and replacing it with a requirement that those who grow or raise an FTL food (other than eggs) must include in their traceability plan a farm map showing the location and name of each field (or, for aquaculture farms, each container) in which the food on the FTL was grown or raised, including geographic coordinates and any other information needed to identify the location of each field (or, for aquaculture farms, each container). (As stated in Section V.F of this document, we had proposed to define ''growing area coordinates'' as geographical coordinates (under GPS or latitude/longitude) for the entry point of the physical location where the food was grown and harvested.) We discuss the farm map requirements in response to the following comments on the proposed requirement concerning growing area coordinates.

(Comment 327) Many comments request the removal of growing area coordinates as a KDE for the growing of an FTL food. The comments maintain that GPS coordinates are susceptible to documentation error due to misplaced decimal places or other recording errors. The comments also assert that obtaining and maintaining growing area coordinates for the entrances to fields where seed for sprouting is grown would place an undue burden on small and mid-size farms, and ask that we clarify if the proposed requirement applies to operations that grow sprouts. The comments suggest several alternatives to the use of growing area coordinates, including satellite printouts, field numbers, Farm Service Agency records, mailing addresses, written directions, and GS1 US GLNs. Some comments express concerns about scalability and privacy concerns with the growing area coordinates requirement. A few comments seek clarification on whether growing area coordinates must be shared with trading partners.

(Response 327) As discussed more fully in Section V.J of this document, we have deleted from the final rule the proposed requirements for persons who grow an FTL food, including the requirement to keep a record of the growing area coordinates for each traceability lot of an FTL food. However, we believe that geographic coordinates provide important information for identifying the location where a food is sourced. We also believe that geographic coordinates are accessible to all farms. Therefore, § 1.1315(a)(5) of the final rule specifies that if an entity grows or raises a food on the FTL (other than eggs, as discussed in Response 349), its traceability plan must include a farm map showing the area in which the food is grown or raised. Except with respect to aquaculture farms (discussed in Response 328), the farm map must show the location and name of each field (or other growing area) in which a food on the FTL is grown, including geographic coordinates and any other information needed to identify the location of each field or growing area (§ 1.1315(a)(5)(i)). The requirement to maintain a farm map as specified in § 1.1315(a)(5)(i) applies to indoor growing operations (*e.g.,* greenhouses, hydroponic farms), as well as outdoor operations. We added the phrase ''or other growing area'' to describe situations where the location in which a food is grown is not a field. Like outdoor operations, indoor operations may consist of multiple growing areas, in which case farm maps will be particularly useful during an outbreak investigation to assist in pinpointing the area where an implicated FTL food was grown. With regard to the comment asking about sprout operations and sprout seed operations, § 1.1315(a)(5)(i) applies to anyone who grows or raises a food on the FTL other than eggs (except it does not apply to aquaculture farms, which are discussed below and in § 1.1315(a)(5)(ii)). Because sprouts are on the FTL, this provision applies to growers of sprouts. Seeds for sprouting, however, are not on the FTL, so this provision does not apply to growers of seeds for sprouting.

With respect to the sharing of growing area coordinates with trading partners, as discussed in Section V.J of this document, the final rule requires harvesters and coolers of FTL foods to provide to the initial packer of the food the location description for the farm where the food was harvested, which can be done by providing either the physical location address or geographic coordinates for the farm (in addition to the other information identified in the definition of ''location description''). The final rule also requires harvesters of FTL produce to provide the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name. Because the field name provided to the initial packer must match the field name used by the grower, this requirement will allow FDA to connect the information we obtain from the initial packer with the farm map that the grower is required to maintain under § 1.1315(a)(5), thus enabling us to identify the specific field where the produce was grown. We conclude that these requirements relating to the location of the farm where the food was harvested and the name of the field from which the food was harvested are essential to ensuring adequate traceability.

(Comment 328) One comment supports the use of GPS coordinates to identify pond-specific harvest of fish and to identify small-scale aquaculture farms.

(Response 328) We agree with the comment that this information is important to accurately identify and locate aquaculture operations. Therefore, § 1.1315(a)(5)(ii) of the final rule specifies that for aquaculture farms, the farm map required as part of the traceability plan must show the location and name of each container (*e.g.,* pond, pool, tank, cage) in which the seafood on the FTL is raised, including geographic coordinates and any other information needed to identify the location of each container. Use of GPS could be one way in which aquaculture farms could meet the requirement to document the relevant geographic coordinates.

(Comment 329) One comment expresses concern over the amount of paperwork that would be necessary to maintain growing area coordinates for multiple commodities over a long period of time.

(Response 329) As previously stated, rather than keeping records on the growing area coordinates for each traceability lot of FTL food grown, the final rule requires entities that grow or

raise FTL foods to keep a farm map as part of their traceability plan. Documenting the relevant field (or container) names and locations, including the geographic coordinates, on the farm map might be a one-time event and would only need to be repeated if the field or container locations change, which should result in a reduced burden compared to the proposed requirement on growing area coordinates.

(Comment 330) One comment suggests that we reference the GPS standard released in April 2020 that GPS coordinates must be accurate to within 5 meters (3 meters longitude and 5 meters latitude).

(Response 330) Although we recognize the importance of the GPS in meeting requirements to record geographic coordinates of farms, because the final rule does not use the term ''global positioning system,'' there is no need to reference any particular GPS standard in the rule.

(Comment 331) Some comments ask for additional clarity regarding how growing area coordinates would help identify fields on a farm. One comment states that farms may have multiple points of entry or maintain properties over multiple jurisdictions and suggests that physical location may be more useful than growing area coordinates. One comment maintains that the reference in the proposed rule to the geographical coordinates of the field entrance does not provide sufficient information about field location, and that without greater specificity, entire farms rather than individual fields might be implicated in a product recall. One comment asks whether a farm needs to assign names to each field.

(Response 331) As previously stated, the final rule deletes the proposed requirement concerning growing area coordinates and replaces it with a requirement for farms to include farm maps in their traceability plans. The farm maps must show the location and name of each field or container in which a food on the FTL is grown or raised, including geographic coordinates and any other information needed to identify the location of each field or container. Presenting this information in the form of a map will provide a greater level of specificity and visual perspective for each field or container on the farm, because it will provide a fuller context to understand the size and location of a field or container as compared to what would be provided by a single set of geographic coordinates in isolation (*i.e.,* not as part of a map). Additional information that may be provided, such as adjacent road names or other identifying information, will help position the farm in its geographic area and provide a better understanding of the farm and where foods are grown or raised than the physical location alone. In some cases, if the size of the farm is small and there are only a few adjacent fields or containers on the farm, it might be sufficient to specify only one set of geographic coordinates.

(Comment 332) One comment maintains that tracking a lot code to a growing location using coordinates is complicated by transplanting.

(Response 332) As stated in Response 327, we have deleted from the final rule the proposed requirement for persons who grow an FTL food to keep a record of the growing area coordinates for each traceability lot of the food. The final rule states that growers need to maintain a farm map showing the location and name of each field (or other growing area) in which food on the FTL is grown, including geographic coordinates and any other information needed to identify the location of each field or growing area. If an FTL food is initially grown in one field and then transplanted to another field, both fields must appear on the farm map, because they are both fields in which an FTL food is grown.

As previously stated, the harvester of an FTL food must provide certain information to the initial packer, including the location description for the farm where the food was harvested and (for harvesters of produce) the name of the field or other growing area from which the food was harvested. Where transplanting had occurred, the harvester would only need to provide the name of the field from which the food was harvested (not information on previous growing locations of the transplanted food).

7. Deleted Requirement To Maintain Other Information Needed To Understand Data

We proposed to require firms to establish and maintain, as part of their traceability program records, any other information needed to understand the data provided within any records required by subpart S, such as internal or external coding systems, glossaries, and abbreviations (proposed § 1.1315(a)(4)). On our own initiative, we have determined that this information needed to understand data in a firm's records is more relevant in the context of an Agency request to review a firm's subpart S records than as a part of a firm's traceability plan. Therefore, as discussed in Section V.R of this document, § 1.1455(c)(1) of the final rule specifies that an entity must make all records required under subpart S available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records provided correspond to the information required under subpart S. Consistent with this determination, we have deleted the proposed requirement to keep records of information needed to understand the data in subpart S records from § 1.1315.

8. Updating and Maintaining the Traceability Plan

We proposed to require that covered entities must retain the records required under proposed § 1.1315(a) (*i.e.,* traceability program records) for 2 years after their use is discontinued (*e.g.,* because the entity changes the records in which it maintains the required information, updates the list of foods on the FTL it ships, or changes its procedures for establishing and assigning traceability lot codes) (proposed § 1.1315(b)).

On our own initiative, we are revising § 1.1315(b) to reflect changes made to § 1.1315(a) and to make explicit what was implied by the parenthetical in the proposed rule, *i.e.,* that we expect a firm's traceability plan to reflect its current practices. Section 1.1315(b) of the final rule therefore states that entities must update their traceability plan as needed to ensure that the information provided reflects their current practices and to ensure that they are in compliance with the subpart S requirements. Consistent with the proposed rule, § 1.1315(b) further specifies that firms must retain their previous traceability plan for 2 years after they update their plan.

H. Assignment of Traceability Lot Codes (§ 1.1320)

We proposed to require entities to establish and assign a traceability lot code when they originate, transform, or create a food on the FTL (proposed § 1.1320(a)). We further proposed that, except as specified elsewhere in subpart S, a person may not establish a new traceability lot code when they conduct other activities (such as shipping or receiving) in the supply chain for an FTL food (proposed § 1.1320(b)). As discussed below, to align with changes we are making to CTE requirements, we have revised the circumstances under which persons are required to assign a traceability lot code, while making only minor changes to proposed § 1.1320(b).

(Comment 333) One comment recommends that we delete the requirement for farmers and harvesters to create lot codes. The comment maintains that retaining this requirement would impose financial hardship, while deleting it would eliminate duplication of regulations imposed by states. Several comments suggest that entities responsible for packing RACs such as produce, eggs, and seafood should be responsible for assigning a traceability lot code to the food. The comments maintain that these entities are better positioned in the supply chain to assign lot codes, and are more likely to have systems in place for storing KDEs for events like growing and harvesting.

(Response 333) We agree with the comments that entities that pack a RAC for the first time generally are better positioned than growers and harvesters to assign a traceability lot code to the food. It is the packed form of the RAC that is distributed throughout the supply chain, and RACs often are harvested into temporary holding containers in a process that does not lend itself well to assigning traceability lot codes. In recognition of this, we have revised the proposed CTE requirements to delete the requirement for growers of FTL foods to establish a traceability lot code (see Section V.J of this document) and to add requirements applicable to the initial packers of RACs other than food obtained from a fishing vessel (see Section V.K of this document), including a requirement to assign a traceability lot code for such food. Regarding food obtained from a fishing vessel, we have identified the first land-based receiver of the food as the entity best positioned to assign a traceability lot code for the food (see Section V.K of this document). In accordance with these and other changes to the CTE requirements, § 1.1320(a) of the final rule specifies that a person must assign a traceability lot code when they initially pack a RAC other than a food obtained from a fishing vessel, perform the first land-based receiving of a food obtained from a fishing vessel, or transform a food.

(Comment 334) One comment requests that all shellfish growers and harvesters be exempt from the requirement to assign or keep lot codes because most shellfish growers and harvesters would be exempt from subpart S, since they produce less than $25,000 in shellfish annually.

(Response 334) As previously discussed, § 1.1305(f) of the final rule exempts from subpart S raw bivalve molluscan shellfish that are: (1) covered by the requirements of the NSSP; (2) subject to the requirements of part 123, subpart C, and § 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish. This means that nearly all raw bivalve molluscan shellfish will not be subject to the rule. However, for shellfish growers and harvesters that are not exempt from the rule under § 1.1305(f) or any other exemption (*e.g.,* the exemption for certain small producers of RACs other than produce or shell eggs in § 1.1305(a)(3)), we conclude that it would not be appropriate to exempt them from the requirements to assign and keep lot codes as may apply to them under subpart S.

(Comment 335) Several comments assert that firms should be required to link the incoming lot code of an FTL food to an outgoing lot code at every node in the distribution chain, and that each entity in the chain be permitted to assign their own lot code to the FTL food in accordance with their internal traceability protocols. Some comments maintain that such a system would be particularly helpful in the case of imported products, where it might not be known at the beginning of the supply chain that the product will eventually be exported to the United States; the comments contend that such an approach would be consistent with Codex recommendations regarding product tracing. The comments assert that this would effectively constitute ''one-up, one-back'' tracing via lot code.

(Response 335) We do not agree that firms should be allowed to create a new traceability lot code for an FTL food whenever they deem it appropriate. Firms that wish to do so may assign their own internal lot codes to FTL foods for the purposes of internal tracing, but they must comply with the subpart S requirement to keep the traceability lot code unchanged except under specified circumstances. As discussed in the preamble to the proposed rule (85 FR 59984 at 60006), assigning a new traceability lot code for a food that has not been transformed can lead to confusion that can hinder traceback and traceforward efforts during investigation of foodborne illness outbreaks.

The use of traceability lot codes that remain unchanged as the food passes through supply chain nodes such as distribution centers will allow us to skip these nodes, at least initially, in a traceback investigation and more quickly identify the firm that initially packed, first received on land, or transformed the food, because firms that receive FTL foods will be required to keep a record of the traceability lot code and the traceability lot code source. For these reasons, we conclude that it is appropriate to specify, in § 1.1320(b) of the final rule, that new traceability lot codes must not be established when conducting activities other than those specified in § 1.1320(a), except as specified otherwise in subpart S. (As discussed in Sections V.K and V.N of this document, the final rule requires firms to assign a traceability lot code upon receipt of an FTL food from a person to whom subpart S does not apply, if one has not already been assigned (see § 1.1345(b)).)

As discussed in Response 525, we believe the rule conforms to the Codex principles for traceability (CAC/GL60–2006), and while the final rule goes beyond one-up, one-back tracing, this is not in conflict with Codex principles. Regarding the concern about imported products for which it might not be known at the beginning of the supply chain that the product will eventually be exported to the United States, as stated in Response 103, U.S. importers will need to work with their foreign suppliers to ensure they are aware of the subpart S traceability requirements. We note that many existing FDA regulations include requirements for imported foods, including requirements regarding the beginning of the supply chain (for example, requirements relating to the growing of produce in the produce safety regulation), and we believe it is reasonable to expect that foreign entities will be able to comply with the final rule. We also note that many foreign entities that produce food that is ultimately exported to the United States already have procedures in place for identifying such food, and the final rule provides flexibility to allow firms to rely on existing procedures and information to meet the rule's requirements.

(Comment 336) One comment asserts that because supply chain systems are not fully interoperable, a traceability lot code designated at the beginning of the supply chain may not be compatible with downstream systems. Therefore, the comment maintains that each covered entity should be able to establish their own traceability lot codes, provided one-up, one-back traceability is maintained.

(Response 336) We do not agree with the comment. As previously stated, limiting the circumstances under which a traceability lot code may be assigned to a product increases the chances that we will be able to rapidly identify and contact the source of a food when conducting an outbreak investigation. This use of traceability lot codes (and traceability lot code source information, as discussed in Section I.B of this

document) is central to subpart S because it enables traceability that is more efficient than what can be attained through one-up, one-back tracing. Allowing firms to assign new traceability lot codes to foods at any point in the supply chain would undermine this key element of subpart S and would create obstacles to efficient traceability. While we agree with the comment that supply chain systems are not fully interoperable, we do not think full interoperability is necessary to accommodate a variety of incoming traceability lot codes.

(Comment 337) One comment asserts that the prohibition in proposed § 1.1320(b) against assigning traceability lot codes other than in the specified circumstances violates section 204(d)(1)(E) of FSMA, which states that we may not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business. The comment maintains that many covered entities have functioning, efficient traceability systems that assign internal lot codes to incoming product that allows the connection of incoming product to outgoing product, and not allowing the use of these systems instead of a traceability lot code that cannot be changed means that information must be duplicated to comply with the rule.

(Response 337) We do not agree that limiting the circumstances in which a traceability lot code may be assigned means that firms must create and maintain duplicate records. Covered entities are free to continue to use tracing systems that assign internal lot codes to products as they come into their systems for internal tracing purposes, but they are not required to do so. To the extent that a firm chooses to assign internal lot codes to FTL foods they receive, and to keep records of those internal lot codes, the requirement to maintain the existing traceability lot code is not a duplication of those records.

As previously discussed, for the rule to improve traceability as intended, the circumstances under which traceability lot codes may be assigned must be limited to allow the applicable traceability lot code to continue to be linked to an FTL food as the food moves through the supply chain, which will enable us to more quickly trace the food. We note that firms that assign traceability lot codes (in accordance with § 1.1320) may opt to use their existing internal lot coding systems in assigning the traceability lot codes.

(Comment 338) One comment suggests that we revise proposed § 1.1320(b) to state that a person ''shall not'' rather than ''may not'' establish a new traceability lot code except under circumstance stated elsewhere in subpart S.

(Response 338) We agree that § 1.1320(b) should be changed to more clearly state that assignment of a traceability lot code except under the specified circumstances is prohibited. Therefore, we are revising § 1.1320(b) to state that except as specified otherwise in subpart S, a person ''must not'' establish a new traceability lot code when they conduct other activities (*e.g.,* shipping) for a food on the FTL.

(Comment 339) One comment asks that we clarify whether a new traceability lot code must be assigned by a third-party warehouse that is within the control of the manufacturer.

(Response 339) Under § 1.1320(a) of the final rule, a firm must assign a traceability lot code to an FTL food when it does any of the following: initially packs a RAC other than a food obtained from a fishing vessel, performs the first land-based receiving of a food obtained from a fishing vessel, or transforms a food. Unless the warehouse is engaging in one of those activities (or unless it received the food from an entity that is not subject to subpart S, as discussed in Section V.N.2 of this document), it would not be required to assign a traceability lot code to the food, and indeed it would not be permitted to do so under § 1.1320(b).

(Comment 340) Some comments suggest that the first receiver of shellfish (under proposed § 1.1330) should assign the traceability lot code rather than the shellfish harvester or aquaculture farm. The comments assert that many shellfish harvesters and small farms are not computer-literate and would either not be able to comply with the requirement to assign a traceability lot code or would be exempt from the rule.

(Response 340) We agree with the comments that harvesters of shellfish are often not the best-positioned entity in the supply chain to assign a traceability lot code. As stated above, we have deleted the proposed requirement for ''originators'' of FTL foods (*i.e.,* entities that grow, raise, or catch a food) to assign a traceability lot code to the food. Instead, § 1.1320(a) specifies that a traceability lot code must be assigned either by the initial packer, for a food not obtained from a fishing vessel (which could include aquacultured shellfish); or else by the first land-based receiver, for a food obtained from a fishing vessel. Note that most raw bivalve molluscan shellfish are exempt from subpart S (see Section V.E.7 of this document).

(Comment 341) One comment asserts that the proposed KDEs would not be necessary if lot codes were required to be printed on all product packaging and related documents for every transaction. Some comments assert that an important precondition for the rule is the identification of physical product with the traceability lot code using industry standards such as those used in the PTI.

(Response 341) The final rule does not require that the traceability lot code for a food appear on the food's labeling or packaging. However, we recognize the potential value of physically identifying foods with the traceability lot code, and we welcome the use of industry-supported standards and best practices, such as those in the PTI, in meeting subpart S requirements, including those regarding assignment and communication of traceability lot codes.

(Comment 342) Many comments assert that the proposed rule would impose a case-level tracking requirement throughout the supply chain, in violation of section 204(d)(1)(L)(iii) of FSMA, because it would require distributors to maintain and send shipping KDEs linked to the specific traceability lot codes of the products in each shipment. The comments maintain that distributors receive shipments with multiple lot codes from their suppliers that would have to be tracked as they fulfill orders for their customers, especially in situations where a mixed pallet is being shipped or smaller quantities of products are being sold; the comments claim that tracking to the case level would be the only way to know the traceability lot code for each case sent to a customer. The comments also maintain that shipments to RFEs move not by an entire traceability lot, but rather by case count. The comments further assert that in circumstances where a pallet-level barcode with a case-level GTIN and applicable date and batch/lot numbers for products on the pallet is not available, distribution centers would need to break down the pallets to record the case-level information. In addition, the comments assert that a case-level tracking requirement is unnecessary because current tracing systems, which link product through POs, BOLs, or other reference records, is equally effective when conducting traceback activities. The comments also suggest that the proposed rule would require entities to place labels on every case, which they maintain would be costly. The comments contend that distribution centers using voice picking would not be able to track individual cases and

would need to shift to case-scanning technology. The comments also claim that in situations where product types are not conducive to paper labeling, firms may need to switch to a reusable plastic container, resulting in additional costs and transportation expenses. In addition, the comments maintain that when an RFE receives a pallet with products from different traceability lots, the RFE would have to keep different sets of KDEs for the same food item if they represent different traceability lots, which would create confusion and complexity. The comments also state that sometimes cases fall off pallets, which can affect traceability.

(Response 342) We disagree with the comments that the rule requires case-level tracking. For each CTE performed by a covered entity, the final rule requires the applicable KDEs to be maintained for each traceability lot of an FTL food, linked with a traceability lot code. We have provided flexibility for how a firm identifies a traceability lot; a firm could define a lot as a case, a pallet, a day's production, or some other amount of product. We recognize that entities such as distribution centers are generally not allowed to assign a new traceability lot code under § 1.1320, and therefore cannot control the size of the traceability lot. This can lead to situations where a single incoming traceability lot gets broken up and shipped to multiple destinations, or to multiple traceability lots being combined into a single pallet or a single shipment. Subpart S does not require case-level tracking in such situations, and we think the final rule provides adequate flexibility for firms to decide how to manage these situations, depending on their individual practices.

One reason why the rule requires KDEs in addition to the traceability lot code is that we recognize that in some situations, parts of a single traceability lot might end up in multiple places. If an entity such as a distribution center breaks up a single traceability lot and ships the product to multiple locations, each shipment will have its own set of KDEs associated with it, and the combination of the traceability lot code and the information regarding the shipping event (*e.g.,* information about the food's recipient) will provide a sufficiently descriptive record of that event despite the fact that another portion of the same traceability lot (with the same traceability lot code) was shipped elsewhere. This approach does not constitute case-level tracking, because there is no requirement to have case identifiers to track which cases are sent to which destination. Conversely, if an entity such as a distribution center receives several small traceability lots of the same product, and therefore needs to combine multiple lots into a single shipment, the records for that shipping event would need to be specific to each traceability lot; however, this too does not constitute case-level tracking, because records would not need to be kept to uniquely identify each individual case. We recognize that if an entity chooses to identify a single case as an entire traceability lot, or to divide a traceability lot into single-case shipments, the result would be recordkeeping for individual cases. However, this would be due to the decisions made by the firm, not to any requirement to engage in case-level tracking.

Regarding the statement that other tracing systems linking products through POs or BOLs are equally effective, we note that those systems can be used as long as such reference documents enable a firm to meet the requirements of subpart S, including linking the traceability lot code of an incoming FTL food to the traceability lot code of an outgoing FTL food. For some points in the supply chain (*e.g.,* those entities performing only shipping and receiving), the traceability lot code will remain the same for the incoming and outgoing food.

The final rule does not require firms to label every case of FTL food (with paper labels or otherwise). However, we realize that for some businesses, this might be the most efficient way to keep track of the quantity and unit of measure of a particular traceability lot that has been received or is being shipped to a customer. Alternate business practices are available, such as labeling a slot or bin in a warehouse with a traceability lot code if all the cases in that holding area have the same traceability lot code.

As comments note, when cases lack any identifying information that links to a traceability lot code and there are multiple traceability lots of the same FTL food, such as in a warehouse, if one case falls off a pallet or gets separated, it could be difficult to identify which traceability lot the case belongs to. Individual firms can decide how to manage this risk. For example, a firm might take steps to prevent individual cases from getting accidentally separated from their pallets; firms might decide to label each individual case; or firms might decide that if a case is separated, they will perform an inventory of all identical product on hand to determine which traceability lot is missing a case.

(Comment 343) Some comments request that FDA allow distribution centers to maintain and send KDEs related to multiple traceability lot codes on a pallet, or a new traceability lot code assigned by the distribution center representing the traceability lot codes on a pallet, rather than the exact traceability lot codes received from the previous source.

(Response 343) We decline to make this change to allow distributors to create new traceability lot codes for foods they do not transform, or to create records that do not distinguish between different traceability lots on a pallet. Except when a distributor receives an FTL food from a person to whom subpart S does not apply (see § 1.1345(b)), a distributor generally would not be permitted to establish a new traceability lot code for a food under § 1.1320(b). An important part of the subpart S requirements is that covered entities must keep a record of the traceability lot code and information on the traceability lot code source or a source reference for each traceability lot of an FTL food they handle and must pass that information along when they ship the food. The final rule does not prescribe how an entity such as a distribution center must maintain this information and provide it to the subsequent recipient, but it should be clear which traceability lots the distribution center handled and which specific traceability lots were included in the shipment. If the information maintained by the distribution center or provided to the subsequent recipient is ambiguous, the information provided to FDA may be unclear, which could slow our investigation.

(Comment 344) Some comments ask that flexibility be incorporated into lot-level identification so that a packer may assign a traceability lot code if the grower has not done so or if a RAC is commingled between harvesting and processing.

(Response 344) As previously stated, we have removed the proposed requirement for growers to assign traceability lot codes. Instead, § 1.1320(a) of the final rule specifies that the initial packer of a RAC other than a food obtained from a fishing vessel must assign a traceability lot code to the newly packed food. If a RAC is commingled before it is initially packed, the initial packer's records will reflect that the traceability lot is associated with multiple fields and/or multiple farms, but there is no requirement to track which parts of the lot come from which fields or farms. If a non-produce RAC is commingled after harvesting and before processing, it may be partially exempt from subpart S under § 1.1305(h) (see Section V.E.9 of this

document). For food obtained from a fishing vessel, see the discussion of commingling in Response 208; for eggs, see the discussion of commingling in Response 206.

(Comment 345) One comment expresses concern that a lack of specificity regarding traceability lot codes and the requirement to pass traceability lot codes along the supply chain may prove to be burdensome for small entrepreneurs.

(Response 345) We disagree with the comment. The assignment of traceability lot codes and the provision of these codes (along with other KDEs for a food) to downstream entities in the supply chain of a food are critical components of recordkeeping requirements that will enable the Agency to more swiftly and efficiently conduct product tracing during an investigation of a foodborne illness outbreak or a recall. We are uncertain as to what aspect of traceability lot codes the comment believes lacks specificity. We believe that the rule provides appropriate flexibility to firms regarding the form and content of traceability lot codes and the manner in which they are assigned to FTL foods. However, because we recognize that meeting the subpart S requirements may be more burdensome for smaller firms, the final rule includes exemptions for certain types of smaller entities, including small producers and small RFEs and restaurants, as discussed in Sections V.E and V.R.3 of this document.

(Comment 346) One comment asks if FDA needs to be able to tie traceability lot codes to a specific production line or facility.

(Response 346) The rule does not require that firms construct traceability lot codes such that they identify particular production lines or facilities. However, consistent with the definition of ''traceability lot code,'' the traceability lot codes that a firm assigns must be able to uniquely identify a traceability lot within the firm's records. Therefore, a firm might choose to, but is not required to, assign traceability lot codes that reflect production on a particular production line or at a particular facility. Furthermore, we note that subpart S contains requirements relating to the traceability lot code source, which is the place where a food was assigned a traceability lot code. For many of the CTEs, records must be maintained that contain either the location description for the traceability lot code source or the traceability lot code source reference. This information allows FDA to identify the place where a specific traceability lot code was assigned, which will often be the facility where the food was manufactured or otherwise transformed (see Response 265). There is no requirement that this information enable FDA to identify the specific production line where the food was manufactured.

I. Critical Tracking Events Framework

At the core of the subpart S traceability recordkeeping requirements are provisions requiring entities that manufacture, process, pack, or hold FTL foods to keep and, at times, provide to immediate subsequent recipients of food certain information related to CTEs in the food's supply chain. The proposed rule included growing, transformation, creating, shipping, and receiving (including requirements for the ''first receiver'' of a food) as CTEs for which KDEs must be maintained. As discussed previously, we received many comments concerning the proposed CTEs, particularly the requirements associated with the first receiver CTE and which entities in the supply chain are best suited to assigning lot codes to FTL foods. In response to these comments, which we discuss below and in the following sections concerning specific CTEs, we have made several changes in the final rule to the CTE framework.

As discussed in Section V.J of this document, many comments maintain that lot codes are often assigned when a harvested food is packed for distribution into commerce rather than during the growing phase. We agree and therefore have placed the responsibility for the assignment of traceability lot codes for RACs not obtained from a fishing vessel on the initial packer of such food. We are deleting entirely the proposed CTE for growing an FTL food, which included requirements to assign traceability lot codes, document growing area coordinates for each traceability lot, and document particular KDEs for sprouts. Instead, as previously discussed, the final rule requires persons who grow or raise an FTL food (other than eggs) to maintain, as part of their traceability plan, a farm map showing the area, including geographic coordinates, in which they grow or raise the FTL food. The specific information related to sprouts is now included in the requirements for the initial packing CTE (see Section V.K of this document).

The proposed provisions for the first receiver CTE would have placed certain recordkeeping requirements on the first person (other than a farm) who purchases and takes physical possession of an FTL food that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested. As previously discussed, several comments express confusion regarding the first receiver concept and suggest that the proposed first receiver requirements would make more sense as requirements for the person who initially packs an FTL food, because packers often have much of the information that would have been required of first receivers. Comments also indicate concern than an entity could be a first receiver and may not know it, including entities that would not typically have the required information on growing, harvesting, cooling, and packing, such as distributors and third-party warehouses.

In response to these comments, we have replaced the proposed requirements of the first receiver CTE with requirements for entities that initially pack or (in the case of food obtained from a fishing vessel) perform the first land-based receiving of certain FTL foods. This places recordkeeping responsibilities on the entity performing a certain activity (*e.g.,* initial packing) and therefore reduces confusion about the type of entity that is required to maintain these KDEs. We had proposed separate requirements for first receivers of (1) seafood products on the FTL obtained from a fishing vessel and (2) all other FTL foods. Similarly, the final rule establishes separate requirements for the CTE of the initial packing of RACs other than food obtained from a fishing vessel (§ 1.1330) and requirements for the CTE of the first land-based receiving of a food obtained from a fishing vessel (§ 1.1335).

We also received comments requesting clarity as to what activities constitute ''transformation'' rather than ''creation'' of an FTL food and asking that the requirements for the transformation and creating events be combined into a single CTE. As discussed in Section V.O of this document, we agree with the comments and have merged the requirements for the creating CTE with the requirements for the transformation CTE in § 1.1350 of the final rule. This action simplifies the requirements by removing the distinction between production of an FTL food with an ingredient(s) on the FTL (*e.g.,* bagged salad) and production of an FTL food without ingredients on the FTL (*e.g.,* peanut butter).

Although the shipping and receiving CTEs in the final rule (§§ 1.1340 and 1.1345, respectively) are similar to those we had proposed, we have made some changes to the proposed requirements for these CTEs. First, we have deleted from the shipping CTE the proposed requirement for farms to provide certain information on the production of a food to the immediate subsequent recipient of the food they ship. Instead, to ensure

that firms that conduct the initial packing of RACs (other than food obtained from fishing vessels) have this important information, we have adopted requirements for harvesters and coolers of such RACs to keep certain records of their activities and provide that information, including information about the farm where the food was harvested, to the initial packer. In addition, we have revised the shipping and receiving CTEs to specify that they do not apply to shipment or receipt of a food (if the food is a RAC not obtained from a fishing vessel) that occurs before the food is initially packed, or to the receipt of a food by the first land-based receiver of the food (if the food is obtained from a fishing vessel). Finally, in response to comments about what requirements apply when a firm receives food from an entity that is exempt from subpart S, we have revised the receiving CTE (as well as the initial packing CTE) to specify certain KDEs that must be kept when a receiver or initial packer receives food from a person to whom subpart S does not apply.

We respond to certain general comments on the proposed CTE framework in the following paragraphs.

(Comment 347) Some comments express support for FDA specifying KDEs.

(Response 347) We agree with the comments that support the rule's framework of KDEs organized by CTEs. We believe that this framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

(Comment 348) One comment maintains that growing fresh produce in a controlled environment is fundamentally different than growing fresh produce outdoors in a field. The comment requests clarification of the difference between the growing, transforming, and creating CTEs for an indoor produce grower who grows, packs, and processes produce.

(Response 348) We do not agree that growing produce in a controlled environment differs fundamentally from growing produce outdoors regarding the general level of safety risk or the type of recordkeeping requirements that are appropriate for facilitating traceability. As previously stated, we have incorporated the proposed requirements applicable to creating an FTL food into the transformation CTE in § 1.1350 of the final rule, and we have eliminated the proposed CTE for growing an FTL food (although, as with farms that grow produce outdoors, indoor produce farmers will have to establish a traceability plan that includes a farm map in accordance with § 1.1315 of the final rule). If an indoor produce farmer harvests and/or cools the produce, the requirements in § 1.1325 of the final rule will apply. If an indoor produce farmer packs the produce, it will be required to comply with the requirements applicable to initial packers under § 1.1330 of the final rule, and it would be required to maintain shipping records for its distribution of the packed produce in accordance with § 1.1340. As discussed in Section V.U of this document, to help covered entities understand their responsibilities under the rule, we intend to provide communication and outreach materials that will provide examples of required records for different supply chain entities for specific FTL foods.

J. Records of Harvesting and Cooling (§ 1.1325)

As discussed in Section V.I of this document, the proposed rule included requirements for persons who grow an FTL food to establish and maintain records containing and linking the traceability lot code of the food to the growing area coordinates for the food (proposed § 1.1325(a)). (Proposed additional requirements applicable to growers of sprouts are discussed in Section V.K of this document.) Proposed § 1.1350(b)(2) would have required farms to send information about the origination, harvesting, cooling, and packing of a food when shipping the food, while proposed § 1.1330 would have required the first receivers of food to maintain a record of this information.

In response to many comments asserting that these proposed requirements would impose significant recordkeeping burden on farms and do not align with current industry practices (including with respect to the assignment of lot codes), we have made several changes to the requirements as they relate to the information about the growing, harvesting, cooling, and packing of FTL foods. As previously discussed, we have removed the requirement for growers to assign traceability lot codes. Instead, the final rule specifies that traceability lot codes must be assigned when a food is initially packed or (in the case of food obtained from a fishing vessel) when it is first received on land, and also when the food is transformed. As previously discussed, we have deleted the proposed growing CTE requirements (including the requirement to maintain growing area coordinates for each traceability lot of a food) and replaced them (in part) with requirements for those who grow or raise an FTL food (other than eggs) to keep a farm map as part of their traceability plan. Under the final rule, some farms will only need to maintain a traceability plan and will not have additional KDE requirements. Finally, to ensure that the initial packer of a RAC has information about the farm where the RAC was grown along with information on the harvesting and cooling of the RAC, § 1.1325 of the final rule establishes certain recordkeeping and sending requirements for persons who harvest or cool RACs, as discussed in response to the following comments on the growing, harvesting, and cooling of foods.

(Comment 349) One comment expresses concern about the requirement for growers to record the growing area coordinates for each harvested traceability lot of food under proposed § 1.1325(a). The comment states that its farm grows many different crops that are very near each other and that are rotated annually. The comment estimates that the GPS technology required to comply would cost $1,000 to $3,000, representing a significant percentage of the farm's revenue (which the comment states may be less than $25,000 in some years). The comment asserts that the growing CTE requirement is better suited for larger farms that do not rotate crops and have more financial resources and staff.

(Response 349) We note initially that, as discussed in Section V.E.2 of this document, the final rule exempts from subpart S certain small producers, including produce farms that make less than $25,000 annually in sales of produce (see § 1.1305(a)). Furthermore, as stated above, the final rule deletes the requirements for growers in proposed § 1.1325. Under § 1.1315(a)(5) of the final rule, farms that grow or raise a food other than eggs are required to keep, as part of their traceability plan, a farm map showing (for non-aquaculture farms) the location and name of each field (or other growing area) in which they grow a food on the FTL. The map must include geographic coordinates and any other information needed to identify the location of each field or growing area. In the circumstances described in the comment, a farm could maintain a map showing all the fields or growing areas on the farm and labeling them by name, with sufficient geographic coordinates to identify the location of each field or growing area. The map would not have to be altered to show the rotation of crops, because records maintained by the harvester will identify what food was harvested from a specific field on a specific day. Therefore, creation of the farm map could be a one-time action

unless the location or names of fields or growing areas change.

(Comment 350) Several comments recommend that the ''growing'' requirements in proposed § 1.1325 should be replaced with ''harvesting'' requirements to reflect the step in the process where tracing begins. Alternatively, the comments suggest that harvesting should be a separate CTE, in addition to growing, where the lot code is assigned.

(Response 350) We agree with the comments that harvesting should be a separate CTE, although not an event at which a traceability lot code should be assigned. As previously discussed, we have deleted the growing and first receiver CTEs. Under § 1.1320(a) of the final rule, an entity must assign a traceability lot code when it initially packs a RAC other than a food obtained from a fishing vessel, performs the first land-based receiving of a food obtained from a fishing vessel, or transforms a food. We have determined that initial packers are better suited to assigning traceability lot codes than growers of RACs. However, we also believe that for initial packers to be able to maintain the records of harvesting and cooling of RACs that we need them to make available to us in an outbreak investigation, the rule must require that certain entities provide the initial packers with this information. Although the proposed rule (under § 1.1350(b)(2)) would have required all farms to provide information to the subsequent receiver regarding the origination, harvesting, cooling, and packing of each traceability lot of food they shipped, we conclude that it is more appropriate and less burdensome to have harvesters and coolers provide information about the activities they perform to the initial packers of RACs. This approach also allows for flexibility to accommodate the varying business models and types of entities that can be involved in harvesting and cooling RACs before they are initially packed.

For these reasons, § 1.1325 of the final rule sets forth requirements for records that persons who conduct harvesting or cooling before initial packing must keep and provide to the initial packer. Section 1.1325(a)(1) specifies that for each RAC (not obtained from a fishing vessel) on the FTL that is harvested, the harvester must maintain records containing the following information: the location description for the immediate subsequent recipient (other than a transporter) of the food; the commodity and, if applicable, variety of the food; the quantity and unit of measure of the food (*e.g.,* 75 bins, 200 pounds); the location description for the farm where the food was harvested; for produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name; for aquacultured food, the name of the container (*e.g.,* pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name; the date of harvesting; and the reference document type and reference document number.

Similarly, § 1.1325(b)(1) specifies that for each RAC (not obtained from a fishing vessel) on the FTL that is cooled before it is initially packed, the cooler of the RAC must maintain records containing the following information: the location description for the immediate subsequent recipient (other than a transporter) of the food; the commodity and, if applicable, variety of the food; the quantity and unit of measure of the food (*e.g.,* 75 bins, 200 pounds); the location description for where the food was cooled; the date of cooling; the location description for the farm where the food was harvested; and the reference document type and reference document number.

In addition to these requirements to maintain certain records, § 1.1325 of the final rule also requires harvesters and coolers to provide certain information to the initial packer of the RAC they harvest or cool. Section 1.1325(a)(2) specifies that for each RAC (not obtained from a fishing vessel) on the FTL that is harvested, the harvester must provide (in electronic, paper, or other written form) its business name, phone number, and the information (listed above) that it must keep (except for the reference document type or reference document number) to the initial packer of the RAC, either directly or through the supply chain. Similarly, § 1.1325(b)(2) requires coolers of RACs (not obtained from a fishing vessel) to provide (in electronic, paper, or other written form) the information the cooler must keep (except for the reference document type or reference document number) to the initial packer of the RAC, either directly or through the supply chain. These provisions allow flexibility for harvesters and coolers to directly provide the required information to the initial packer or to have another entity in the supply chain, such as the farm where the RAC was grown, a third-party entity directing the movement of the RAC, or a supply chain partner who will handle the food before it reaches the initial packer, provide the information to the initial packer. However, we note that while supply chains have the flexibility to determine how and by whom this information is sent to the initial packer, it is the responsibility of harvesters and coolers to somehow send the information to the initial packer, and it is the responsibility of the initial packer to have the required information for each FTL food they pack.

Consistent with these provisions requiring harvesters and coolers to provide certain information to the initial packers of the RACs they harvest or cool, we have added provisions to the shipping and receiving CTE requirements specifying that, for RACs not obtained from a fishing vessel, the shipping and receiving KDEs do not apply to any shipment or receipt of the food that occurs before it is initially packed. This means that entities that harvest or cool RACs (not obtained from a fishing vessel) before they are initially packed are not required to keep and send the shipping and receiving KDEs. We conclude that this approach is appropriate because the shipping and receiving KDEs are linked to the traceability lot code and are designed to be used for products that have already been assigned a traceability lot code and packed for commercial distribution. The separate KDEs for harvesters and coolers that we have established in § 1.1325, and which take the place of the shipping and receiving KDEs for these entities, are better suited to the specific situation of food that has not yet been initially packed. Because the KDEs in § 1.1325 are not tied to a traceability lot code, they can be organized in whatever way is practical for the operation, for example, on a shipment-by-shipment or day-by-day basis.

(Comment 351) One comment expresses support for the fact that the proposed rule does not require records of recipients of a food beyond the immediate subsequent recipient, in accordance with section 204(d)(1)(L)(ii) of FSMA.

(Response 351) We agree, and the final rule also does not require records of recipients of a food beyond the immediate subsequent recipient. The harvesting and cooling CTE requirements contain the only provisions under which an entity would potentially have a direct interaction with a recipient of a food beyond the immediate subsequent recipient. Under § 1.1325(a)(2) and (b)(2), the harvester and cooler of a RAC not obtained from a fishing vessel are required to ''provide'' certain information about the

food to the initial packer of the food, who might not be the immediate subsequent recipient of the food. As discussed above, we are taking this approach in response to comments requesting greater flexibility regarding methods of exchanging information at the beginning of the supply chain. A food that has not yet been initially packed may, in a short period of time, pass through the hands of multiple entities that would have all been considered shippers and receivers under the proposed rule. We have concluded that the structure of the proposed rule, which involved each of these entities keeping shipping and receiving records and (in the case of farms) passing along information on the harvesting and cooling of the food, was overly prescriptive and burdensome, particularly because it is our understanding that the entities that handle a food before it is first packed will often have a relationship with the entity that first packs the food, even if that entity is not the immediate subsequent recipient. The final rule's requirements for harvesters and coolers would provide the requested flexibility. In accordance with section 204(d)(1)(L)(ii) of FSMA, § 1.1325 would not require harvesters or coolers to keep records about any entities (such as the initial packer) who are not the immediate subsequent recipient of the food. Nor would § 1.1325 necessarily require the harvester or packer to send information directly to the entity that initially packs the food. As discussed above, under § 1.1325(a)(2) and (b)(2), the harvester or cooler may provide the information directly to the initial packer or they may elect to pass the relevant information through their supply chain partners (*e.g.,* a harvester providing information to a cooler) until it reaches the initial packer.

We also note that, although the exemptions in § 1.1305(d)(6) and (h)(2) potentially involve a series of written agreements meant to ensure that a future supply chain entity will take a certain action (*e.g.,* apply a kill step or commingle a RAC), these provisions do not require the exempt entity to know the identity of the future supply chain entity that will take that action, let alone to keep a record of who that future recipient will be. Instead, these provisions are structured so that each supply chain member only needs to interact with their immediate subsequent recipient to create the required written agreements.

(Comment 352) One comment suggests that the KDEs required for the growing CTE include information on chemicals (*e.g.,* pesticides) applied on the farm, including days, times, types, and amounts of chemicals, information on farm inspections, and any water testing performed on the farm. The comment maintains that the addition of these KDEs would be consistent with stricter standards that the comment asserts are needed to address food safety hazards at the farm level.

(Response 352) We decline to require growers of FTL foods or any other entities subject to the rule to keep the suggested information on chemicals. Such a requirement would not be consistent with the purpose of the rule, which is to establish recordkeeping requirements for foods designated for inclusion on the FTL to help us conduct rapid and effective traceback when investigating foodborne illness outbreaks.

(Comment 353) One comment asserts that although the proposed rule did not define ''growing,'' it appears from the preamble of the proposed rule that the requirement for linking the traceability lot code to growing area coordinates applies to produce and sprouts but not to aquacultured foods or foods from fishing vessels.

(Response 353) As previously stated, we have deleted the recordkeeping requirements for growing an FTL food in proposed § 1.1325, which included a requirement for growers to keep a record of the growing area coordinates for each traceability lot of food. Under the final rule, a traceability lot code is not assigned for a RAC until the RAC is initially packed (in the case of food not obtained from a fishing vessel, including aquacultured seafood) or until the RAC is received by the first land-based receiver (for food obtained from a fishing vessel) (see § 1.1320). In the case of produce, including sprouts, that traceability lot code will be linked in the initial packer's records to the name of the field or other growing area from which the food was harvested (see § 1.1330(a)(5)). In the case of aquacultured food, the traceability lot code will be linked in the initial packer's records to the name of the container from which the food was harvested (see § 1.1330(a)(6)). In both of those situations, the name of the field or container must correspond to the name used by the farmer, and the farmer is required under § 1.1315(a)(5) to maintain a farm map as part of their traceability plan, which must include geographic coordinates and any other information needed to identify the location of each field or container. This approach replaces the requirement in the proposed rule for the grower to maintain records linking each traceability lot of food to the growing area coordinates where the food was grown. For eggs, § 1.1315(a)(5) specifically notes that the farm map requirement does not apply to egg farms, and there is no obligation under § 1.1330 for an initial packer to maintain a record of the specific poultry house or field where eggs were harvested. This is because, in the case of egg farms, we think that the information the initial packer must maintain under § 1.1330(a)(4), identifying the location description for the farm where the food was harvested, is sufficient, and we do not see a traceability benefit to requiring more specific information about where a specific lot of eggs was harvested (especially in light of the fact that eggs are often collected from multiple poultry houses via a single conveyor belt that moves through all of the houses, thus making it impracticable to associate an egg with a specific poultry house). For food obtained from a fishing vessel, as discussed below, the first land-based receiver of the food must maintain records linking each traceability lot of the food to, among other things, the locations for the trip during which the food was caught (see Section V.L of this document).

(Comment 354) One comment asks that FDA reference, in the final rule or a future guidance document, our ''Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities'' (Ref. 27) to help entities subject to the subpart S requirements understand how we will classify certain activities of farms and facilities.

(Response 354) We will consider whether to reference the draft guidance on ''Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities'' in a future guidance document related to the food traceability recordkeeping requirements in subpart S. Section 1.1305 of the final rule defines ''farm'' to mean ''farm as defined in § 1.328'' (except for producers of shell eggs). As noted in Response 250, we plan to issue a proposed rule revising the definition of ''farm'' in several food safety regulations, including § 1.328, and we might reissue the above-noted draft guidance to align with any revision of the farm definition we might adopt in that rulemaking. We recognize that there is significant interest in how the term ''farm'' is defined, and we will provide communications as needed to ensure that entities covered by subpart S have clarity on this topic as the rulemaking related to the farm definition proceeds.

(Comment 355) One comment expresses concern about maintaining KDEs related to cooling foods on the FTL because cooling can occur multiple times and at multiple locations.

(Response 355) We agree that foods can be cooled at multiple points in the supply chain, and we believe it is important to traceability to keep records of all of the locations where a food is held, including all of the locations where cooling occurs. As discussed above, § 1.1325(b) requires persons who cool a RAC (not obtained from a fishing vessel) before the RAC is initially packed to keep certain records and to provide certain information to the initial packer of the RAC. Once a RAC is initially packed, anyone that subsequently cools the food would be required to keep the KDEs applicable to shipping and receiving of FTL foods under §§ 1.1340 and 1.1345, respectively.

(Comment 356) One comment maintains that because eggs are often batched in lots based on weekly date of pickup and, within that large lot, there would be many different data points on day and time of cooling for the lot, requiring the transmission of this information to a first receiver would be burdensome for both egg producers (especially small ones) and first receivers. The comment suggests that compliance with the refrigeration requirements of the egg safety regulation (21 CFR part 118 (part 118)) and the regulation for safe handling and refrigeration of eggs (21 CFR part 115 (part 115)) should be regarded as adequate documentation of the cooling of eggs, making additional records under subpart S unnecessary; alternatively, the comment suggests that records kept to meet the egg regulations should satisfy any subpart S requirements.

(Response 356) We disagree with the suggestion that maintaining and providing records of cooling of eggs under subpart S is not necessary for traceability. However, we think that revisions we have made in the final rule will alleviate many of the concerns expressed in the comment. As previously stated, § 1.1325(b) of the final rule requires that persons who cool RACs (including eggs) before they are initially packed must keep and provide to initial packers certain information on the cooling, including the date of cooling. Although proposed § 1.1350(b)(2)(iv) would have required egg farms to inform the immediate subsequent recipient of the eggs of the time of cooling, the time of cooling is not a required KDE under § 1.1325(b). Furthermore, under the final rule, egg producers are not required to link the § 1.1325(b) KDEs on cooling to a particular traceability lot, as traceability lot codes are not assigned until the eggs reach the initial packer (see § 1.1320). As discussed above, the cooling KDEs in § 1.1325(b) can be organized in whatever way is practical for the operation, such as on a shipment-by-shipment or day-by-day basis. Finally, we agree that egg producers should be able to use records they keep in accordance with part 115 or part 118 to comply with applicable subpart S requirements (including those for cooling in § 1.1325(b)), and this is permitted under § 1.1455(f) of the final rule.

K. Records of Initial Packing (§ 1.1330)

As previously discussed, the proposed rule included recordkeeping requirements applicable to the first receiver of a FTL food (proposed § 1.1330), which the proposed rule defined as the first person (other than a farm) who purchases and takes physical possession of a food on the FTL that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested. In addition to records of receipt, the proposed rule required first receivers to establish and maintain records containing and linking the traceability lot code of the food received to the following information:

- The location identifier and location description of the originator of the food;
- The business name, point of contact, and phone number of the harvester of the food, and the date(s) and time(s) of harvesting;
- The location identifier and location description of the place where the food was cooled, and the date and time of cooling (if applicable); and
- The location identifier and location description of the place where the food was packed, and the date and time of packing.

We stated in the preamble to the proposed rule (85 FR 59984 at 60008) that we were proposing these recordkeeping requirements for first receivers because we believed that a first receiver was the person best positioned to maintain comprehensive information about the origination and subsequent handling of a food, including information identifying the persons who originated, harvested, cooled, and packed the food. We stated that identifying the first receiver of a food as the first person who purchases and takes physical possession of the food would ensure that comprehensive records relating to the origination and handling of the food are maintained by a single person who both owns and possesses the food.

However, in response to many comments opposing the designation of ''first receiving'' of a food as a CTE, we are deleting the proposed first receiver requirements from the final rule. Instead, we are establishing requirements for the initial packing of a RAC other than a food obtained from a fishing vessel (in § 1.1330) and for the performance of the first land-based receiving of a food obtained from a fishing vessel (in § 1.1335). In accordance with this change (as well as the deletion of the proposed CTE for growing of FTL foods, including sprouts), § 1.1330(b) specifies the requirements applicable to the initial packing of sprouts (except soil- or substrate-grown sprouts harvested without their roots). In the following paragraphs, we discuss certain comments on the proposed requirements for first receivers as they apply to the requirements for initial packers, followed by a discussion of comments on the proposed requirements related to sprout operations.

1. Initial Packing of a RAC Other Than a Food Obtained From a Fishing Vessel

(Comment 357) Several comments express opposition to the proposed requirements for first receivers, maintaining that the requirements are impractical, overly burdensome, unnecessary for traceback, confusing, complicated, and challenging to implement, and that the cost of keeping such records would exceed the benefit. Several of these comments include suggestions for improvements if the first receiver requirements are retained.

Some comments maintain that, with respect to the produce industry, most of the proposed first receiver KDEs are held by the packinghouse where produce is initially packed and stored, but these facilities do not meet the definition of a first receiver, either because they do not purchase the produce or because they are considered farms. Other comments assert that the KDEs associated with the first receiver CTE are generally not shared between trading partners in the fresh produce supply chain today, so requiring such sharing would be a departure from existing industry event-based traceability practices. The comments instead ask that the rule require that traceability event-based information be kept by the performers of CTEs. Some comments also express concerns about data privacy and sharing sensitive farm information with parties that do not normally receive it, such as brokers,

processors, retail buyers, and even competitors. Some comments maintain that such data sharing would sometimes require changes to existing contractual provisions that restrict this type of data sharing.

(Response 357) We agree that the proposed requirements for first receivers caused confusion among many commenters, might not have aligned with some business practices in the produce industry, and could have been challenging to implement in some cases. Therefore, we are deleting the proposed requirements for first receivers from the final rule. However, much of the information we had proposed to require first receivers to keep remains critical information for traceability. We agree with the comments stating that the traceability information we proposed to require first receivers to maintain is often kept by packers. Therefore, in the final rule we have replaced the proposed requirements for first receivers of FTL foods with requirements for the initial packing of a RAC (other than food obtained from a fishing vessel) (§ 1.1330) and the first land-based receiving of a food obtained from a fishing vessel (§ 1.1335).

The KDEs that initial packers must keep under § 1.1330(a) are similar to the KDEs that a first receiver would have had to keep as a receiver of an FTL food under proposed § 1.1335 and as the first receiver of the food under proposed § 1.1330. Section 1.1330(a)(1) of the final rule specifies that for each traceability lot of a RAC (other than a food obtained from a fishing vessel) on the FTL that is initially packed, the initial packer must maintain records containing the following information and linking this information to the traceability lot:

- The commodity and, if applicable, variety of the food received (§ 1.1330(a)(1));
- The date the initial packer received the food (§ 1.1330(a)(2));
- The quantity and unit of measure of the food received (*e.g.,* 75 bins, 200 pounds) (§ 1.1330(a)(3));
- The location description for the farm where the food was harvested (§ 1.1330(a)(4));
- For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name (§ 1.1330(a)(5));
- For aquacultured food, the name of the container (*e.g.,* pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name (§ 1.1330(a)(6));
- The business name and phone number for the harvester of the food (§ 1.1330(a)(7));
- The date of harvesting (§ 1.1330(a)(8));
- The location description for where the food was cooled (if applicable) (§ 1.1330(a)(9));
- The date of cooling (if applicable) (§ 1.1330(a)(10));
- The traceability lot code the initial packer assigned (§ 1.1330(a)(11));
- The product description of the packed food (§ 1.1330(a)(12));
- The quantity and unit of measure of the packed food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds) (§ 1.1330(a)(13));
- The location description for where the food was initially packed (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference (§ 1.1330(a)(14));
- The date of initial packing (§ 1.1330(a)(15)); and
- The reference document type and reference document number (§ 1.1330(a)(16)).

Because the information that initial packers must keep under § 1.1330(a) is often shared with packers today, we do not believe that data privacy will be as much of a concern for producers as it was with the proposed requirement for farms to share information about the origination, harvesting, cooling, and packing of a food with a first receiver under proposed § 1.1350(b)(2). However, we recognize that some changes to current practices, including to contracts, may be necessary for certain covered entities. With regard to comments asking that information be kept only by those entities that performed an activity and not shared with others in the supply chain, we reiterate that the goal of this rulemaking is to increase the efficiency of traceback investigations and therefore better protect public health. Therefore, it is critical that we are able to determine as quickly as possible the nodes in the supply chain where product was handled. Being able to access information maintained by the initial packer about what farm a RAC came from, who harvested it and when, and (if it was cooled) where and when cooling was performed will shorten the time it takes to perform tracebacks and, therefore, support the public health benefits anticipated for the rule. For this reason, as discussed in Section V.J of this document, § 1.1325(a)(2) and (b)(2) require harvesters and coolers to provide initial packers with this information.

We also note that, in the proposed rule, we used the term ''returnable plastic containers'' as an example for unit of measure. We have corrected that terminology in the final rule with ''reusable plastic containers.''

(Comment 358) One comment expresses concern that a requirement to keep first receiver KDEs would discourage direct sourcing from farms by RFEs and processors.

(Response 358) As previously stated, we are deleting the proposed first receiver requirements, which should eliminate any concerns related to local sourcing posed by those requirements. We also note that the final rule provides a partial exemption from the subpart S requirements for RFEs and restaurants purchasing directly from a farm (§ 1.1305(j)) and a full exemption for small RFEs and restaurants (§ 1.1305(i)).

(Comment 359) Some comments request information on how KDEs should be linked to the traceability lot code.

(Response 359) As stated in Response 333, § 1.1330(a) requires initial packers to maintain records that contain several KDEs (including the traceability lot code) and that link this information to a particular traceability lot of an FTL food. While the rule does not prescribe how this linkage must be accomplished, examples include placing the traceability lot code on a reference document for the packing of the food that contains the relevant KDEs, or keeping records in an electronic database that can sort data based on the traceability lot code and provide the KDEs related to that traceability lot. These are just two examples, and there are many other ways that firms might choose to link KDEs to individual traceability lots. As set forth in § 1.1455(g), firms do not have to keep all of the information required by subpart S in a single set of records, and firms might maintain records for a specific traceability lot on multiple reference documents, provided the information can all be linked together (*e.g.,* by the fact that each document contains the traceability lot code). As previously discussed, linking the traceability lot code with the other KDEs for a CTE such as initial packing will help us efficiently trace the movement of a product through the supply chain and appropriately scope any regulatory or product actions.

(Comment 360) Some comments assert that FDA's ability to conduct investigations by navigating a single lot code being sent to multiple firms, which

could be a first receiver at different points in their supply chain, may be disrupted if or when a lot code is changed.

(Response 360) Although we have deleted the term ''first receiver'' from the final rule, we agree that changes to a lot code can disrupt traceability. As previously stated, § 1.1320(a) requires that a traceability lot code be assigned to an FTL food when it is initially packed, received by the first land-based receiver, or transformed. Because we conclude that changing the traceability lot code in other circumstances can hinder traceback efforts, § 1.1320(b) generally prohibits establishment of a new traceability lot code when conducting other activities, such as shipping, with the only exceptions being for situations where an FTL food is received from a person to whom subpart S does not apply.

(Comment 361) One comment suggests we focus on the traceability lot code, including a product identifier (GTIN) and internal lot code, rather than the product description.

(Response 361) We agree that traceability lot codes are a fundamental component of the subpart S recordkeeping requirements. A traceability lot code may include a product identifier such as a GTIN and/or an internal lot code (provided the definition of ''traceability lot code'' in § 1.1310 is met), but firms are not required to use GTIN or any other particular coding system or technology. On the other hand, we do not agree that the product description should not be part of the required KDEs for traceability. The final rule requires maintaining and providing product descriptions because they contain important distinguishing information about the product that can help us trace the correct product during a traceback.

(Comment 362) One comment asserts that the proposed requirements for first receivers to maintain information on harvesting (§ 1.1330(a)(2)) and packing (§ 1.1330(a)(4)) should be limited to ''as applicable'' because the information may not be necessary for tracing purposes for first receivers of aquacultured seafood. On the other hand, one comment asks that packers be required to maintain records supporting the production of the traceability lot code, including the harvest location or field, harvest date, and cooling and packing information.

(Response 362) We do not agree that maintenance of harvesting and packing information by initial packers may not be appropriate or relevant to tracing food, including food obtained from aquaculture operations. To identify the source of an FTL food, it is important to obtain information about where it was harvested and where it was initially packed. In traceback investigations, we need access to records documenting the movement of the food being investigated, particularly for locations in the supply chain where the food is handled in a way that could introduce contamination. Therefore, § 1.1330(a) includes requirements for initial packers to keep information on, among other things, the harvesting of the RAC they pack, including, for aquacultured food, the name of the container from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name (§ 1.1330(a)(6)).

(Comment 363) One comment asserts that requiring the first receiver of a food to maintain the location identifier and location description of the originator of the food is duplicative of the growing area coordinates tied to the lot code. Instead, the comment suggests that we require firms to keep the growing area coordinates and contact information for the originator.

(Response 363) As stated in Response 350, we have deleted the proposed growing CTE, which included the requirement to document growing area coordinates for each traceability lot of food. Instead, a farm that grows or raises an FTL food (other than eggs) must maintain a farm map showing the location and name of each field or other growing area in which FTL foods are grown (or, in the case of aquaculture, the location and name of each container in which FTL seafood is raised), including geographic coordinates and any other information needed to identify the location of each field, growing area, or container. The harvester must maintain the location description for the farm from which the food was harvested (see § 1.1325(a)). As defined in § 1.1310, the location description must include the physical location address or geocoordinates. (As previously discussed, we have deleted proposed requirements to keep location *identifiers* as KDEs for certain CTEs.) For produce, the harvester also must maintain the name of the field or other growing area from which the food was harvested, which must correspond to the name used by the grower; and for aquaculture, the harvester must maintain similar information relating to the container from which the food was harvested. Information regarding both the location description for the farm and the fields or containers from which the food was harvested is passed by the harvester to the initial packer, who will assign the traceability lot code to the food it packs. The initial packer must link that traceability lot code and the other KDEs (including the location description for the farm and the name of the field or container from which the food was harvested) to the relevant traceability lot.

We do not think it is duplicative to require both a location description for the farm where the food was harvested and (in the case of produce and aquacultured seafood) the name of the field or container from which the food was harvested. The location description is important for traceability because it helps FDA contact and visit a farm. The field number and container number serve different traceability purposes because they can help narrow the scope of an action such as a recall. (They can also be helpful after the traceback for root-cause investigations.) For small farms consisting of a single field, the field name and farm map might not add substantially more detail than the location description for the farm, but in most situations this will not be the case. Most farms have multiple fields, and some farms have fields that are not at all adjacent to each other (in some cases they are miles apart), in which case a single location description for the farm would provide considerably less precise information about where the food was grown than a farm map combined with a field name. We decline to require that geographic coordinates be passed through the supply chain, because we received comments expressing privacy concerns about sharing that information. By requiring the harvester to pass along the field or container name, while allowing the geographic coordinates to remain unshared in the grower's traceability plan, we can achieve the necessary level of traceability without requiring the sharing of sensitive information.

(Comment 364) Some comments suggest that clarity is needed concerning the proposed first receiver requirements to keep records about the harvester of the food in situations when a harvester is the owner of the company rather than a field employee.

(Response 364) Under the proposed requirements, the first receiver would have been responsible for maintaining harvesting information on harvested FTL foods, including the business name, point of contact, and phone number of the harvester. As discussed previously, we have removed the proposed requirements relating to the first receiver. Under § 1.1330 of the final rule, the initial packer must keep, among other KDEs, the business name

and phone number for the harvester (§ 1.1330(a)(7)), which the harvester must provide to the initial packer in accordance with § 1.1325(a)(2). Because the final rule does not require harvesters to provide the initial packer with a point of contact or the name of an individual, this eliminates any need to distinguish between the entity that owns the harvesting company and a field employee.

(Comment 365) Several comments request removal of the proposed requirement for first receivers to maintain dates of cooling and harvesting. One comment expresses support for maintaining records related to the date of harvesting but not the date of cooling.

(Response 365) We decline to eliminate requirements to record the dates of harvesting and cooling. We believe that dates for both harvesting and cooling are critical for helping us determine whether particular products may or may not have been impacted by a contamination event. Because we have removed the proposed first receiver requirements from the final rule, requirements relating to the date of harvesting and cooling are now found in the harvesting and cooling KDEs in § 1.1325, and in the initial packing KDEs in § 1.1330.

(Comment 366) Several comments suggest that time be removed as a KDE from all of the CTEs where it was proposed. Some comments maintain that requiring firms to record the time an event occurred would create an unnecessary burden, would not enhance traceability, or is not legally permissible. One comment asserts that it is not necessary to know when a food was packed to perform a traceback investigation, and that it would make recordkeeping requirements overly burdensome to maintain that information. Some comments assert that documenting time as a KDE would be challenging due to variability as to when in the event the time should be identified. One comment suggested that time should be optional or only required if applicable. However, one comment claims that packers already maintain records on the date and time of packing, so this information could easily be shared with FDA with little additional burden.

(Response 366) The proposed rule included KDEs relating to the time of cooling, packing, harvesting, receipt, and shipping. We agree with the comments asserting that the time of day when these events occurred is not information that is essential for effective traceability. Therefore, we have deleted all proposed KDEs regarding the time an event occurred. However, for operations that are able to keep records relating to time when an event occurred, we note that such records can be helpful during traceability, including in narrowing the scope of an action such as a recall. We therefore encourage the keeping of such records when possible, although the information is not required under subpart S.

(Comment 367) One comment asserts that any firm that packs, packages, or ships a product should be required to maintain grower-level records (*e.g.,* grower/harvester, field location and/or production location, harvest date/time).

(Response 367) As stated in Response 350, the final rule requires the initial packers of RACs on the FTL not obtained from a fishing vessel to maintain much of the information mentioned in the comment. However, once a food has been initially packed, entities other than the initial packer who ship the food are not required to keep such information. As discussed in Section V.M of this document, entities that ship a packed RAC (or any other FTL food) must maintain and provide to the immediate subsequent recipient the location description for the traceability lot code source or the traceability lot code source reference for the food, which should enable us to quickly identify the initial packer in the event of an outbreak. Once the initial packer has been identified, they can provide FDA with the type of grower-level information the comment discusses. We conclude that these requirements will allow for sufficient efficiency during traceback without unnecessarily burdening entities in the supply chain by requiring them to keep and share more information than needed.

(Comment 368) Several comments ask that we delete requirements to record the location identifier and location description of where the food was packed. One comment asserts that it is not necessary to know where a food was packed in order to perform a traceback investigation, and maintains that keeping this information would be overly burdensome. Some comments suggest that location information should either be optional or eliminated entirely for multiple CTEs, including transforming, receiving (including first receiver), and creation. One comment asserts that location identifiers should only have to be maintained if they are supplied by a shipper.

(Response 368) As previously stated, we have deleted proposed requirements to maintain a record of location identifiers. However, we do not agree that location information (in the form of location descriptions) is not necessary for traceability. As stated in the preamble to the proposed rule (85 FR 59984 at 59987), traceback begins at the end of the supply chain at the point of purchase or point of service (*e.g.,* grocery stores and restaurants) and follows the food product back through the points of distribution, processing, and production to determine the source of the product and its ingredients. Following the movement of a food through its supply chain, including events such as packing, receiving, shipping, and transforming, is an essential part of any traceback investigation.

The final rule includes recordkeeping requirements for initial packing because packing is the point in the supply chain where RACs are packed into a form that can be put into distribution. Because the packed product often is the first form of the food that has a production code assigned to it, the final rule requires initial packers to assign a traceability lot code to the RACs they initially pack (see § 1.1320). Given the importance of packing in defining the traceable product, we disagree with comments that it would be overly burdensome to keep and provide information on the location where a food was packed. Similarly, it is important to have information to identify the location where food was transformed, as that is another location where a traceability lot code must be assigned, and it is important to know the locations of shippers and receivers in case we need to visit those entities in the course of an investigation. Initially in a traceback, we might try to skip locations that only perform shipping and receiving, but we need to know those locations so that we can follow each physical movement of food should an investigation lead us to such a site. Having information on shipping and receiving locations is also critical in traceforward activities where we are tracking the movement of potentially contaminated food forward in distribution from the point of production.

(Comment 369) One comment suggests that first receivers be required to maintain records of the quantity and unit of measure of food received. However, one comment suggests that it is not necessary and would be overly burdensome.

(Response 369) Although we have deleted the proposed first receiver requirements, we believe that quantity and unit of measure are important KDEs for all CTEs in the final rule. These KDEs assist industry and the Agency in understanding and tracking how much of a product was harvested, cooled, packed, received, transformed, or

shipped as the food was handled and moved through the supply chain, as well as how much product would have been available for purchase in a given time period at RFEs and restaurants. Information on quantity and unit of measure is also critical when there is a need for an action, such as a recall, as a result of a traceback or traceforward.

(Comment 370) One comment maintains that the send-only KDEs in proposed § 1.1350(b)(2) effectively duplicate the KDEs kept by the first receiver.

(Response 370) As previously stated, we have deleted the proposed requirements for first receivers. We have also deleted the requirement in proposed § 1.1350(b)(2) that would have required all farms to pass certain information through the supply chain until it reached the first receiver. As discussed in Response 351, we conclude that it is more appropriate and less burdensome to have harvesters and coolers provide information about the activities they perform to the initial packers of RACs.

More generally, we recognize that in many cases the KDEs that must be sent by an entity to the immediate subsequent recipient are closely aligned with the KDEs that the recipient is required to maintain. This is intentional, as it helps ensure that the entity receiving the food will have the information they need, that any inaccuracies in the data can be quickly identified, and that both entities will maintain the information in a similar way, which helps us link shipments to each other. It is this linkage in records that will allow for efficient tracing of product during an investigation and assist in any needed traceforward operations.

(Comment 371) One comment maintains that it would be difficult for harvesters or initial buyers of seafood in foreign countries to determine if they need to comply with the first receiver requirements of the rule because they may not know the final destination of the product.

(Response 371) As noted above, we have deleted the first receiver requirements, which should alleviate some of the concerns expressed in the comment. Nevertheless, we understand that under the final rule, foreign suppliers will still need to know whether their product will be exported to the United States. Because the rule applies to both domestic and imported foods on the FTL, importers and other U.S.-based entities will need to work with their foreign suppliers to ensure that they understand their responsibilities under subpart S. However, because many of FDA's existing food safety regulations require compliance from foreign suppliers, we anticipate that many foreign suppliers already have mechanisms in place to determine if their foods will be exported to the United States.

(Comment 372) Several comments maintain that it is difficult to understand how the proposed first receiver requirements would apply under various scenarios where responsibility, ownership, and possession are not coincidental, such as when contract manufacturing and packing, consignment, brokerage, third-party logistics warehouses, co-operatives, or consolidators are involved.

(Response 372) As previously stated, we have deleted the proposed requirements for first receivers from the final rule and replaced them with requirements for the initial packing of a RAC (other than food obtained from a fishing vessel) (§ 1.1330) and the first land-based receiving of a food obtained from a fishing vessel (§ 1.1335). These requirements are not tied to ownership of the FTL food, which should reduce the confusion expressed in the comments. Physical possession of the food and performance of the activity (*e.g.,* initial packing) are what determines who must comply with §§ 1.1330 and 1.1335, as well as with the other CTEs and KDEs in the final rule. Thus, for example, if a contract manufacturer performed the initial packing of an FTL food, it would be required to comply with the initial packing requirements in § 1.1330. Similarly, if a third-party logistics warehouse received a food after it was initially packed, it would be subject to § 1.1345 due to its taking physical possession of the food in receiving it. As discussed in Section V.R of this document, entities that are subject to the subpart S requirements are allowed to have another entity (such as the owner of the food) establish and maintain the required records on their behalf; but it is the entity that manufactures, process, packs, or holds the food that is ultimately responsible for compliance, regardless of whether or not they own the food.

(Comment 373) One comment maintains that the effort to send certain KDEs to first receivers will be ineffectual if there is no mechanism for ensuring accuracy. According to the comment, because the KDEs are not all related to the immediate previous source of an FTL food, the first receiver would not be able to verify their accuracy. Some comments ask who will be held accountable if the data firms receive are not accurate. The comments maintain that in some cases the first receiver may not know they are the first receiver, or the shipper may not identify themselves as a farm, possibly leading to inadvertent non-compliance. One comment maintains that such a situation may arise because shipments of the exact same product with different traceability lot codes could have different first receiver recordkeeping requirements at the same receiver, depending on the path the foods took to the receiver.

(Response 373) As previously stated, we have deleted the proposed requirements for first receivers from the final rule, which should alleviate some of the concerns expressed in the comment. We believe it will be clear which entity in the supply chain is the initial packer or the first land-based receiver of an FTL food because those entities are performing specific activities. This is in contrast to the situation that would have existed under the proposed rule, in which the first receiver would have had to rely in part on information from their supplier that the supplier was a farm, which meant that they were the first receiver of the food.

More generally, we agree that data accuracy is critical to effective tracking and tracing of food. This is a principal reason why the final rule requires harvesters and coolers to provide the applicable KDEs to the initial packer of a RAC, and why it also requires shippers to provide the applicable KDEs to receivers. Every entity that is covered by subpart S is required to accurately maintain and (when applicable) pass along the required information. Where there are concerns about data accuracy, we encourage supply chain partners to work together to address those concerns.

(Comment 374) One comment states that first receivers may have challenges in obtaining required first receiver KDEs from ''small originators'' that are exempt from the rule.

(Response 374) Although we have removed the first receiver requirements from the final rule, we recognize that similar concerns could arise for an initial packer if the harvester and/or cooler that would usually be required to send required information to the initial packer is exempt from the rule. Therefore, the initial packing requirements include a provision specifying the records that initial packers must keep when they receive a RAC from someone to whom the subpart S requirements do not apply. Section 1.1330(c) specifies that for each traceability lot of a RAC (other than a food obtained from a fishing vessel) on

the FTL that a firm initially packs that it receives from a person to whom subpart S does not apply, the initial packer must maintain records containing the following information and linking this information to the traceability lot:

- The commodity and, if applicable, variety of the food received (§ 1.1330(c)(1));
- The date the initial packer received the food (§ 1.1330(c)(2));
- The quantity and unit of measure of the food received (*e.g.,* 75 bins, 200 pounds) (§ 1.1330(c)(3));
- The location description for the person from whom the initial packer received the food (§ 1.1330(c)(4));
- The traceability lot code the initial packer assigns (§ 1.1330(c)(5));
- The product description of the packed food (§ 1.1330(c)(6));
- The quantity and unit of measure of the packed food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds) (§ 1.1330(c)(7));
- The location description for where the food was initially packed (*i.e.,* the traceability lot code source) and (if applicable) the traceability lot code source reference (§ 1.1330(c)(8));
- The date of initial packing (§ 1.1330(c)(9)); and
- The reference document type and reference document number (§ 1.1330(c)(10)).

We think the information required under § 1.1330(c) is information that initial packers can be reasonably expected to know in situations where they receive a RAC from someone who is exempt from subpart S. Section 1.1330(c) does not require initial packers to maintain records relating to information they would have needed to rely on the harvester or cooler to provide, such as the name of the field from which the food was harvested.

(Comment 375) One comment requests clarification on how information will be shared downstream, specifically among firms before the first receiver if a lot code has not yet been assigned to the food. Some comments express concern about whether FDA would bring enforcement actions against first receivers that were not provided a traceability lot code.

(Response 375) As previously discussed, the final rule deletes the first receiver requirements and shifts the requirement to assign a traceability lot code from the grower of the food to the initial packer. This should eliminate any concerns about what a first receiver (or a packer) should do if it receives a food to which a traceability lot code has not been assigned. Furthermore, as discussed in Section V.N of this document, we have created modified requirements under the receiving CTE for any covered entity that receives an FTL food from a person to whom subpart S does not apply (§ 1.1345(b)). In that circumstance, the receiver of the food must assign a traceability lot code if one has not already been assigned (§ 1.1345(b)(1)). However, that is the only circumstance under which someone receiving the food (who is not the initial packer or the first land-based receiver, and who is not transforming the food) may assign a traceability lot code to the food. In all other circumstances, a traceability lot code must be provided by the person who ships the food, and must be maintained by the person who receives the food. If a required KDE, such as the traceability lot code, is not provided by the shipper, we encourage the receiver to address this concern with the shipper.

(Comment 376) One comment asserts that retailers will be challenged to determine if they are the first receiver when they purchase foods from brokers, because brokers are not covered by the rule and are not required to provide first receiver KDEs.

(Response 376) Because we have deleted the proposed first receiver requirements, we do not believe that RFEs and restaurants that purchase food from brokers will be challenged in understanding their recordkeeping responsibilities under subpart S. In most cases, the only KDEs that an RFE or restaurant will be required to maintain are the receiving KDEs under § 1.1345. RFEs and restaurants that purchase foods from brokers will need to work with their suppliers and/or brokers to ensure they receive the information provided by the shipper of the food in accordance with § 1.1340(b) (see Section V.N of this document).

(Comment 377) One comment suggests that, if FDA retains the first receiver requirements in the final rule, the Agency should make clear that covered entities may rely on other parties to establish and maintain records on their behalf.

(Response 377) As previously stated, we have deleted the proposed first receiver requirements. We discussed in the preamble to the proposed rule that entities subject to the rule may have third parties maintain records on their behalf. However, to be more explicit in the final rule that covered entities may do this, we have added language to specify that a person subject to the rule may have another entity establish and maintain records required under subpart S on their behalf, but the person is responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review (see § 1.1455(b)).

(Comment 378) One comment requests clarification on whether an egg processing plant that is owned by an egg farmer but not necessarily co-located with the farm (*e.g.,* it is separated by a few miles) would be the first receiver of the eggs.

(Response 378) As previously discussed, we have deleted the proposed first receiver requirements and have added requirements for the initial packing of RACs other than food obtained from a fishing vessel. In the situation described in the comment, it seems likely that the egg farmer is the harvester of the eggs, and the egg processing plant is the initial packer. This is based on the activities performed and does not depend on ownership or location. The final rule provides flexibility as to how the harvester of the eggs provides the initial packer with the information on harvesting required under § 1.1325(a)(2). Additionally, as discussed in Response 206, if an egg processing plant commingles eggs from a farm it owns with eggs from other farms under different company management, and it does so after harvesting but before processing, the commingled eggs are partially exempt from the final rule (see § 1.1305(h)).

2. Additional Records for Initial Packing of Sprouts

In the proposed rule as part of the growing CTE, we proposed to require that sprout growers establish and maintain records linking the traceability lot code for each lot of sprouts to certain information about the seeds they use for sprouting (proposed § 1.1325(b)). Specifically, we proposed to require sprout growers to establish and maintain records containing the following information, if applicable:

(1) The location identifier and location description of the grower of seeds for sprouting, the associated seed lot code assigned by the seed grower, and the date of seed harvesting;

(2) The location identifier and location description of the seed conditioner or processor, the associated seed lot code assigned by the seed conditioner or processor, and the date of conditioning or processing;

(3) The location identifier and location description of the seed packinghouse (including any repackers, if applicable), the associated seed lot code assigned by the seed packinghouse, and the date of packing (and of repacking, if applicable);

(4) The location identifier and location description of the seed supplier;

(5) A description of the seeds, including the seed type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment;

(6) The seed lot code assigned by the seed supplier, including the master lot and sub-lot codes, and any new seed lot code assigned by the sprouter;

(7) The date of receipt of the seeds by the sprouter; and

(8) For each lot code for seeds received by the sprouter, the sprout traceability lot code(s) and the date(s) of production associated with that seed lot code.

As discussed in the following paragraphs, in response to comments we have made changes to the requirements for sprout growers and we have moved these requirements to the CTE for initial packers, so that the requirements apply to initial packers of sprouts. In addition, on our own initiative, we have clarified that these requirements for the initial packers of sprouts do not apply to soil- or substrate-grown sprouts harvested without their roots, consistent with the types of sprouts that are subject to subpart M (''Sprouts'') of the produce safety regulation. In the preamble to the final rule adopting the produce safety regulation (80 FR 74353 at 74497), we stated that soil- or substrate-grown sprout shoots that are harvested above the soil or substrate line, such that their roots are not harvested for human consumption, do not present the same risks as other types of sprouts. Therefore, soil- or substrate-grown sprouts that are harvested without their roots are not covered by the sprout-specific provisions in subpart M, but are covered by the remainder of the produce safety regulation. Similarly, we conclude that soil- or substrate-grown sprouts that are harvested without their roots should not be covered by the sprout-specific provisions in § 1.1330(b), but they are covered by the remainder of the requirements in subpart S.

(Comment 379) One comment requests clarification on who is responsible for maintaining the proposed records of sprout growing. Some comments maintain that entities other than the sprout grower would be better positioned to establish and maintain the required KDEs. For example, several comments suggest that either the growers of seed for sprouting, the suppliers of seed for sprouting, or both should be required to maintain the records. A few comments assert that sprout growers should only be required to maintain records that trace back to the seed supplier, contending that the proposed requirements would place too great a burden on sprout growers by requiring them to have information to which they might not have access (*e.g.,* information on seed growers). One comment suggests that the records should be maintained by the seed grower and seed supplier, as appropriate, and only be provided to the sprout grower during an investigation of an outbreak of foodborne illness, citing concerns related to sharing proprietary business information through the supply chain.

(Response 379) As discussed above, we have revised the final rule so that the sprout-specific KDEs are kept by the initial packer of the sprouts, not the grower. (We recognize that in many cases the grower is also the initial packer.) We do not agree that entities such as the seed supplier or seed grower should be required to maintain these KDEs. Because sprouts are the commodity that is on the FTL, we do not think it is appropriate to require entities in the supply chain before the sprouts have been grown (*e.g.,* seed suppliers) to maintain information under subpart S. However, under § 1.1455(b), an initial packer of sprouts may arrange for a seed supplier or another entity to maintain information required by the rule on their behalf, as long as the initial packer can provide the required information to FDA within 24 hours of a request.

(Comment 380) Several comments express support for some or all of the proposed KDEs related to sprouts and seed for sprouting. However, one comment asserts that the proposed requirements fail to reflect the complexity of the international supply chain for seeds for sprouting, especially mung beans. The comment describes challenges associated with tracing mung beans grown overseas, specifically with obtaining information such as the location identifier and location description of the grower of seed for sprouting, the seed lot code assigned by the seed grower, and the date of seed harvesting. The comment maintains that tracing to the seed level would prevent importation of internationally sourced mung beans and suggests revising the provisions to require traceback of seed lots to the farm level only when such information is reasonably available and obtainable.

(Response 380) We agree that some of the proposed recordkeeping requirements related to seed growers may be challenging for sprout growers to obtain and we have made changes to the requirements in the final rule. As previously discussed, we have deleted the proposed requirements for the growing and first receiver CTEs and have added requirements for initial packing of RACs other than food obtained from a fishing vessel that include specific requirements for sprout growers. Regarding the proposed sprout-specific requirements, we agree with the comments that it would be challenging for sprout growers (and initial packers of sprouts) to consistently obtain information related to the growing and harvesting of seed used for sprouting, particularly in situations where the seed was sourced from multiple small entities. Therefore, in § 1.1330(b)(1) we have deleted the requirement to keep the seed lot code assigned by the seed grower (proposed § 1.1325(b)(1)) and are requiring information related to the location description for the seed grower and the date of harvesting of the seed (proposed § 1.1325(b)(1)) only if either is available to the initial packer of sprouts. We deleted the requirement to maintain information on the seed lot code assigned by the seed grower because it might be especially burdensome, as there might be a considerable number of small farms growing seed for sprouting, which could result in having to record a large number of seed lot codes for a single shipment of seeds. However, we encourage initial packers of sprouts to maintain the seed lot code assigned by the seed grower, if it is available to them. We have changed the language relating to seed lot codes in final § 1.1330(b)(2) through (4) to better reflect the variation in industry practices regarding the assignment of seed lot codes. Thus, while proposed § 1.1325(b)(2) required a record of the seed lot code assigned by the seed conditioner or processor, final § 1.1330(b)(2) omits the language ''assigned by the seed conditioner or processor,'' in recognition of the fact that the lot code associated with the conditioning or processing of the seeds might not have been assigned by the conditioner/processor. Final § 1.1330(b)(3) and (4) both contain language about ''any'' seed lot code that may have been assigned by the packinghouse (§ 1.1330(b)(3)), the supplier, or the sprouter (§ 1.1330(b)(4)). This revised language recognizes that new seed lot codes might not always be assigned by these entities; however, any new seed lot codes that are assigned must be maintained.

As previously stated, we are deleting all proposed requirements regarding location identifier, including in proposed § 1.1325(b)(1) through (4). We have also removed the requirement to keep information on volume for the description of the seeds in final

§ 1.1330(b)(5) in response to comments asking that we simplify and streamline the KDEs, and because we determined that this information was not necessary. We removed the proposed requirement to keep, for each lot code of seeds received by the sprouter, the sprout traceability lot code(s) and the date(s) of production associated with that seed lot code (proposed § 1.1325(b)(8)) because the information necessary for traceability is captured in the KDEs required for the initial packer in the final rule. Finally, we added the requirement to keep reference document type and reference document number (final § 1.1330(b)(7)) for the sprout-related records for consistency with the KDEs required for other CTEs in the final rule.

As a result of these changes, § 1.1330(b) of the final rule specifies that for each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) that is initially packed, in addition to maintaining the initial packing KDEs set forth in § 1.1330(a), the initial packer must also maintain records containing the following information and linking it to the traceability lot of sprouts:

- The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available (§ 1.1330(b)(1));
- The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing (§ 1.1330(b)(2));
- The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse (§ 1.1330(b)(3));
- The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter (§ 1.1330(b)(4));
- A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment (§ 1.1330(b)(5));
- The date of receipt of the seeds by the sprouter (§ 1.1330(b)(6)); and
- The reference document type and reference document number (§ 1.1330(b)(7)).

Other than the deletion of the location identifier KDEs and the changes regarding seed lot codes, the final requirements related to the maintenance of information concerning seed conditioning, seed packinghouses, and seed suppliers are the same as the proposed requirements. We did not receive comments indicating that this information would be difficult to obtain for sprout growers and we continue to believe this information is needed to facilitate the tracing of seed used for sprouting. The specific food safety concerns relating to sprouts (including concerns about the seeds used for sprouting) are discussed in the preamble to the proposed rule (see 85 FR 59984 at 60007).

(Comment 381) Several comments maintain that there is overlap between the subpart S requirements and organic certification, and one comment asserts that current industry best practices cover the proposed requirements for sprouts.

(Response 381) As discussed in Response 119, any records that an organic farm may keep under the National Organic Program (or other certification program) that contain information required by subpart S, such as the field where product was harvested or the date of harvest, can be used to comply with this subpart. Therefore, to the extent that initial packers of sprouts maintain records for organic certification (or for any other purpose) that contain information required in § 1.1330 or other applicable subpart S requirements, they may use such records to meet the requirements of this rule (see § 1.1455(f)).

(Comment 382) Several comments ask whether the requirement in proposed § 1.1325(b)(1) refers to the date of seed (for sprouting) harvest or the date of sprout harvest.

(Response 382) Proposed § 1.1325(b)(1) referred to the ''date of seed harvesting,'' by which we meant the date of harvesting of the seeds used for sprouting. Section 1.1330(b)(1) of the final rule requires initial packers of sprouts to maintain records including, among other information, the ''date of seed harvesting,'' if it is available. This refers to the harvest date for the seeds used for sprouting, not of the sprouts themselves. Initial packers of sprouts also must maintain records identifying the harvest date of the sprouts (§ 1.1330(a)(8)).

(Comment 383) Several comments suggest adding a requirement for sprout growers to maintain records of seed testing results (*e.g.,* tests for pathogens, germination, and/or purity).

(Response 383) We decline to make this change because we conclude that a requirement for sprout operations to maintain records of seed testing would be beyond the scope of this rulemaking. Such records would not improve the efficiency of traceback for sprouts in the event of an outbreak of foodborne illness, which is the purpose of this rulemaking. However, we note that there are sprout testing requirements in subpart M of the produce safety regulation, including a requirement to establish and keep records documenting the results of all analytical tests conducted for purposes of compliance with subpart M (see 21 CFR 112.150(b)(4)).

(Comment 384) One comment disagrees with the statement in the preamble to the proposed rule that seeds that are primarily intended for livestock or field cultivation are sometimes diverted for sprouting for human consumption (see 85 FR 59984 at 60007). The comment maintains that their firm only sources seed for sprouting from growers that produce seed specifically for sprouting for human consumption.

(Response 384) We acknowledge that some sprout growers may use seeds from growers that produce seed specifically for sprouting for human consumption, and we support and encourage those efforts. However, we are aware that the intended use of seed when it is grown (*e.g.,* animal consumption or field cultivation) is not always commensurate with how it is ultimately used (Ref. 28).

L. Records of First Land-Based Receiving of Food Obtained From a Fishing Vessel (§ 1.1335)

We proposed to require first receivers of seafood products on the FTL that were obtained from a fishing vessel to keep, in addition to records of receipt of food required under proposed § 1.1335, records containing and linking the traceability lot code of the seafood product received to the harvest date range and locations (National Marine Fisheries Service Ocean Geographic Code or geographical coordinates) for the trip during which the seafood was caught (proposed § 1.1330(b)). Included among the proposed KDEs for receivers of FTL foods was the location identifier and location description for the immediate previous source (other than a transporter) of the food (proposed § 1.1335(a)), which for food obtained from a fishing vessel meant the vessel identification number or license number (both if available) for the fishing vessel (under the proposed definition of ''location identifier'') and the name of the fishing vessel that caught the seafood, the country in which the fishing vessel's license (if any) was issued, and a point of contact for the fishing vessel (under the proposed definition of ''location description'') (see proposed § 1.1310).

However, as previously discussed, we are deleting the proposed first receiver recordkeeping requirements and replacing them with requirements related to the initial packing of RACs other than food obtained from a fishing vessel (§ 1.1330) and the first land-based receiving of food obtained from a fishing vessel (§ 1.1335). As previously stated, the final rule defines ''first land-based receiver'' as the person taking possession of a food for the first time on land directly from a fishing vessel (see § 1.1310). We are also removing the concept of a ''location identifier'' from the final rule (including the parts of that term that were specific to fishing vessels), and we are revising the definition of ''location description'' so that it no longer includes information specific to fishing vessels.

Section 1.1335 of the final rule specifies that for each traceability lot of a food obtained from a fishing vessel for which a person is the first land-based receiver, such person must maintain records containing the following information and linking this information to the traceability lot:

- The traceability lot code they assigned (§ 1.1335(a));
- The species and/or acceptable market name for unpackaged food, or the product description for packaged food (§ 1.1335(b));
- The quantity and unit of measure of the food (*e.g.,* 300 kg) (§ 1.1335(c));
- The harvest date range and location (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught (§ 1.1335(d));
- The location description for the first land-based receiver (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference (§ 1.1335(e));
- The date the food was landed (§ 1.1335(f)); and
- The reference document type and reference document number (§ 1.1335(g)).

These records required for first land-based receivers of food obtained from a fishing vessel are similar to the records that first receivers of food obtained from a fishing vessel would have been required to keep under proposed §§ 1.1330(b) and 1.1335, although as discussed below we have removed information that would have identified specific fishing vessels. In the following paragraphs, we discuss in more detail the requirements applicable to the first land-based receivers of foods obtained from a fishing vessel in response to comments we received on the proposed requirements for first receivers of food obtained from a fishing vessel.

(Comment 385) One comment maintains that because the first receiver in the shrimp industry will likely be the unloading dock or a fish house, it will be difficult for these entities to meet the requirements to create and maintain the required first receiver records.

(Response 385) As previously stated, we have deleted the proposed first receiver requirements. If the shrimp was obtained from a fishing vessel, and an unloading dock or fish house is the first entity that takes possession of the shrimp on land, they would be required to comply with the requirements for first land-based receivers of food obtained from a fishing vessel in § 1.1335. We think these entities will be well-positioned to comply with these requirements. Information regarding harvest location and harvest date ranges (§ 1.1335(d)) will be more readily available to the first land-based receiver because they are receiving fish directly from the vessels, and the unloading dock or fish house should readily know the other information required under § 1.1335, which includes the traceability lot code they must assign (in accordance with § 1.1320(a)) as the first land-based receiver of the food (§ 1.1335(a)), and the species and/or acceptable market name for unpackaged food or the product description for packaged food (§ 1.1335(b)). Species name is information often used to describe seafood, as is the acceptable market name, examples of which can be found in FDA's ''Guidance for Industry: The Seafood List'' (Ref. 29). The first land-based receiver also must keep a record of the quantity and unit of measure of the food received (§ 1.1335(c)) and the date the food was landed (§ 1.1335(f)), which is the date when the food is transferred for the first time from a fishing vessel to land. In addition, the first land-based receiver must keep a record of its own location description (§ 1.1335(e)), which is also the traceability lot code source (because the first land-based receiver assigns the traceability lot code to the food), and, if applicable, the traceability lot code source reference (if the first land-based receiver elects to provide a traceability lot code source reference to its customers when it ships the food) (see § 1.1340(b) and Section V.F of this document). Lastly, the first land-based receiver must keep a record of the reference document type and number for the reference document (or documents) associated with their receipt of the food.

(Comment 386) Several comments agree that the first receiver of seafood products should be the buyer or the first person (other than a fishing vessel or aquaculture farm) who purchases and takes physical possession of a food on the FTL. However, one comment asks that we allow fishing vessels that process fish and that are registered food facilities to fulfill the first receiver recordkeeping requirements because they are best suited to meet these requirements based on their role in the supply chain. This comment suggests that some companies may be integrated such that the food remains in their control from harvest through processing (first and secondary), and the end point of service may be the first transfer of ownership of the food.

(Response 386) As discussed above, fishing vessels are exempt from most of the requirements of subpart S (see § 1.1305(m)), and a fishing vessel, including one that processes on the vessel, would not meet the definition of a first land-based receiver. However, a fishing vessel could establish and maintain the required records on behalf of the first land-based receiver, in accordance with § 1.1455(b). More generally, a fishing vessel could assign a lot code to the lot it processes and provide the lot code and other relevant information (*e.g.,* harvest date range and location) to the first land-based receiver to assist that entity in meeting the requirements of § 1.1335. The first land-based receiver would then have the option of retaining the lot code assigned on the vessel as the traceability lot code for the food or assigning its own traceability lot code. Under either option, the first land-based receiver would be the traceability lot code source for the food.

Regarding an integrated company such as is described in the comment, § 1.1305(m)(1) specifies that (except as stated in § 1.1305(m)(2)) subpart S does not apply to entities that manufacture, process, pack, or hold food obtained from a fishing vessel until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel. Thus, in a situation where the owner, operator, or agent in charge of the fishing vessel retains ownership of the food obtained from the fishing vessel after the food is received on land, the partial exemption in § 1.1305(m) would continue to apply even though the food is now on land. As discussed in Response 225, this may lead to situations where the first land-based receiver is partially exempt under § 1.1305(m), and where a traceability lot code is therefore not required until the food is sold to a non-exempt receiver,

who would be required to assign a traceability lot code under § 1.1345(b)(1) (unless they are an RFE or restaurant). Similar to the discussion above, an integrated company of this sort could assign lot codes to the food it handles and could provide those lot codes and other relevant traceability information to the first non-exempt receiver to assist that entity in meeting the requirements of § 1.1345(b). More generally, we recognize that many integrated companies of this sort are adopting practices to improve traceability, and we encourage such efforts even in situations where a company's activities are partially exempt under § 1.1305(m).

(Comment 387) One comment asserts that for molluscan shellfish, the permitted dealer who makes the first purchase of the shellfish should be considered the first receiver under the rule. The comment maintains that if the permitted dealer is a harvester or aquaculture farmer, they would become the first receiver once the product is landed and taken to a land-based facility for processing and sale.

(Response 387) If the permitted dealer described in the comment meets the definition of the first land-based receiver of the shellfish (*i.e.,* it is the person taking possession of the food for the first time on land directly from the fishing vessel), that permitted dealer would be responsible for maintaining the relevant KDEs for the shellfish in accordance with § 1.1335. However, we note that raw bivalve molluscan shellfish that meets the criteria in § 1.1305(f) is exempt from the rule.

(Comment 388) One comment states that transshipment of fish between vessels of different ownership is a common business practice in the seafood industry that increases the efficiency of fishing fleets, but may also be used to conceal illegal, unreported, and unregulated (IUU) catch. The comment asserts that, to combat IUU catch, many seafood industry leaders and retailers have published at-sea transshipment policies that require data collection on the occurrence of transshipment. The comment recommends that the first receiver KDEs include vessel identification numbers of both harvesting and transshipment vessels and dates of harvest and transshipment. The comment also suggests that mass balance recalculations be required at each CTE for the fish (*i.e.,* accounting for the amount of fish before and after the event, including transformation of fish into another form (*e.g.,* processing) and movement of fish out of a person's control (*e.g.,* transfer to another boat)).

(Response 388) As previously discussed, for food obtained from a fishing vessel, we have replaced the proposed first receiver requirements with the first land-based receiver requirements in § 1.1335. The KDEs for first land-based receivers include information on the harvest location and harvest date range for the food obtained from a fishing vessel (§ 1.1335(d)). However, we have deleted the proposed requirements to maintain information identifying the fishing vessel, whether a landing or transshipment vessel. Specifically, we have deleted the proposed requirements for first receivers of food obtained from fishing vessels to maintain the ordinary records of receipt of foods (see proposed § 1.1330(b)), including the location identifier and location description for the immediate previous source (other than a transporter) of the food (proposed § 1.1335(a)), which, under the definitions set forth in proposed § 1.1310, would have included the name of the fishing vessel that caught the seafood, the vessel identification number or license number (both if available) for the fishing vessel, the country in which the fishing vessel's license (if any) was issued, and a point of contact for the fishing vessel. We conclude that it is not necessary to require first land-based receivers to maintain information identifying the fishing vessel because that is generally not information we need to identify contaminated food during a traceback, and it is unlikely we would go to a fishing vessel during an investigation of foodborne illness. Moreover, we decline to adopt fishing vessel identification requirements to facilitate identification of IUU fishing because that concern is beyond the scope of subpart S, which is intended to assist with traceback and traceforward operations in response to foodborne illness outbreaks. However, we support efforts to combat IUU fishing practices, including efforts to maintain records beyond those required under subpart S that might provide additional information on the movement of seafood and seafood products.

Regarding the request that we require mass balance calculations for fish at each CTE, the final rule requires the first land-based receiver to maintain a record of the quantity and unit of measure of food obtained from a fishing vessel (§ 1.1335(c)). Quantity and unit of measure are also required as part of the shipping, receiving, and transformation KDEs. However, we cannot require fishing vessels to keep information on the amount of fish that is transferred among vessels at sea, as fishing vessels are largely exempt from the subpart S requirements under § 1.1305(m).

(Comment 389) One comment recommends that a transshipment vessel capture first receiver KDEs, rather than designating the first receiver as the first person other than a fishing vessel or farm to take possession of the food. The comment maintains that some seafood products have long journeys before being landed with a first receiver, during which the seafood must be kept at a proper temperature to maintain freshness and prevent foodborne illness. Therefore, the comment suggests that first receivers be required to keep a record of the first frozen date and location and the packing date and location.

(Response 389) Because section 204(d)(6)(C) of FSMA (codified in § 1.1305(m) of the final rule) partially exempts owners, operators, and agents in charge of a fishing vessel from the subpart S recordkeeping requirements, we cannot require that operators of fishing vessels maintain the suggested KDEs. However, the rule requires the first land-based receivers of food obtained from a fishing vessel to maintain certain KDEs, including information on the harvest date range and harvest location of the food, the description of the food, and the quantity and unit of measure of the food, which could include information on whether the product was frozen and how it was packed. First land-based receivers are not required to record the dates of any freezing or packing of the food on the fishing vessel. However, information on any processing that occurs on vessels may need to be kept for compliance with other FDA regulations, such as the seafood HACCP regulation in part 123.

(Comment 390) Some comments express concern that harvesters and initial buyers might be unlikely to know the final destination or market form of the fish they capture or purchase. The comments request additional information on how the rule would apply in this situation.

(Response 390) As previously stated, the final rule requires that first land-based receivers of food obtained from a fishing vessel maintain certain KDEs about the food as it was caught (*e.g.,* harvest date range and harvest location) and information on the food as it was handled by them *(e.g.,* the quantity and unit of measure of the food, the date of landing). It is not necessary for entities such as harvesters and initial buyers to know the final destination or market form of the food to maintain the KDEs for which they are responsible. However, if such firms know that the

food they harvest or buy will eventually be subjected to a kill step or changed such that it is no longer on the FTL, they may be eligible for an exemption under § 1.1305(d)(6) of the final rule if they enter into a written agreement specifying that a kill step will be applied or the food will be changed such that it is no longer on the FTL. Similarly, if the seafood is a RAC and they know that it will be commingled after it is harvested but before it is processed, they may be eligible for an exemption under § 1.1305(h)(2), if they enter into a written agreement as set forth in that provision.

(Comment 391) One comment recommends separately listing first receiver KDEs required for aquacultured products and seafood products from a fishing vessel to make the rule easier to understand. The comment also suggests specifying that the KDEs for harvesting and packing be considered ''as applicable'' because some may not apply to aquaculture.

(Response 391) We agree that the requirements for food from aquaculture farms and food obtained from fishing vessels should be listed separately. As previously stated, the final rule deletes the proposed first receiver requirements and replaces them with requirements applicable to the initial packing of RACs other than food obtained from a fishing vessel, which includes food from aquaculture farms (see § 1.1330(a)(6)), and requirements for the first land-based receiving of food obtained from a fishing vessel (§ 1.1335). Under § 1.1330(a), the initial packer of aquacultured food must keep information on the harvesting and packing (among other things) of food from aquaculture farms. We believe that all of the information required under § 1.1330(a) is relevant to aquaculture (see Response 122 for a discussion of initial packing of aquacultured food).

(Comment 392) One comment suggests that ''location identifier'' be an optional requirement because most organizations do not assign ''identifiers'' to locations that are referenced by their organization and their customers. The comment maintains that the proposed rule's reference to a fishing vessel as a ''location'' is confusing because of the artificial distinction between an identifier and a description. Another comment suggests that maintaining the location identifier and location description for a fishing vessel should only be required if there are hazards associated with the harvest location. Both comments ask why fishing vessels are the only location descriptions that require a point of contact. One comment also recommends that the location description for fishing vessels be any of the applicable proposed attributes, including vessel identification number, license number, name of the vessel, or the country in which the vessel is licensed.

(Response 392) We agree with the comment that requiring both a location identifier and location description would be confusing for organizations that do not assign identifiers to locations or for locations with multiple location identifiers. Therefore, we have deleted the proposed definition for ''location identifier'' along with all proposed requirements to keep a record of the location identifier. With respect to fishing vessels, we have deleted the proposed definition of ''location description'' as specifically applicable to fishing vessels (*i.e.,* the name of the fishing vessel that caught the seafood, the country in which the fishing vessel's license (if any) was issued, and a point of contact for the fishing vessel), and we have deleted all proposed requirements to record fishing vessel identification information. Instead, the rule requires the first land-based receiver of food obtained from a fishing vessel to maintain records linking the traceability lot to the harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught. The first land-based receiver must maintain this information regardless of whether the relevant fishing waters are associated with known hazards.

(Comment 393) Several comments state that seafood catches from multiple fishing vessels are commingled at various points in the supply chain, including while at sea, immediately following landing before receipt by a first receiver, or both. The comments assert that it will be challenging to maintain traceability information on the catches given the commingling opportunities, and they contend that it would be impossible to separate the catches from each other once they are commingled.

(Response 393) As discussed in Section V.E.14 of this document, fishing vessels are largely exempt from the requirements of this rule (see § 1.1305(m)). The first land-based receiver of food obtained from a fishing vessel is required to designate a traceability lot (or multiple traceability lots) of food obtained from the fishing vessel and assign a traceability lot code or codes to each traceability lot (§§ 1.1320(a) and 1.1335). Among other KDEs, the first land-based receiver must keep harvest information (location and date range) for each traceability lot. However, multiple harvest dates can be kept as a date range representing the entire catch on a vessel, rather than lists of dates of each catch. Similarly, multiple harvest locations can be kept as a single, larger harvest location, encompassing all of the locations of multiple catches. Thus, the rule does not require a vessel that has multiple catches to keep the fish separate or maintain information on dates or locations that is linked to a specific subset of fish on the vessel (*i.e.,* there is no need to identify a date or location a given fish was caught if the vessel contains fish harvested over multiple dates at multiple locations). Finally, we note that there is a partial exemption from subpart S for commingled RACs (§ 1.1305(h)), which for food obtained from a fishing vessel means that food from different landing vessels was combined or mixed after the vessels landed but before processing (see the definition of ''commingled raw agricultural commodity'' in § 1.1310).

(Comment 394) Some comments assert that the harvest location for a fishing vessel trip should not be restricted to the National Marine Fisheries Service Ocean Geographic Code or geographical coordinates (as specified in proposed § 1.1330(b)). The comments maintain that there are other methods used in the industry to identify harvest location, including Food and Agriculture Organization Fishing Areas or approved harvest areas used under the NSSP (which requires an area identifier code maintained by each state).

(Response 394) We agree with the comments that other standards may be used to identify the harvest location for a fishing vessel trip. Section 1.1335(d) specifies that the harvest location for food obtained from a fishing vessel may be identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard. With regard to the NSSP, we note that raw bivalve molluscan shellfish that are covered by the requirements of the NSSP are exempt from subpart S, as are all raw bivalve molluscan shellfish that meet the criteria in § 1.1305(f).

(Comment 395) One comment states that the location identifier, location description, and point of contact for the traceability lot code generator, which shippers of shellfish would be required

to keep under proposed § 1.1350(a)(4), are all contained in the State Shellfish Control Authority Dealer permit, which uses the standards outlined by the NSSP to certify shellfish dealers to ship or process shellfish for shipment. The comment recommends that for raw bivalve molluscan shellfish covered by the requirements of the NSSP, the shellfish dealer should be regarded as the first receiver of the shellfish and the traceability lot code generator. The comment asserts that because FDA's Interstate Certified Shellfish Shippers List (ICSSL) already has the location and point of contact information for the shellfish dealer, a simple reference code containing the state, dealer type, and dealer number is all that would be needed to access the traceability lot code generator information for the first receiver.

(Response 395) We agree that the NSSP requires robust traceability information for raw bivalve molluscan shellfish. We also understand that each Authority will certify shellfish facilities and subsequently request that FDA list them on the ICSSL via the form FDA 3038. This form does contain the dealer's name and a contact name and address. As previously stated, the final rule exempts from subpart S raw bivalve molluscan shellfish that is covered by the requirements of the NSSP (see § 1.1305(f)).

M. Records of Shipping (§ 1.1340)

We proposed to require that for each food on the FTL that is shipped, the shipper must establish and maintain records containing and linking the traceability lot code of the food to the following information: the entry number(s) assigned to the food (if the food is imported) (proposed § 1.1350(a)(1)); the quantity and unit of measure of the food (*e.g.,* 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1350(a)(2)); the traceability product identifier and traceability product description for the food (proposed § 1.1350(a)(3)); the location identifier, location description, and point of contact for the traceability lot code generator (proposed § 1.1350(a)(4)); the location identifier and location description for the immediate subsequent recipient (other than a transporter) of the food (proposed § 1.1350(a)(5)); the location identifier and location description for the location from which the food was shipped, and the date and time the food was shipped (proposed § 1.1350(a)(6)); the reference record type(s) and reference record number(s) (*e.g.,* ''BOL No. 123,'' ''ASN 10212025'') for the document(s) containing the previously stated information (proposed § 1.1350(a)(7)); and the name of the transporter who transported the food from the shipper (proposed § 1.1350(a)(8)). As discussed below, in response to comments as well as on our own initiative (to align the shipping KDEs with other changes we are making to the proposed rule), we have deleted some of the proposed shipping KDEs and have revised others.

In addition to the records that shippers of FTL foods must maintain, we proposed to require shippers to send records (in electronic or other written form) containing the information the shipper was required to keep (except for the information on reference record types and numbers) to the immediate subsequent recipient (other than a transporter) of each traceability lot shipped (proposed § 1.1350(b)(1)). We further proposed to require that farms must also send the following information to the recipient: a statement that the entity is a farm; the location identifier and location description of the originator of the food (if not the farm providing this information); the business name, point of contact, and phone number of the harvester of the food (if not the farm providing this information), and the date(s) and time(s) of harvesting; the location identifier and location description of the place where the food was cooled (if not the farm providing this information), and the date and time of cooling; and the location identifier and location description of the place where the food was packed (if not by the farm providing this information), and the date and time of packing (proposed § 1.1350(b)(2)). As discussed below, we have maintained the proposed requirement specifying that for most of the KDEs that a shipper must maintain, they must also send that information to the recipient of the food; however, we have deleted the proposed requirement for farms to send additional, farm-related information to the recipient.

Finally, we have added a provision to the shipping CTE requirements to specify that these requirements do not apply to any shipment of food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel). This change means that the recordkeeping requirements for shippers do not apply to farms (or other entities) that perform activities such as growing, harvesting, or cooling before a RAC is initially packed (unless the entity is also the initial packer, in which case it must keep records regarding the shipping of the packed food). Because fishing vessels are exempt under § 1.1305(m) from most of the subpart S requirements, including the shipping CTEs, we did not think it was necessary to add a parallel provision stating that the shipping requirements under § 1.1340 do not apply to the shipment of food that occurs before the first land-based receiving of food obtained from a fishing vessel.

1. Records of Shipment That Must Be Maintained

(Comment 396) One comment asks for clarification of the ''name of the transporter'' and whether that refers to a broker, a transport company, or the driver of the vehicle.

(Response 396) By the ''name of the transporter,'' we meant the name of the transport company that transported the food. However, we have deleted the proposed requirements for shippers and receivers to maintain a record of the name of the transporter.

In addition to this deletion to the proposed requirements for shipping, we also made the following changes:

- We moved the reference to the traceability lot codes from the ''introductory'' paragraph (proposed § 1.1350(a)) to the listing of required KDEs;
- We deleted requirements related to the entry number assigned to imported food (as discussed below);
- We changed ''returnable plastic containers'' to ''reusable plastic containers'' (as discussed in Response 357);
- We deleted requirements concerning product identifiers and location identifiers (as discussed in Section V.F of this document);
- We deleted the requirement to record the time of shipment (as discussed in Response 366);
- We replaced the term ''traceability lot code generator'' with ''traceability lot code source,'' and we are allowing entities to provide to their customers a traceability lot code source reference instead of the location description for the traceability lot code source (as discussed in Section V.F of this document); and
- We changed ''reference record type(s)'' and ''reference record number(s)'' to ''reference document type'' and ''reference document number'' (as discussed in Section V.F of this document). (We note that we have deleted as unnecessary the use of ''(s)'' (indicating pluralization of terms as applicable) from all provisions in which we had proposed to include it (except with respect to the definition of ''retail food establishment,'' where we have retained it so that the definition is the same as in other FDA regulations). However, having or using more than one

of such items is permissible; for example, a firm might use two different reference documents (with different numbers) to maintain the KDEs required for shipment of an FTL food, or a firm might have multiple points of contact who are tasked with traceability responsibilities.)

As a result, § 1.1340(a) of the final rule specifies that for each traceability lot of a food on the FTL that an entity ships, the entity must maintain records containing the following information and linking this information to the traceability lot:

- The traceability lot code for the food (§ 1.1340(a)(1));
- The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds) (§ 1.1340(a)(2));
- The product description for the food (§ 1.1340(a)(3));
- The location description for the immediate subsequent recipient (other than a transporter) of the food (§ 1.1340(a)(4));
- The location description for the location from which the food was shipped (§ 1.1340(a)(5));
- The date the food was shipped (§ 1.1340(a)(6));
- The location description for the traceability lot code source or the traceability lot code source reference (§ 1.1340(a)(7)); and
- The reference document type and reference document number (§ 1.1340(a)(8)).

(Comment 397) Some comments suggest that we eliminate the proposed requirement for persons who ship a food on the FTL to establish and maintain records containing and linking the traceability lot code for the food to the entry number assigned to the food if the food is imported. One comment suggests that we make the requirement to maintain the entry number optional. Some comments assert that the entry numbers for food imports are irrelevant to the question of food traceability and that maintaining import entry numbers for FTL foods would be duplicative and unnecessary.

(Response 397) We agree that it is not necessary to require shippers to keep records of the entry numbers for imported foods. Therefore, we have deleted this proposed requirement from the shipping KDEs.

(Comment 398) Some comments suggest that requiring shippers and receivers to keep information on the traceability lot code generator is inconsistent with FSMA section 204(d)(1)(L)(i)'s prohibition against requiring a full pedigree because this information represents the point of origin of the food. One comment expresses concern about the extent of the responsibility of an entity to maintain information about previous CTEs associated with an FTL food they manufacture, process, pack, or hold. The comment urges us to make clear that companies do not have to maintain records for CTEs that occurred several steps back in the supply chain (which the comment refers to as a ''product pedigree'').

(Response 398) The final rule does not require a full pedigree or a record of the complete previous distribution history of the food from the point of origin of such food. Under § 1.1340(a)(7) and (b), the shipper of an FTL food must keep and provide to its customer the location description for the traceability lot code source or the traceability lot code source reference, which provides a means of identifying and locating the person who assigned the traceability lot code to the food. However, maintaining a record of the traceability lot code source or source reference is not the same as maintaining a full pedigree of the food, or a record of the complete previous distribution history of the food from the point of origin of such food. The traceability lot code source is just one part of a food's distribution history, and for most foods there will be other elements of the distribution history for which the shipper and receiver of the food will not be required to maintain records.

(Comment 399) One comment recommends that phone numbers for traceability lot code generators not be required.

(Response 399) We decline this request. Among the required KDEs for shipping (and other CTEs) is the location description for the traceability lot code source, which includes the phone number for the place where the traceability lot code was assigned to the food. We believe that the phone number for the traceability lot code source is a critical piece of information during an outbreak investigation or recall event because it enables FDA to communicate directly with the entity that assigned the traceability lot code to the food. As previously stated, a firm may keep and provide to customers a traceability lot code source reference instead of the location description for the traceability lot code source. A traceability lot code source reference will enable FDA to have access to the phone number and other key contact information for the traceability lot code source.

(Comment 400) One comment asserts that the proposed rule is inconsistent with section 204(d)(1)(E) of FSMA (which specifies, in part, that the rule may not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business) because the proposed requirement to maintain the reference record type and number would require duplication of existing records, such as invoices.

(Response 400) We do not agree. We realize that the proposed requirements for covered entities to maintain the reference record type and reference record number for certain CTEs could have been interpreted as requiring duplicative records, but this is not our intent. As discussed in Section V.F of this document, we are deleting the terms ''reference record'' and ''reference record number'' from the rule and adding definitions of ''reference document'' and ''reference document number.'' Because they are KDEs for certain CTEs, firms would have to list the applicable reference document types and corresponding reference document numbers in any electronic sortable spreadsheet they might provide to FDA in accordance with § 1.1455(c)(3)(ii) (see Section V.R of this document) to indicate the specific reference documents that contain the information included in the spreadsheet. For the CTEs, such as shipping, where this information is required, maintaining the reference document type and number does not require creation of a duplicate record because firms may rely on the reference document itself, such as a BOL, invoice, or ASN, to meet the requirement to keep a record of the reference document type and number. For example, if an invoice created by a shipper contains some of the information required under § 1.1340, such as the date the food was shipped, the product description for the food, the quantity and unit of measure of the shipped food, and the traceability lot code for the shipped food, that invoice (which bears the corresponding invoice number) can itself serve to document the reference document type and reference document number. The shipper could also use another reference document, such as a BOL or PO, as a record for the remaining required shipping KDEs. (By also including the traceability lot code of the shipped product on this document, a linkage would be established between this document and the invoice that contains the other required KDEs for the same traceability lot.) If the firm's practice, as described in its traceability plan, is to retain these reference documents (*i.e.,* the invoice and the BOL or PO) as a means of complying with § 1.1340(a), then the documents themselves—each

of which presumably bears the relevant document number—would serve to satisfy § 1.1340(a)(8). If a firm's practice, as described in its traceability plan, is to comply with subpart S without retaining specific business documents such as invoices and BOLs—for example, if a firm instead maintains a master database of all of the required KDEs, rather than relying on the related business documents—then the relevant portion (*e.g.,* page, spreadsheet) of the database itself would be the reference document, and any sortable spreadsheet that might be requested under § 1.1455(c)(3)(ii) could list the database entry number, spreadsheet number, etc., as the relevant reference document type or number.

Consequently, the requirements to keep records of reference document types and reference document numbers do not necessitate maintenance of duplicate records. Existing records, such as invoices and BOLs with document numbers, or databases with spreadsheet numbers, can be maintained to meet the requirements of § 1.1340(a)(8) and can be listed as the applicable reference document types and numbers (*e.g.,* ''invoice 7534,'' ''BOL 227534,'' ''shipping spreadsheet 127'') in an electronic sortable spreadsheet that may be provided to FDA in accordance with § 1.1455(c)(3)(ii). Note that under § 1.1455(a)(1), records (including reference documents) can be kept as original paper or electronic records or as true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records).

(Comment 401) One comment maintains that the most important information to link to the lot code is the firm that originated the product and the date when the product was produced. The comment cites feasibility studies that identified these pieces of information as most essential for traceability. The comment further maintains that lot codes should be linked to a firm's underlying records so that additional information can be provided for root-cause analysis, if necessary.

(Response 401) We agree with the importance of linking a food's traceability lot code to information identifying the traceability lot code source, which is why this information is required under several of the CTEs, including the shipping CTE. We also agree that date of production is an important KDE, as reflected in § 1.1330(a)(15) (date of initial packing) and § 1.1350(a)(2)(iii) (date transformation was completed). We also think that other information about the food and its movement through the supply chain—such as the quantity and unit of measure of the food, the product description of the food, and the location description of the immediate subsequent recipient—is important not only for root-cause analysis, but also for traceability, which is why the final rule requires shippers and others to maintain this information. We agree that linkage of traceability lot codes to a firm's reference documents is a useful way to organize and maintain the relevant information.

(Comment 402) One comment maintains that for the purpose of traceability, the product identifier and brand owner information, along with the lot code, would be more efficient KDEs than the lot code originator. The comment asserts that the lot code originator may not be with the same company or may not be authorized to speak to regulators. One comment maintains that the point of contact should be the person authorized to speak to regulators.

(Response 402) The phrase ''lot code originator'' did not appear in the proposed rule, but as discussed in Section V.F of this document, we have replaced the term ''traceability lot code generator'' with the term ''traceability lot code source'' because we believe that the focus for traceability should be on the place where the lot code was assigned, rather than the specific individual or entity who assigned the code. We recognize that the traceability lot code source might not be the brand owner. We think that information regarding the location where the traceability lot code was assigned (which is generally the location where the food was initially packed, first received on land, or transformed) is more important for traceability than the name of the brand owner, because the goal of traceability is to follow the physical movement of the food through the supply chain. During outbreak situations, information about the traceability lot code source will allow FDA to more quickly identify key locations and prioritize where we need to collect tracing data, which in turn will help us more quickly identify the origin of contaminated foods. Therefore, the rule requires firms to keep a record of the location description for the traceability lot code source (or the traceability lot code source reference, which is an alternative method for providing FDA with access to that information). The location description includes the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country.

However, we agree that it is also very important during outbreak investigations that firms make someone available to FDA who is knowledgeable about the firm's traceability operations. Therefore, a firm's traceability plan must include a statement identifying a point of contact for questions regarding the plan and associated records (§ 1.1315(a)(4)). During a traceback investigation, when we contact the traceability lot code source (by using the location description or the traceability lot code source reference that shippers and others are required to maintain), we expect the person we reach to be able to access the firm's traceability plan and put us in touch with the point of contact listed in the plan. The rule defines ''point of contact'' to mean an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and phone number (§ 1.1310). Speaking to this point of contact will allow us to conduct a more efficient investigation, and we expect the point of contact to be a person who is authorized to speak to FDA. A firm may choose to designate another person to speak with us during other discussions regarding an outbreak investigation or recall; however, for questions regarding traceability, speaking with the person most knowledgeable to assist in understanding the firm's internal tracing system will result in a more efficient investigation.

2. Information the Shipper Must Provide

(Comment 403) Some comments request clarity on the format in which records can be sent (such as by sending a link to the required information electronically), especially as it pertains to electronic recordkeeping. Some comments specifically ask whether sending a link to the information required to be sent by the shipper to the subsequent recipient under proposed § 1.1350(b) is sufficient. The comments recommend focusing on the outcome (that the information reaches the RFE or other point at the end of the supply chain) rather than how and by whom information is shared within the food supply chain. As an alternative, the comments also suggest that information could be shared through a central repository where the information is uploaded.

(Response 403) We recognize that the industry uses numerous means, both paper-based and electronic, to share information between supply chain partners. The rule does not prescribe the manner in which shippers may meet the

requirement in § 1.1340(b) to send information to the immediate subsequent recipient. Sections 1.1325(a)(2) and (b)(2) and 1.1340(b) specify that persons may provide information to other entities in the supply chain in electronic, paper, or other written form. We have also added language to § 1.1455(a)(1), specifying that electronic records may include valid, working electronic links to the information required to be maintained under subpart S. Therefore, a shipper may provide the required information to the recipient by providing an electronic link through which the information can be obtained. A firm also could use a central data repository to provide the required information as long as the recipient was able to access the information through the repository. However, for purposes of tracing the product through the supply chain, we think it is important that the information somehow be provided to the immediate subsequent recipient of the food, as opposed to focusing solely on ensuring that the information reaches the end of the supply chain.

(Comment 404) One comment maintains that a reference record is not the only method for communicating the traceability lot code and associated KDEs, and requests flexibility on when to use reference records and how to maintain and provide KDEs. Some comments generally support adding traceability lot codes to invoices, BOLs, ASNs, or other bill of sale documentation, while one comment expresses concern about this being a requirement.

(Response 404) We agree there are multiple ways to communicate the traceability lot code and associated KDEs between shippers and receivers, and we have provided flexibility to do so in the final rule. The rule does not require firms to put traceability lot codes on documents such as BOLs or ASNs when shipping an FTL food. Covered entities may prefer to use other methods for documenting and providing the traceability lot code for a food, and for ensuring that all of the relevant KDEs are linked to the specific traceability lot. However, we believe that in most cases, including the traceability lot code on reference documents for FTL foods will be a useful practice to help ensure adequate traceability for that food.

(Comment 405) One comment asserts that location identifiers and descriptions of the places where the food was cooled and packed should not be sent to the immediate subsequent recipient, although the comment does support sending the packing date. The comment maintains that cooling may happen more than once at multiple locations and that cooling information is maintained by the cooler, not the farm, and is typically not provided as the product is moved.

(Response 405) In the final rule, we have deleted the requirements in proposed § 1.1350(b)(2) for farms to send information on the originating, harvesting, cooling, and packing of the food for FTL foods they ship. We also note that the requirements for shippers of FTL foods in § 1.1340 of the final rule do not apply to harvesters or to entities that cool food before it is initially packed (see Response 414 below). However, we do not agree that cooling and packing locations are not critical for traceability. Therefore, entities that harvest, cool, or initially pack FTL foods must maintain information on the harvest location, cooling location, and packing location in accordance with §§ 1.1325 and 1.1330 (as applicable), and harvesters and coolers are required to send information on their activities to the initial packer of the food in accordance with § 1.1325(a)(2) and (b)(2), respectively.

(Comment 406) Some comments ask why shippers should provide information to the subsequent recipient, including the location identifier and description of the subsequent recipient.

(Response 406) As discussed in the preamble to the proposed rule (85 FR 59984 at 60012), requiring shippers of food to send certain information on the foods and the entities that have handled it is essential for ensuring traceability of the foods throughout the supply chain, particularly because under current business practices, firms do not always provide this information to their customers in a way that can easily be linked for traceability purposes. Therefore, § 1.1340(b) of the final rule requires covered entities who ship FTL foods to provide certain information in electronic, paper, or other written form to the immediate subsequent recipient of the food.

We recognize that it may seem unnecessary for shippers to provide receivers with information that the receiver is already aware of, such as the receiver's own location description (as discussed in Response 267, we have removed the requirements relating to location identifier). However, we have concluded that requiring shippers to send this information will promote more efficient traceback because it will ensure that the information is kept in the same way by both the shipper and the receiver, which will make it easier to link the information during a traceback. Furthermore, this approach reduces the burden on receivers because the required information will have already been provided to them in a format that aligns with the receiver's own subpart S requirements under § 1.1345. Because shippers will be required to maintain this information under § 1.1340(a)—and because many shippers already communicate much of this information in the course of their regular business practices, though not necessarily in a format that aligns with subpart S or that can easily be linked with the receiver's own records—we think that shippers will be well-positioned to provide this information to the receiver.

(Comment 407) One comment maintains that a responsible entity should only have to pass forward certain data, such as a lot code or GTIN, while other data (such as the case-level GTIN of the originator) could just be maintained.

(Response 407) We disagree with the comment, which appears to suggest that the only information shippers should be required to provide to their customers is a lot code or GTIN for the food. As discussed above, we believe that providing all of the information required under § 1.1340(b) is necessary to ensure adequate traceability.

(Comment 408) One comment requests additional clarification regarding how traceability lot codes travel with a food through the supply chain. The comment asserts that proposed § 1.1350(b) directs shippers to send electronic or written records to the immediate subsequent recipient but does not state when this information must be provided, relative to the physical shipment of the product (*e.g.,* concurrently with each transaction, or batched with other transactions and sent daily or weekly).

(Response 408) The final rule does not prescribe the manner in which a shipper must provide traceability lot codes and other KDEs to immediate subsequent recipients. A shipper could provide this information in one or more records, which could include product labeling or packaging as well as commonly used reference documents such as BOLs and ASNs. The information could also be sent in other ways, such as in a separate email or by embedding the information in a quick response (QR) code that appears on the packaging of the food or on a related document. The information would not have to physically accompany the food sent to the recipient but must be provided in a way that permits the receiver of the food to keep the records it is required to maintain under subpart S.

(Comment 409) One comment recommends that we require packers or processors to print their business name and product lot code information on packaging. The comments suggest that for private label products, in addition to the packer or processor, the brand owner should be added to the packaging. The comment maintains that this approach would establish a linkage between the physical product and supporting records.

(Response 409) We decline to require this approach. The final rule does not specify the manner in which required KDEs must be provided to the subsequent recipient of the food. In light of the wide range of different business practices, and the comments we received expressing different preferences for how to transmit the required information, we conclude that a flexible approach is warranted.

(Comment 410) One comment maintains that less than half of the fresh produce cases they purchase include the packer's lot code in the form of a PTI label. The comment requests that the final rule require firms to place the traceability lot code on commercial documents such as BOLs for companies selling fresh produce.

(Response 410) As previously stated, although the final rule does not require firms that ship FTL foods, including packers, to put the traceability lot code for the food on a reference document such as a BOL, shippers must by some means link the traceability lot code to the other information that must be provided to the recipient, and we anticipate that most shippers will do so by placing the traceability lot code on a reference document for the shipment. Firms that follow labeling standards outlined by traceability programs, such as the PTI, may use those standards in meeting their subpart S requirements as long as they include the information required under the rule.

(Comment 411) One comment maintains that requiring the shipper to send the location identifier, location description, and point of contact for the traceability lot code generator will allow FDA to move quickly up the food chain during traceback investigations, thereby preventing illnesses, reducing death, and minimizing business impact.

(Response 411) As discussed in Section V.F of this document, we have replaced the term ''traceability lot code generator'' with ''traceability lot code source,'' and the final rule permits entities to provide to their customers a traceability lot code source reference instead of the location description for the traceability lot code source. We agree that providing recipients with information on the traceability lot code source will greatly assist firms and the Agency in conducting effective tracking and tracing of FTL foods.

(Comment 412) Many comments maintain that a company's supply base represents significant investment and competitive advantage for some food businesses. Some comments express concern that this competitive advantage might be compromised by the proposed requirements to pass forward original, unchanged traceability lot codes and contact and location information for the traceability lot code generator (the supplier). The comments maintain that the requirements in the proposed rule would result in the disclosure of confidential information to supply chain partners, expose processing and/or manufacturing logistics information, reveal recipes to customers and third parties, and expose confidential supplier/buyer relationships as well as the identities of contract manufacturers for large branded and private labeled products. Many comments assert that having to pass confidential commercial information forward would adversely affect many supply chains and result in loss of business for some entities by revealing proprietary relationships. As examples, the comments state that first receivers would need to collect harvesting, cooling, and packing data from farm entities, and receivers would be required to keep location data of the shipping entity and a point of contact for the originator of the food. The comments express concern about what might happen when a first receiver or other receiving entity experiences a data breach and information is compromised, or a theft of information results in a major financial loss to the firm that supplied the information because the information is used to sabotage the business of an upstream entity.

Some comments maintain that requiring businesses to share sensitive information violates section 204(d)(3) of FSMA, which directs FDA to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information obtained by FDA under the rule. One comment recommends that we consult with European Union (EU) stakeholders to ensure that data capture regulated by this rule does not conflict with the EU's General Data Protection Regulation (GDPR). Some comments suggest that the requirement to pass KDEs related to the traceability lot code generator be deleted, while other comments suggest that we permit the use of alternatives methods, such as encoding data into the traceability lot code or use of the GTIN to identify the brand owner. One comment suggests that requiring only the firm identity and the identity of the records to be linked to the lot code, rather than the critical information from the record itself or the names and contact information for knowledgeable individuals, would provide a less satisfying target for cybercrime. One comment suggests making the location identifier for the traceability lot code generator an optional KDE.

(Response 412) The traceability lot code for a food and the location and contact information for its source are fundamental to effective traceability under this rule. However, we understand the concerns regarding the confidentiality of supplier data expressed in the comments. We are therefore deleting the proposed requirements for shippers to maintain and provide the location identifier, location description, and point of contact for the traceability lot code generator, and replacing them with requirements to keep and provide either the location description for the traceability lot code source or the traceability lot code source reference (see § 1.1340(a)(7) and (b)). A traceability lot code source reference is a method for giving FDA access to the traceability lot code source location description required under subpart S without providing the traceability lot code source location information directly to subsequent recipients (§ 1.1310). Examples of traceability lot code source reference types include, but are not limited to, the FDA Food Facility Registration Number assigned to the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source (§ 1.1310). To protect the confidentiality of business information, a shipper could choose to provide its customers with the traceability lot code source reference, instead of directly identifying the location description of the traceability lot code source of an FTL food they handle. If the firm uses a website as the traceability lot code source reference, the website may employ reasonable security measures, such as only being accessible to a government email address, provided the Agency has access to the information at no cost and without delay. We believe that the option to use a traceability lot code source reference is an appropriate measure for those entities concerned with sharing the traceability lot code source information through the supply chain.

(Comment 413) One comment states that many food distribution centers are

well equipped to trace food without a lot code-based system by using inbound receiving reference records (*e.g.,* BOLs, invoices, POs) in conjunction with pallet license plate numbers and location identifiers (pick slots) within a warehouse to connect to outbound shipping reference records.

(Response 413) The tracing method described in the comment is not as efficient as the method set forth in subpart S. Traceability lot codes are critical to the subpart S traceability framework because they are the piece of information to which the other KDEs for a traceability event are linked, including the traceability lot code source. The traceability lot code (along with other linked KDEs) explicitly connects the food received by a distribution center with the food that is then shipped by the distribution center and received at an RFE or other establishment. Importantly, the traceability lot code also connects this food to the traceability lot code source (the place where the traceability lot code was assigned to the food), thus allowing FDA to identify that source at the first location we investigate (often an RFE or restaurant). During outbreak situations, this will allow us to more quickly identify the traceability lot code source location and prioritize where we need to collect tracing data, which in turn will help us more quickly identify the origin of potentially contaminated foods. Reference documents such as BOLs, POs, and invoices are primarily designed to describe a business transaction between two parties and may not include the lot code and contact information for the entity that assigned the lot code to the product. While existing business records may be used to satisfy subpart S, the information required under final § 1.1340, including the traceability lot code and source, must be included within those documents or provided to the immediate subsequent recipient in some other manner. Communication of this information between supply chain partners is essential to ensuring adequate traceability.

3. Shipment of a Food That Occurs Before the Food Is Initially Packed

(Comment 414) One comment requests clarification on whether movement of raw product from an orchard or field to a packinghouse constitutes shipping, when the grower maintains ownership.

(Response 414) We conclude that it is not necessary or appropriate to apply the shipping recordkeeping requirements in § 1.1340 to the movement of RACs before they are initially packed, including the movement of raw product from an orchard or field to a packinghouse. Therefore, § 1.1340(c) specifies that the shipping CTE requirements do not apply to the shipment of a food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel). As a result, any movement of RACs by farms, harvesters, coolers, or other entities that occurs before the food is initially packed is not subject to the requirements in § 1.1340.

(Comment 415) One comment requests that phone numbers be removed as a requirement for the lot code generator point of contact. The comment raises privacy concerns that some small farms may only have a home phone number, which would then be shared with other entities in a supply chain. The comment also notes that individuals may change positions and that the privacy of a named individual could be compromised in the event of a data breach at an operation later in the supply chain.

(Response 415) Although the final rule deletes the proposed requirement (in proposed § 1.1350(a)(4)) for shippers to provide immediate subsequent recipients with the point of contact for the traceability lot code generator (which would have included that individual's name and telephone number under the proposed definition of ''point of contact''), the final rule includes a requirement to provide the immediate subsequent recipient with the phone number for the traceability lot code source. This is because shippers must provide the location description for the traceability lot code source (or else provide that information through a traceability lot code source reference), and the definition of ''location description'' includes, among other things, a phone number. We believe that having a phone number is essential to being able to contact the traceability lot code source when necessary for tracing purposes. However, as discussed in Section V.L.2 of this document, in response to comments expressing concern about privacy associated with sharing information on the traceability lot code generator (now the traceability lot code source), the final rule also allows firms to instead provide the recipient with a traceability lot code source reference, which is an alternative method for providing FDA with access to the location description for the traceability lot code source.

We have removed the requirement for shippers to provide the recipient with a point of contact for the traceability lot code source. We believe that the phone number and other location description information is adequate for traceability purposes, and that once we contact the firm using that information, the firm will be able to provide us with the traceability point of contact listed in their traceability plan. Also, as discussed in Section V.F of this document, we have revised the definition of ''point of contact'' so that it no longer requires a specific individual's name.

(Comment 416) Some comments suggest that it would be difficult for growers to access and verify for accuracy the shipping information required in proposed § 1.1350(b)(2)(iii) through (v), which the comments characterize as the business name, point of contact, and phone number of the harvester, cooler, and packer of the food (if not the farm), and the date(s) and time(s) of harvesting, cooling, and packing, due to a lack of supply chain visibility.

(Response 416) We have made modifications in the final rule in response to comments. In the final rule, shipping and receiving information is not required to be kept and shared until FTL foods from farms have been initially packed (see §§ 1.1340(c) and 1.1345(c)). Therefore, harvesters and coolers do not need to provide shipping and receiving information. Though we have changed the requirements in the final rule, we note that the proposed shipping provision referenced in the comment would not have required the grower to send information on harvesters, coolers, and packers unless they also performed those activities. However, the proposed rule would have required some farms (ones that were not growers) to pass along certain information about activities that they did not perform, *e.g.,* a cooler that met the definition of a farm might have been required to pass along information about the harvester of the food. In the final rule, we have provided flexibility for information about harvesting and cooling to be sent either directly to the initial packer or passed through the supply chain (§ 1.1325(a)(2) and (b)(2)) (see Response 350). We think this flexibility will help address concerns about the proposed rule's requirements regarding this information.

N. Records of Receiving (§ 1.1345)

We proposed that for each food on the FTL received, the receiver must establish and maintain records containing and linking the traceability lot code of the food to the following information: the location identifier and location description for the immediate previous source (other than a

transporter) of the food; the entry number(s) assigned to the food (if the food is imported); the location identifier and location description of where the food was received, and the date and time the food was received; the quantity and unit of measure of the food (*e.g.,* 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds); the traceability product identifier and traceability product description for the food; the location identifier, location description, and point of contact for the traceability lot code generator; the reference record type(s) and reference record number(s) (*e.g.,* ''Invoice 750A,'' ''BOL 042520 XYZ'') for the document(s) containing the previously stated information; and the name of the transporter who transported the food to the receiver (proposed § 1.1335(a) through (h)). In response to comments and on our own initiative to align the requirements for receiving with other changes we are making in the final rule, we have deleted several of the proposed receiving KDEs and revised others.

In addition to these changes to the proposed receiving requirements, we have added requirements for circumstances in which an entity receives an FTL food from a person to whom subpart S does not apply. Final § 1.1345(b) states that for each traceability lot of a food on the FTL an entity receives from a person to whom this subpart does not apply (*i.e.,* a person who is exempt from the rule), the entity must maintain records containing the following information and linking this information to the traceability lot: the traceability lot code for the food, which the entity must assign if one has not already been assigned (except that this requirement does not apply to RFEs and restaurants); the quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); the product description for the food; the location description for the immediate previous source (other than a transporter) for the food; the location description for where the food was received (*i.e.,* the traceability lot code source) and (if applicable) the traceability lot code source reference; the date the food was received; and the reference document type and reference document number. We also have added a provision (§ 1.1345(c)) specifying that the receiving requirements do not apply to the receipt of a food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

We received several comments on the proposed requirements for receiving, to which we respond in the following paragraphs.

1. Records of Receiving of Foods

(Comment 417) Some comments assert that it is effective for distribution centers to inform RFEs which traceability lot codes are supplied to which locations as well as which are subject to a recall. One comment requests that distributors and RFEs be required to keep traceability lot codes for purchased foods.

(Response 417) We agree that distributors and RFEs should be required to keep traceability lot codes, and that it is effective for distribution centers to provide RFEs with the traceability lot codes of the foods they ship to those RFEs. As we had proposed, the final rule requires receivers of FTL foods, including distributors and RFEs, to keep a record of the traceability lot code for the received food. (We have moved the requirement to record the traceability lot code from the ''introductory'' paragraph of proposed § 1.1335 to the listing of required KDEs, specifically § 1.1345(a)(1).) A receiver of an FTL food may not change the traceability lot code unless they transform the food (see § 1.1320). Therefore, records maintained and provided by distributors and maintained by RFEs should include the same traceability lot code that was assigned by the initial packer of a RAC (other than food obtained from a fishing vessel), by the first land-based receiver of a food obtained by a fishing vessel, or by an entity that transformed the food. However, as stated in § 1.1345(b)(1), if a receiver (such as a distributor) receives the FTL food from an entity that is exempt from subpart S, the receiver must assign a traceability lot code if one has not already been assigned (except that this requirement does not apply to RFEs and restaurants).

(Comment 418) One comment asks that we finalize the requirements for receivers of FTL foods as proposed. On the other hand, one comment states that the proposed list of receiving KDEs is too prescriptive and beyond what is necessary for traceability. The comment recommends that receivers should only be required to keep the traceability lot code, the GTIN, the location identifier (*e.g.,* GLN) of the immediate previous source, the traceability lot code generator contact information, the quantity and unit of measure, and the name of the transporter. Some comments suggest that to simplify production of an electronic sortable spreadsheet (in accordance with proposed § 1.1455(b)(3)) and reduce recordkeeping burden, the required receiving KDEs should be reduced to only those that are truly necessary for traceability. Therefore, the comments suggest deletion of the following KDEs: entry number, location identifier, point of contact for a traceability lot code generator, traceability lot code generator, location where the CTE occurred, name of the transporter, and time the event occurred. Another comment recommends that location identifier, import entry number, and time of receipt be optional, and suggests that the traceability lot code generator location identifier, description, and point of contact be required only if provided by the shipper.

(Response 418) We agree that some of the proposed receiving KDEs are not absolutely necessary for tracing, and we agree that reducing the required KDEs will reduce the recordkeeping burden and simplify the production of the electronic sortable spreadsheet under § 1.1455(c)(3)(ii). Therefore, as requested by these comments (as well as comments that made similar points about these KDEs as they appeared in other proposed CTEs, as discussed elsewhere in this document), the final rule deletes the following proposed KDEs for receiving an FTL food: the entry number of the food (if imported); location identifiers; the traceability product identifier of the food; the time the food was received; the point of contact for the traceability lot code generator (under the final rule, the traceability lot code source); and the name of the transporter. In addition, as previously discussed, we have replaced the requirement to record location information about the traceability lot code generator with a requirement to record the location description for the traceability lot code source or the traceability lot code source reference.

As a result of these changes, § 1.1345(a) of the final rule specifies that, except as specified in § 1.1345(b) and (c) (discussed below), for each traceability lot of a food on the FTL that an entity receives, the receiving entity must maintain records containing the following information and linking this information to the traceability lot:

- The traceability lot code for the food (§ 1.1345(a)(1));
- The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds) (§ 1.1345(a)(2));
- The product description for the food (§ 1.1345(a)(3));
- The location description for the immediate previous source (other than a transporter) for the food (§ 1.1345(a)(4));

• The location description for where the food was received (§ 1.1345(a)(5));
• The date the food was received (§ 1.1345(a)(6));
• The location description for the traceability lot code source or the traceability lot code source reference (§ 1.1345(a)(7)); and
• The reference document type and reference document number (§ 1.1345(a)(8)).

(Comment 419) Some comments suggest that we eliminate the proposed requirement for persons who receive FTL foods to establish and maintain records containing and linking the traceability lot code for the food to the entry number assigned to the food if the food is imported. Some comments contend that maintaining import entry numbers would make recordkeeping requirements overly burdensome, would provide no additional meaningful traceability information, and would be duplicative and unnecessary given the maintenance of other KDEs.

(Response 419) We agree and as stated in Response 396, we have deleted all proposed requirements to record the entry number for an imported FTL food.

(Comment 420) One comment questions the value of requiring receivers to maintain records that identify the location where they received a food. The comment maintains that this information is not necessary because other information would be more relevant for traceability.

(Response 420) We do not agree. Knowing the physical locations where a food on the FTL has been, including where a food has been received by an entity such as a distributor, RFE, or other firm subject to the receiving CTE requirements, is critical for traceability. If a food is contaminated, we need to be able to identify the source of that food and trace its movements accurately and efficiently.

(Comment 421) One comment requests clarification on whether the date and time refers to the start or finish of the receiving process for an FTL food.

(Response 421) As previously stated, we have deleted the proposed requirement to record the time of receipt, but we have retained the requirement to record the date of receipt. If the receiving process spans multiple days (*e.g.,* if it starts shortly before midnight and ends after midnight), we recommend recording the date when the receiving process began.

(Comment 422) One comment maintains that proposed § 1.1335 clearly outlines the required receiving records and is consistent with the 2012 IFT Final Report (Ref. 1), which recommends that any traceability regulations that FDA adopts should ensure the communication of needed information to promote accuracy.

(Response 422) We agree with the comment that the requirements in proposed § 1.1335 align with the 2012 IFT Final Report's recommendation to ensure the communication of needed information, and we believe the revisions to this section (final § 1.1345) also remain in alignment with this recommendation. We believe that the requirements we are establishing for receivers of FTL foods as well as for others who manufacture, process, pack, or hold such foods should help to ensure the effective and accurate communication of needed traceability information throughout the supply chain and to the Agency.

(Comment 423) Some comments express concern that the rule will prohibit a food industry practice of linking internal traceability identifiers to supplier-provided traceability lot codes, such as the GS1–128 barcode and associated human readable text.

(Response 423) The rule does not prohibit covered entities from using internal identifiers to facilitate the internal storage and management of FTL foods they handle, provided that the traceability lot code and traceability lot code source information received is kept in accordance with the receiving CTE requirements and provided to the subsequent recipient in accordance with the shipping CTE requirements, and provided that new traceability lot codes are only assigned under the circumstances described in § 1.1320. Considering the example in the comment, a covered entity that receives FTL foods may use a warehouse management system that links internal identifiers to supplier-provided traceability lot codes, such as the GS1–128 barcode and associated human readable text, provided that the entity maintains all of the KDEs required under subpart S, and the KDEs to be provided as required under § 1.1340 are available to the next receiver of the FTL food.

(Comment 424) Several comments request clarification on the applicable subpart S requirements when food is provided to a retailer through direct store delivery (DSD). The comments state that under the DSD system, a food vendor delivers food directly to a retail store location and stocks the retail shelves with the food. The comments further state that these products are not included in the retailer's inventory; the retailer only facilitates the sale of the products to the consumer, with the vendor's invoices being reconciled against the retailer's scanned sales data. The comments maintain that the retailer does not receive the food and therefore would not have access to traceability data for the food.

(Response 424) We do not agree with the statement that a retailer of an FTL food obtained through DSD does not ''receive'' the food as that term is used in subpart S. The retailer of a food obtained through DSD is the receiver of the food, and is therefore responsible for the receiving KDEs in § 1.1345. However, the DSD vendor could maintain the receiving records on behalf of the retailer. As discussed in Section V.R of this document, § 1.1455(b) of the final rule specifies that a person may have another entity establish and maintain records required under subpart S on the person's behalf, but the person is responsible for ensuring that such records can be retrieved and provided onsite to FDA within 24 hours of our request. Therefore, a vendor and a retailer participating in a DSD system could make an arrangement under which the DSD vendor establishes and maintains the relevant receiving records on the retailer's behalf. However, the retailer would still be the entity that is subject to the receiving requirements of § 1.1345, and as stated in § 1.1455(b), the retailer would be responsible for ensuring that the records can be retrieved and provided onsite within 24 hours of request for official review.

2. Records of Receipt of Foods From Persons Not Subject to Subpart S

(Comment 425) One comment asks that FDA clarify a receiver's recordkeeping responsibilities for FTL foods shipped by exempt and non-compliant entities. The comment describes the potential challenges to meeting the receiving requirements if FTL foods are received from exempt entities that are not required to notify receivers that they are exempt, as in the case of foodservice distributors sourcing food from local entities that will not be subject to the rule. The comment asks that receivers be permitted to assume that suppliers who fail to provide the records required from shippers are subject to an exemption, and that FDA not hold downstream actors accountable for non-compliance if they rely in good faith on upstream actors providing the records required by the rule.

(Response 425) We agree that the receiving requirements must take into account those situations in which an entity receives an FTL food from a person who is not subject to the rule, such as because they are exempt from subpart S under one of the exemptions set forth in § 1.1305. Therefore, we have added to the final rule § 1.1345(b),

which specifies that for each traceability lot of a food on the FTL that is received from a person to whom subpart S does not apply, the receiver must maintain records containing the following information and linking this information to the traceability lot:

- The traceability lot code for the food, which the receiver must assign if one has not already been assigned (except that this requirement does not apply to RFEs and restaurants) (§ 1.1345(b)(1));
- The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds) (§ 1.1345(b)(2));
- The product description for the food (§ 1.1345(b)(3));
- The location description for the immediate previous source (other than a transporter) for the food (§ 1.1345(b)(4));
- The location description for where the food was received (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference (§ 1.1345(b)(5));
- The date the food was received (§ 1.1345(b)(6)); and
- The reference document type and reference document number (§ 1.1345(b)(7)).

Under § 1.1345(b)(1), if the received FTL food does not already have a traceability lot code assigned, the receiver must assign one (unless the receiver is an RFE or restaurant; we conclude that it is not necessary to require assignment of a traceability lot code to food that has already reached the end of the supply chain). Section 1.1345(b)(5) makes clear that the receiver (*i.e.,* the place where the food is received) will also become the traceability lot code source for the food. (However, this is not the case if the receiver is an RFE or restaurant; such an entity would still record the location description for where the food was received, in accordance with § 1.1345(b)(5). But because RFEs and restaurants that receive food from exempt entities are not required to assign a traceability lot code under § 1.1345(b)(1), that location description would not be the traceability lot code source.) It is important for the traceability lot code source—which serves a crucial function as discussed in Sections V.F and V.M of this document—to be an entity that is covered by subpart S.

The rule does not allow receivers to assume that any received food for which the shipper did not provide the information required under § 1.1340(b) was from an exempt entity. Instead, we expect receivers of FTL foods to work with their suppliers to be familiar with whether the suppliers are subject to the rule and, if so, to know what records they must provide to enable the receivers to meet their requirements under § 1.1345.

(Comment 426) One comment asks that we clarify the requirements for FTL foods received when traceability records provided by distributors are incomplete or inaccurate. The comment offers the example of a GS1–128 barcode label that has been damaged, was not printed well initially, or was torn off the food packaging in transit. The comment asks if we will require suppliers to label multiple sides of food cases, and if retailers and restaurants will be required to verify received data, correct errors, and otherwise ''police'' distributors. Another comment maintains that there may be unavoidable errors during shipment or receiving due to human error or misprinted or damaged barcode labels.

(Response 426) We expect persons who manufacture, process, pack, or hold any food covered by the final rule to be in compliance with these regulations (unless an exemption applies). If the immediate previous source of an FTL food is subject to the rule and provides the receiver with illegible or incomplete records, the receiver should ask the source to provide, in legible/readable form, the complete information required of the shipper under § 1.1340(b). We note that the rule does not specify the manner in which shippers must provide the required information to their recipients, nor does it specify the manner in which shippers must label the FTL foods they ship.

(Comment 427) Several comments ask that we clarify the responsibilities of a receiving entity whose supplier fails to comply with the requirements of subpart S or does not provide the receiving entity with accurate data. The comments request that we clarify how we will enforce the regulation against receiving entities in such circumstances. Specifically, some comments assert that RFEs are not able to verify the accuracy of data received from distributors and ask whether RFEs that provide supplier-generated data to FDA will be responsible for its accuracy. These comments maintain that entities upstream of RFEs have the logistical expertise and infrastructure (such as barcode scanners and management systems) required to implement traceability recordkeeping, and that to require RFEs to verify data from those firms would be complicated and inefficient.

Some comments urge FDA to clarify that a receiving entity may continue to supply a food without being in violation of the regulation even if their supplier does not provide them with the information required under subpart S. These comments maintain that prohibiting a receiving entity from supplying food in such circumstances could lead to supply chain disruptions or food waste. Some comments suggest that even if a supplier does not provide the receiving entity with the necessary information, it does not mean that the food is adulterated or unsafe. Some comments request that we create a ''safe harbor'' that would allow a receiving entity to assume that the subpart S requirements do not apply if their supplier does not provide them with traceability information, the receiving entity has no knowledge that the food is covered by the regulation, or the receiving entity relies on a one-time, ongoing guarantee from the supplier that the supplier will provide traceability information when required. Some comments assert that because a receiving entity's ability to comply with subpart S depends on whether its supplier provides the required records, the receiver should not be held liable for its supplier's non-compliance.

(Response 427) Receivers of FTL foods must maintain records of KDEs as specified in § 1.1345, including records of certain information that shippers are required to provide to them under § 1.1340(b). As discussed in Response 425, recognizing that a receiving entity's supplier might be exempt from subpart S, we have added to the final rule § 1.1345(b), which specifies the information a receiver must maintain if they receive an FTL food from a person to whom subpart S does not apply. In circumstances where a receiver's supplier is subject to the rule, if the receiving entity has reason to believe that required information from the shipper is inaccurate or incomplete, the receiver should work with their supplier to ensure that appropriate and accurate records are provided. We expect firms will use the years leading up to the compliance date for the rule to work with their suppliers to ensure that all entities are ready to comply with the rule and to provide the necessary information to others within their supply chain, as required under the rule. Because of such efforts, we do not believe that adoption of these recordkeeping requirements will result in significant supply chain disruptions or food waste.

We do not agree that the rule should provide a ''safe harbor'' that would allow a receiving entity to assume that subpart S requirements do not apply when their supplier does not provide them with traceability information, the

receiver has no knowledge that the food is covered by the rule, or the receiver relies on a one-time, ongoing guarantee from the supplier that the supplier will provide traceability information when required. As stated above, receivers are responsible for maintaining the records required under § 1.1345. The requested ''safe harbor'' would relieve firms of that responsibility and encourage a head-in-the-sand approach that would seriously undermine the ability of the requirements to facilitate swift and effective traceability throughout the supply chain. Furthermore, with respect to the receiver's knowledge of whether a food is covered by the rule, we note that entities subject to the rule must have a traceability plan in place that includes a description of the procedures the entity uses to identify foods on the FTL that it manufactures, processes, packs, or holds (§ 1.1315(a)(2)). Consequently, receivers of FTL foods must have a procedure for knowing whether a particular food they receive is on the FTL.

3. Receipt of a Food That Occurs Before the Food Is Initially Packed

As discussed in Sections V.M and V.N of this document, we have added provisions to the shipping and receiving CTE requirements to make clear that those requirements do not apply to the movement of food that occurs before the food is initially packed (for example, movement of a RAC from the harvester to a cooler, or from the cooler to the initial packer). While we noted that such language was not needed under the shipping CTE with respect to food obtained from a fishing vessel (due to the partial exemption for fishing vessels), we have added a provision to the receiving CTE to make clear that the first land-based receiver of food obtained from a fishing vessel does not need to keep the receiving records required under § 1.1345. This is because the records required under § 1.1335 already set forth the information we think is necessary for the first land-based receiver of a food obtained from a fishing vessel to maintain with respect to their receipt of that food. Therefore, § 1.1345(c) specifies that the receiving requirements do not apply to receipt of a food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

O. Records of Transformation (§ 1.1350)

We proposed in § 1.1340(a) that, except as specified in proposed § 1.1340(b), for each new traceability lot of food produced through transformation, the person who transforms the food must establish and maintain records containing and linking the new traceability lot code of the food produced through transformed to certain information regarding the food on the FTL used in transformation and the food produced through transformation. For the food(s) on the FTL used in transformation, we proposed that the transformer would have to establish and maintain records containing the following information: the traceability lot code(s) for the food; the traceability product identifier and traceability product description for the food to which the traceability lot code applied; and the quantity of each traceability lot of the food (proposed § 1.1340(a)(1)(i) through (iii)). For the food produced through transformation, we proposed that records containing the following information would have to be established and maintained: the location identifier and location information for where the food was transformed (*e.g.,* by a manufacturing/processing step), and the date transformation was completed; the new traceability product identifier and traceability product description for the food to which the new traceability lot code applied; and the quantity and unit of measure of the food for each new traceability lot code (*e.g.,* 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1340(a)(2)(i) through (iii)). The final required KDE we proposed was the reference record type(s) and reference record number(s) (*e.g.,* ''Production Log 123,'' ''Batch Log 01202021'') for the document(s) containing the information in proposed § 1.1340(a)(1) and (2) (proposed § 1.1340(a)(3)). We further proposed that these transformation KDEs would not apply to RFEs with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers) (proposed § 1.1340(b)).

We also proposed to establish recordkeeping requirements for the creation of an FTL food. Because we proposed to define ''creating'' as making or producing a food on the FTL (*e.g.,* through manufacturing or processing) using only ingredients that are not on the FTL, the creator of a listed food would not be required to maintain tracing records on the ingredients used to create the FTL food. Instead, we proposed that for each food on the FTL that was created, the creator of the food would have to establish and maintain records containing and linking the traceability lot code of the created food to the following information: the location identifier and location description for where the food was created (*e.g.,* by a manufacturing/processing step), and the date creation was completed; the traceability product identifier and traceability product description for the food; the quantity and unit of measure of the food (*e.g.,* 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds); and the reference record type(s) and number(s) (*e.g.,* ''Production Log 123,'' ''Batch Log 01202021'') for the document(s) containing the previously listed information (proposed § 1.1345(a)(1) through (4)). As with the proposed requirements for transformation, we specified that proposed § 1.1345(a) would not apply to RFEs with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers).

In the final rule, we are combining the proposed requirements for transformation and creation of FTL foods into the requirements for transformation in § 1.1350 and making minor changes to the proposed KDEs for transformation. We are retaining the concept that records only need to be kept regarding incoming ingredients if those incoming foods are on the FTL; thus, for foods that were ''created'' under the proposed rule, it is still the case that the required records will only relate to the finished product, not the incoming ingredients. We also are adding clarifying language (§ 1.1350(b)) specifying that the transformation KDEs do not apply when a RAC (other than a food obtained from a fishing vessel) is transformed before it is initially packed; instead, only the initial packing KDEs will apply. In addition, we are finalizing our proposed exclusion from the transformation requirements for RFEs and restaurants with respect to foods they do not ship. We respond to the comments on the proposed requirements for transformation and creation of FTL foods in the following paragraphs.

1. Records of Transformation (§ 1.1350(a))

(Comment 428) Several comments support transformation as a CTE and maintain that the proposed requirements for transformation are well defined, including the requirement to include lot codes for inputs.

(Response 428) We agree with the comments, and the final rule includes requirements for transformation, with certain changes to the proposed requirements discussed below.

(Comment 429) A comment supports the ''creation'' CTE regarding the production of foods on the FTL from foods that are not on the FTL. The comment asks for clarification on which

KDEs would be required for the processing of whole apples, which are not on the FTL, into sliced apples, which are listed on the FTL as ''Fruits and Vegetables (fresh-cut).'' One comment appreciates the clarification provided by FDA after the publication of the proposed rule that ingredient suppliers for FTL foods that are ''created'' would not be subject to subpart S because those ingredients are not on the FTL, and encourages the Agency to finalize this approach in the final rule.

(Response 429) In the final rule, we have merged the CTE for creation of an FTL food into the CTE for transformation of an FTL food, so there is no longer a separate creation CTE. We believe that it is appropriate to use the term ''transformation'' to cover both the activities of ''creation'' and ''transformation'' (see Response 247). Given that the output of both the creation and the transformation CTEs is an FTL food and both CTEs are manufacturing events, we decided to simplify the number of CTEs and merge ''creation'' into ''transformation.'' The revised definition of ''transformation'' more closely aligns with current industry practices as ''transformation'' is already a term used by industry while ''creation'' is not. As part of this change, § 1.1350(a)(1) of the final rule, which relates to the incoming FTL foods that are used in transformation, has been revised to include the phrase ''if applicable.'' Consequently, § 1.1350(a)(1) records are not required for foods that do not have any incoming FTL ingredients (*i.e.,* foods regarded as ''created'' under the proposed rule).

Regarding the transformation of whole apples into sliced apples, the apple farm, apple harvester, apple cooler, and initial packer of the whole apples would not be covered by the rule because whole apples are not on the FTL. Deliveries (shipping and receiving) from the apple packer to the fresh-cut processor would also not be subject to the rule. However, the fresh-cut processor who transforms the whole apples into apple slices (which are included on the FTL under ''Fruits and Vegetables (fresh-cut)'') and packages the sliced apples would be required to keep the transformation records specified under final § 1.1350(a)(2), as well as the shipping records (for shipment of the sliced apples) specified under final § 1.1340. If the apples are sliced before initial packing, then, as specified under § 1.1350(b), the entity who transforms the whole apples into sliced apples would be required to keep the initial packing records specified under § 1.1330(a) or (c), and would not be required to keep transformation records under § 1.1350(a) (see Response 444 (434 (creation CTE requirements would not apply to the creation of an FTL food solely for the purpose of being transformed into another food in continuous processing)).

In addition to merging the proposed creation CTE requirements into the transformation CTE requirements, we are also making the following changes:

- We deleted requirements concerning product identifiers and location identifiers (as discussed in Sections V.F.46 and V.F.18 of this document);
- We added unit of measure to the requirement to specify the quantity of food used from each traceability lot of an FTL food used in transformation;
- Regarding the food produced through transformation, we moved the reference to the new traceability lot code from the ''introductory'' paragraph (§ 1.1340(a)) to the listing of required KDEs;
- We clarified that the location description for where the food was transformed is the traceability lot code source, and we added that the traceability lot code source reference must also be recorded ''if applicable''; and
- We changed ''returnable plastic containers'' to ''reusable plastic containers'' (as discussed in Section V.K.1 of this document).

As a result of these changes, § 1.1350(a)(1) and (2) of the final rule states that, except as specified in § 1.1350(b) and (c), for each new traceability lot of food produced through transformation, the transformer of the food must maintain records containing the following information and linking this information to the new traceability lot:

- For the food on the FTL used in transformation (if applicable), the following information:
  - The traceability lot code for the food;
  - The product description for the food to which the traceability lot code applies; and
  - For each traceability lot used, the quantity and unit of measure of the food used from that lot.
- For the food produced through transformation, the following information:
  - The new traceability lot code for the food;
  - The location description for where the food was transformed (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;
  - The date transformation was completed;
  - The product description for the food;
  - The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and
  - The reference document type and reference document number for the transformation event.

(Comment 430) One comment requests that firms be required to link production input traceability lot codes to output traceability lot codes.

(Response 430) We agree. As stated above, § 1.1350(a) requires firms to document, among other KDEs, the traceability lot code for the FTL food used in transformation (if any) and the new traceability lot code for the food produced through transformation, and to link that information to the new traceability lot.

(Comment 431) One comment asks that we clarify what is meant by the quantity used in transformation or the quantity of each traceability lot code.

(Response 431) We recognize that the language used in proposed § 1.1340(a)(1)(iii) (''[t]he quantity of each traceability lot of the food'') caused some confusion. Therefore, in response to comments, we have revised the language to be clearer. Final § 1.1350(a)(1)(iii) states that for each traceability lot used, the quantity and unit of measure of the food used from that lot must be maintained as part of the required transformation records. For example, if a person used multiple traceability lots of whole green peppers (which are on the FTL) to manufacture a single traceability lot of fresh-cut green peppers (which are also on the FTL), their records might indicate that the incoming ingredients consisted of 10 pounds of whole green peppers from traceability lot 1111, 10 pounds of whole green peppers from traceability lot 1112, and 5 pounds of whole green peppers from traceability lot 1113. (This might represent only half of traceability lot 1113, a fact that would be clear from the person's receiving records for that traceability lot.) If the manufactured product were a fresh-cut mixture of green and red peppers, the person's records might also indicate an incoming ingredient consisting of 10 pounds of red peppers from traceability lot 2222.

(Comment 432) One comment questions the value of requiring transformers and creators of FTL foods to maintain records identifying the location where the food was transformed/created. The comment maintains that this information is not necessary because other information is

more relevant for traceability, and asserts that deleting this requirement would also mean less information to compile for the electronic sortable spreadsheet.

(Response 432) We disagree with the comment. If a food is contaminated, we need to be able to identify all of the locations where the food was handled (see Response 420). The location where the food was transformed is particularly important because contamination can be introduced during transformation. Furthermore, because a traceability lot code must be assigned whenever a food is transformed (see § 1.1320(a)), the place of transformation takes on additional significance as the traceability lot code source (see § 1.1350(a)(2)(ii)). Transformation records are crucial to traceability because they provide a connection between the incoming traceability lots of FTL foods (when applicable) and the outgoing traceability lots of the transformed FTL food. For all of these reasons, it is important for FDA to be able to quickly identify the location where transformation occurred.

(Comment 433) One comment requests that location identifier be an optional KDE for the transformation CTE and that it not be required for creation events.

(Response 433) We agree that location identifier is not necessary and have deleted it from the final rule (see Response 267). However, § 1.1350(a)(2)(ii) requires transformers to keep a record of the location description for where the food was transformed. Under the definition of location description in § 1.1310, this must include the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country.

2. Transformation of RACs Not Initially Packed Before Transformation (§ 1.1350(b))

(Comment 434) Several comments ask that we clarify that the creation CTE requirements would not apply to the creation of an FTL food solely for the purpose of being transformed into another food in a continuous processing protocol. As examples of such continuous processing, the comments suggest a nut butter created by a confectioner solely for the purpose of being turned into confections, and cream cheese created solely to be further processed into dips or spreads. The comments maintain that FTL foods created solely for the purpose of being turned into another FTL food generally are not given separate identifiers or lot codes before transformation into the final FTL food. The comments contend that requiring creation CTE records for such continuous processing would serve no purpose and add unnecessary burden. Some comments request clarification on how traceability lot codes would apply to bulk and commingled ingredients used in continuous processing operations. The comments state that commodity ingredients often are received in bulk form and multiple lots of the same ingredient are stored together before being used in food production, often commingled with other lots of the same ingredient.

(Response 434) As previously stated, we are combining the proposed CTEs for transformation and creation into one CTE for transformation. We recognize that continuous processing operations may present unique circumstances when transforming a food. In some continuous processing operations, a RAC is processed before it is initially packed. (For example, whole heads of lettuce are harvested, chopped, and then initially packed as chopped lettuce.) We conclude that in such situations, where a RAC (other than a food obtained from a fishing vessel) is transformed before it is initially packed, the KDEs relating to initial packing are more appropriate than the KDEs relating to transformation, in part because the incoming RAC has not yet been packed and will not yet have a traceability lot code. Therefore, § 1.1350(b) specifies that for each traceability lot produced through transformation of a RAC (other than a food obtained from a fishing vessel) on the FTL that was not initially packed prior to the transformation of the food, the person performing this transformation (which we assume will include packing of the finished product) must maintain records containing the information specified in § 1.1330(a) or (c) (the requirements for initial packers), and if the RAC is sprouts, the information specified in § 1.1330(b).

We are aware that there are other types of continuous processing operations that differ from this scenario. To address an example from the comments, if a food that is not on the FTL (*e.g.,* nuts) is processed into an intermediate food that is on the FTL (*e.g.,* nut butter) and is very soon thereafter fully processed at the same location into a finished food containing an FTL food that has not been subjected to a kill step (*e.g.,* a confection with nut butter), we would consider this to be one processing event. The food produced through transformation would be the confection, which would be on the FTL because it contains nut butter. The incoming ingredients would include nuts, which are not on the FTL. Nut butter would not be considered an incoming ingredient because the manufacturing of the nut butter was incidental to the overall process of manufacturing the confection. Records under § 1.1350(a)(1) would therefore not be required (assuming none of the other incoming ingredients are on the FTL), and the only records of the transformation event would be those required under § 1.1350(a)(2). We think this approach is appropriate because as described in the comments, the nut butter that is manufactured as an intermediate step (as part of the process of manufacturing the confection) would generally not be given a separate identifier or lot code. We agree with the comments that requiring two sets of records in this situation—one for the manufacturing of the nut butter, and a second for the manufacturing of the confection—would add unnecessary burden.

However, there are some situations where an ingredient such as nut butter is manufactured as a stand-alone product, and then later—not as part of a continuous processing operation—the nut butter is used as an ingredient in a confection. In such situations, the nut butter would have been packed in some way, and possibly stored before its incorporation into the confection. Factors such as these indicate that it was not a continuous processing operation, and that instead there were two separate manufacturing events (one for the nut butter, one for the confection). In that situation, transformation records would be kept for each manufacturing event, including the assigning of a traceability lot code to the nut butter and then assigning of a different traceability lot code to the confection containing the nut butter.

In response to the request for clarification on how the transformation requirements would apply to bulk and commingled ingredients used in continuous processing operations, we note that the concerns expressed in the comment do not seem to be specific to continuous processing operations. In general, if bulk or commingled FTL foods are used as ingredients in another FTL food, the requirements of this subpart would apply. (However, note that some non-produce commingled RACs are partially exempt under § 1.1305(h), and as discussed above there is a specific provision governing RACs (not obtained from a fishing vessel) that are transformed before they are initially packed.) The traceability lot codes for those FTL ingredients would

need to be maintained when received from the shipper as specified in § 1.1345. During transformation, for each traceability lot of the ingredient that is used, the quantity and unit of measure of the food used from that lot would need to be maintained (see § 1.1350(a)(1)(iii) and Response 431). If multiple lots of the same FTL ingredient are stored together before being transformed, entities will need to employ practices to ensure that the different traceability lot codes associated with the FTL ingredient are able to be identified and recorded as required under § 1.1350.

(Comment 435) One comment suggests that the owner of the food being repacked should be required to establish the traceability lot code, rather than a firm, such as a third-party logistics provider, who is under contract to repack or relabel the food.

(Response 435) Subpart S applies to persons who manufacture, process, pack, or hold FTL foods (see § 1.1300); this is true regardless of whether such person owns the food (see Response 155). Similarly, the requirement in § 1.1320(a) to assign a traceability lot code when a food is transformed does not depend on ownership. Thus, in the example given in the comment, it is the entity that repacks the food (*i.e.,* the third-party logistics provider) who is responsible for assigning the traceability lot code (and for maintaining the transformation KDEs under § 1.1350). The third-party logistics provider could enter into an agreement with the owner of the food, under which the owner maintains the relevant KDEs and makes decisions relating to traceability lot codes. However, the third-party logistics provider would still retain the ultimate responsibility for compliance with the relevant portions of the rule. Also, as discussed in Response 296, the traceability lot code source for the food would be the place where the food was transformed (*e.g.,* the third-party logistics provider's repacking facility).

(Comment 436) Several comments request that foods repacked on a farm within the same lot retain the same lot code. For example, a farm may repack 30 boxes of tomatoes from the same lot, sort them by size or quality, and retain the original lot code to maintain traceability to the grower.

(Response 436) We agree that repacked product (regardless of whether it was repacked on a farm) could retain the traceability lot code from the original traceability lot as long as the food is repacked within the same traceability lot (repacking ''like into like''). An example is a single lot of tomatoes repacked so that it is still a single lot, but the individual tomatoes have been sorted into packages within that lot based on their size. In this situation, § 1.1320 is being complied with because the person who transforms the food (*i.e.,* the repacker) is assigning the traceability lot code (even though they are deciding to assign the same traceability lot code that had previously been assigned to the food). Furthermore, the definition of traceability lot code is being complied with, because the code uniquely identifies a single traceability lot within the firm's records. In this situation, the repacker would keep the required transformation records under § 1.1350, with the lot codes in § 1.1350(a)(1)(i) and (2)(i) being the same. Because the repacker in this scenario is required under § 1.1320 to assign a traceability lot code to the food (even if it is the same code that was used previously), under the definition of traceability lot code source in § 1.1310, the traceability lot code source would be changed to reflect the place where the repacking occurred. We think this approach is responsive to the concerns expressed in the comments while still allowing for effective and efficient traceability. Identifying the repacking facility as the traceability lot code source would make us aware that the repacking took place and allow us to contact the repacker in the event of an outbreak investigation. However, if a repacker combines or commingles lots, they cannot use the same traceability lot code, because it would no longer uniquely identify the lot. The repacker in this situation would be required to keep the transformation records under § 1.1350, with the lot codes from the incoming product being identified in § 1.1350(a)(1)(i) and the newly assigned lot code in § 1.1350(a)(2)(i).

(Comment 437) One comment expresses concern that traceability information will not be maintained if produce is repacked further down the supply chain.

(Response 437) Unless they are exempt from subpart S, entities that engage in activities defined as transformation, including repacking, would be required to maintain records of receiving as specified in final § 1.1345, to assign a new traceability lot code as specified in § 1.1320, and to maintain records of transformation in accordance with § 1.1350. In addition, shipping KDEs for the food produced through transformation would need to be maintained and provided to the immediate subsequent recipient of the food in accordance with § 1.1340. We believe that compliance with these requirements will ensure that adequate traceability information on repacked produce will be available later in the supply chain.

(Comment 438) Several comments ask that we provide further definitions and specific requirements for distributors, retailers, and food service operations regarding transformation.

(Response 438) The terms ''distributor,'' ''retailer,'' and ''food service operation'' are not used in subpart S, and we therefore do not see a need to define them. We note that, as discussed in Section V.F of this document, the final rule defines the terms ''retail food establishment'' and ''restaurant.''

In most cases, we do not anticipate that entities who identify as distributors would perform transformation. However, if they were to do so, they would need to keep the transformation records specified in § 1.1350. As discussed in Section V.O.3 of this document, § 1.1350(c) states that the transformation KDEs do not apply to RFEs and restaurants with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers). However, if an RFE or restaurant transforms an FTL food which it then ships to an entity other than a consumer, it would be subject to the transformation requirements in § 1.1350.

(Comment 439) One comment asks whether RFEs will be held responsible for maintaining traceability information for foods they receive that are not identified with barcodes and other traceability lot code information. The comment states that produce vendors may divide up and repackage cases of produce for restaurants because they cannot always use the whole case, and those repackaged cases might not include barcodes or other traceability lot code information.

(Response 439) In the situation described in the comment, the produce vendor would need to keep transformation records under § 1.1350 because they divided up the cases and repacked them. (As discussed in Response 436, the vendor might be able to retain the traceability lot code from the original traceability lot if they repacked ''like into like,'' but this would still be a transformation event.) When the vendor then ships the FTL food to the RFEs or restaurants, the vendor would need to comply with the requirements for shipping under § 1.1340, including the requirement to provide the traceability lot code and other required information to the receiving RFE or restaurant (see § 1.1340(b)). Shippers may use barcodes to provide the required information to RFEs and restaurants (or to any immediate subsequent recipient), but

the rule does not require them to do so. RFEs and restaurants should work with their suppliers if they believe they are not receiving the information required to be provided under § 1.1340(b).

(Comment 440) Some comments assert that the proposed rule would require seafood processors to keep individual shipments separate once processing begins, so that the traceability lot code for the transformed product would not correspond to a significant amount of product from a variety of sources. The comments maintain that if there is a public health issue with an individual shipment, the entire transformed lot would be implicated.

(Response 440) Processing of seafood would be considered a transformation event. Therefore, unless an exemption applies, the seafood processor would be required to maintain records that link the traceability lot code (and the other KDEs listed in § 1.1350(a)(1)) of the food being used in transformation (the input) to the new traceability lot code for the food produced through transformation. There is no requirement to limit the number of incoming lots in a transformation event. As noted in the comments, if a processor creates one traceability lot of product using input from a large number of different incoming traceability lots, it is possible that one contaminated incoming traceability lot could lead to contamination in the entire outgoing traceability lot. However, this risk of contaminating a large traceability lot of product exists regardless of whether traceability records are maintained. The maintenance of traceability records—and especially records of transformation such as those set forth in § 1.1350—can help identify which traceability lots have been exposed to contamination in a situation such as the one described in the comments.

We note that § 1.1305(h) provides a partial exemption for certain commingled non-produce RACs (see Section V.E.9 of this document). See Response 208 for a description of when and how this partial exemption applies to seafood obtained from a fishing vessel, and to seafood that is raised in aquaculture operations. Processors of seafood who are subject to this partial exemption may nonetheless choose to maintain some form of transformation records (in addition to the one-up, one-back records that they may be required to maintain under § 1.1305(h)(3)), for example if they are concerned that a lack of such records would lead to uncertainty about whether a product had been exposed to contamination.

3. Inapplicability of Transformation Requirements to RFEs and Restaurants With Respect to Foods They Do Not Ship (§ 1.1350(c))

We proposed that the transformation and creation requirements would not apply to RFEs with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers). We stated in the preamble to the proposed rule (85 FR 59984 at 60011) that, as with records of sales of FTL foods by RFEs to consumers, we did not believe it was reasonable to require RFEs to keep records of transformation for foods they then sell directly to consumers (or that they donate or dispose of).

(Comment 441) Some comments express support for exempting from the transformation requirements RFEs that transform food sold directly to consumers.

(Response 441) We received no comments opposing the proposed exemption, and we are finalizing it essentially as proposed. Thus, § 1.1350(c) specifies that § 1.1350(a) and (b) do not apply to RFEs and restaurants with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers).

(Comment 442) One comment asks whether restaurants, grocery stores, or other commercial kitchens would be considered to be ''transforming'' foods. The comment suggests that tracking FTL foods that are being transformed or used as an ingredient in another food would not be feasible in these locations because they can be ''wet areas'' where it is challenging to keep records. Other comments request clarification on whether the exemption from the transformation requirements for RFEs that sell food directly to consumers would apply to restaurants or retailers that operate ''central kitchens'' or commissaries, often under common ownership, that prepare food in a larger workspace for transfer (by sale or internal transfer) to nearby stores for sale to consumers or that provide prepared food to entities such as schools or corporate cafeterias for resale to consumers.

(Response 442) As discussed above, under § 1.1350(c) the transformation CTE requirements in § 1.1350(a) and (b) do not apply to RFEs and restaurants with respect to food they do not ship. Shipping is defined in § 1.1310 as an event in a food's supply chain in which a food is arranged for transport (*e.g.,* by truck or ship) from one location to another location. The definition goes on to state that shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food; and that shipping does include sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm. Thus, when an RFE or restaurant sells food directly to a consumer, the food is not ''shipped,'' and therefore under § 1.1350(c) the transformation CTE requirements in § 1.1350(a) and (b) do not apply. However, when an entity such as a central kitchen prepares food and then ships the food to a restaurant or RFE, the exclusion in § 1.1350(c) would not apply. Therefore, if the preparation of the food meets the definition of transformation, the required KDEs under § 1.1350(a) or (b) would need to be maintained.

We think this approach appropriately balances feasibility concerns with the need for robust traceability records. As previously stated, we do not believe it is reasonable to expect RFEs and restaurants to keep records on foods they transform and then sell directly to consumers (*e.g.,* a salad prepared in a restaurant kitchen and then sold to a restaurant customer). However, an entity such as a central kitchen that transforms a food and ships it to a business is functioning as a manufacturer/processor, and should be well-positioned to keep the required records.

(Comment 443) Some comments request that FDA explicitly state in the final rule that repackaging, such as into multipacks or variety packs, constitutes transformation and would require the establishment of a new traceability lot code. One comment asks whether repacking and repackaging are considered transformation events; the comment expresses concern that for firms that frequently divide and label lots into smaller groups, printing new tags each time could create opportunities for error.

(Response 443) As previously stated, transformation includes changing a food (such as by commingling, repacking, or relabeling) or its packaging or packing when the output is a food on the FTL. Thus, repacking and repackaging are both considered transformation events. However, there are some situations (when repacking ''like into like'') where the incoming traceability lot code can be maintained (see Response 436).

P. Procedures for Modified Requirements and Exemptions (§§ 1.1360 to 1.1400)

In accordance with section 204(d)(6)(E) and (F) of FSMA, we proposed to codify provisions allowing the Agency to modify the subpart S

recordkeeping requirements applicable to certain foods or types of entities, or to exempt foods or types of entities from the requirements, under certain circumstances. In the following paragraphs, we clarify certain aspects of the proposed provisions in response to comments we received, but we have made no changes to the provisions and are finalizing them as proposed.

1. Circumstances Under Which FDA Will Modify Requirements or Grant Exemptions (§ 1.1360)

a. General

We proposed to codify the circumstances under which we would modify the requirements in subpart S that apply to a food or type of entity or exempt a food or type of entity from the requirements of subpart S. Under proposed § 1.1360(a), except as stated in proposed § 1.1360(b) (discussed below), we would modify the requirements of subpart S applicable to a food or type of entity, or exempt a food or type of entity from subpart S, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

We have made no changes to the provisions and are finalizing them as proposed.

(Comment 444) One comment requests that FDA provide examples of how the modification and exemption provisions might be applied.

(Response 444) The standards and procedures surrounding modified provisions and exemptions are set forth in §§ 1.1360 through 1.1400. As prescribed by Congress and as stated in § 1.1360(a) of the final rule, we will provide modifications and exemptions for specific foods or types of entities if we determine that application of the relevant requirements is not necessary to protect the public health. It is difficult to anticipate all of the various circumstances that might lead to such a conclusion.

(Comment 445) Some comments support the proposed procedures under which entities may request exemptions or modified requirements based on grounds that application of the requirements that would otherwise apply is ''not necessary to protect the public health.'' However, one comment maintains that modifications and exemptions based on these grounds would be problematic because it would result in inconsistent nationwide application and enforcement of the rule. Another comment asserts that modified requirements or exemptions in one part of the supply chain will affect other parts of the supply chain and may require additional modifications and exemptions. The comment requests that FDA consider in the preamble the impact on others in the supply chain relative to maintaining and sending traceability records/information when it grants requests for modified requirements and exemptions. Other comments request that we consider the financial impacts to the industry when modifying requirements.

(Response 445) We agree that consistent application and enforcement of the rule is important, especially because subpart S depends on the sharing of traceability information through the supply chain. As provided in § 1.1360(a), we will only grant a modification or exemption if we determine that the relevant requirements are not necessary to protect the public health. In making this determination, we will consider the effect that the modification or exemption would have on the entire supply chain, and thus on the traceability of the affected foods. A modification or exemption that could impair our ability to conduct timely and efficient traceback investigations could adversely affect our ability to protect public health, and thus likely would not be granted.

Subpart S already contains several full and partial exemptions, in addition to allowing interested parties to petition for modified requirements and exemptions. As discussed in Section V.E, the final rule contains provisions to address the potential impact of these exemptions on other entities in the supply chain, and to clarify the responsibilities of entities that receive food from suppliers to whom subpart S does not apply. For example, recognizing that some firms might not be provided with certain traceability information they are required to keep because their suppliers are exempt from the rule, the final rule includes special requirements for initial packers (in § 1.1330(c)) and receivers (in § 1.1345(b)) who receive food from persons not subject to subpart S. Under these provisions, we do not believe that industry members would be negatively impacted financially if we were to grant an exemption or modified requirements to a member of their supply chain.

(Comment 446) One comment asks if retail chains with in-store food production will be able to petition for an exemption from transformation records.

(Response 446) Any interested party may submit a citizen petition requesting modified requirements or an exemption from the subpart S requirements for a food or type of entity, as described in §§ 1.1365 and 1.1370. This may include a request for an exemption from the requirements for a particular CTE, such as transformation, as is described in the comment. However, we note that under § 1.1350(c) of the final rule, RFEs and restaurants are not required to keep transformation records related to in-store processing of foods they do not ship (*e.g.,* foods they sell or send directly to consumers) (see Response 441).

(Comment 447) One comment suggests that the provisions allowing exemptions, modifications, and waivers be used broadly as we collect more data on small farms with short supply chains, and asks that these provisions of the rule be used to allow modifications and to ensure flexibility and appropriateness of scale.

(Response 447) A specific type of entity, such as farms of a specific size that participate in a specific type of supply chain, can request an exemption/modified requirements or a waiver, using the procedures in § 1.1370 or § 1.1425, respectively, if they think they meet the relevant requirements. We agree that these procedures can help provide flexibility and appropriateness of scale, for example if a petitioner is able to demonstrate that some of the subpart S requirements are not necessary (or could be modified) for a certain type of entity, in light of the particular circumstances that apply to that type of entity. However, we note that these procedures are not meant to substitute for the decisions that were made regarding exemptions for small entities, as reflected in § 1.1305(a) and (i), and § 1.1455(b)(3)(iii).

b. Registered Facilities

In accordance with section 204(d)(6)(E) and (F) of FSMA, we proposed that if a person to whom modified requirements or an exemption applied under § 1.1360(a) (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under § 1.1360(a)) is required to register with FDA under section 415 of the FD&C Act (and in accordance with subpart H) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person would be required to maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345 (in the subpart J requirements). Proposed § 1.1360(b) further stated that such records would have to be

maintained for 2 years. We are finalizing § 1.1360(b) as proposed.

(Comment 448) Some comments ask that we clarify in these provisions that entities with exemptions, modifications, or waivers still must register with FDA as a food facility under the Bioterrorism Act (and part 1, subpart H) and follow a ''one-up, one-back'' traceability standard.

(Response 448) Section 1.1360(b), which we proposed in accordance with section 204(d)(6)(E) and (F) of FSMA, essentially requires that even if a person is subject to modified requirements or an exemption from subpart S under § 1.1360(a), the person must keep ''one-up, one-back'' traceability records for the FTL foods it handles in accordance with §§ 1.337 and 1.345 *if* it is required to register as a food facility with respect to the manufacturing, processing, packing, or holding of that food. In many cases this will not constitute a new requirement, because many entities that are required to register as food facilities under subpart H are also subject to subpart J, in which case they are already required to keep ''one-up, one-back'' records under §§ 1.337 and 1.345. However, under § 1.1360(b), if a person to whom modified requirements or an exemption applies under § 1.1360(a) is required to register as a food facility under subpart H and is not already subject to subpart J, such an entity would have a new obligation, as a result of § 1.1360(b), to keep ''one-up, one-back'' records in the manner that is specified in §§ 1.337 and 1.345. Similar provisions in § 1.1305(h)(3) and (m)(2) operate in the same manner.

Congress did not specify a similar requirement with respect to the waivers of the subpart S requirements that it authorized us to issue (see Section V.Q of this document), nor did we choose to create such a provision. If FDA waives one or more of the subpart S requirements in accordance with § 1.1405, there is no requirement for the entity that received the waiver to begin keeping ''one-up, one-back'' records if it is not already required to do so. However, a waiver of subpart S requirements has no effect on the applicability of subpart J. Therefore, if the entity that receives the waiver is subject to subpart J, it must continue to comply with that regulation, including (if applicable) by keeping ''one-up, one-back'' records under §§ 1.337 and 1.345.

2. Means by Which FDA Will Consider Whether To Adopt Modified Requirements or Grant Exemptions (§ 1.1365)

We proposed that we will consider modifying subpart S requirements applicable to a food or type of entity, or exempting a food or type of entity from these requirements, on our own initiative or in response to a citizen petition submitted under § 10.30 (21 CFR 10.30) by any interested party (proposed § 1.1365). As stated in the preamble to the proposed rule (85 FR 59984 at 60013 and 60014), the citizen petition regulations in § 10.30 provide standardized procedures for asking the Agency to take (or refrain from taking) an administrative action. We received no comments on this provision and are finalizing it as proposed.

3. Requirements for Citizen Petitions Requesting Modified Requirements or an Exemption (§ 1.1370)

Proposed § 1.1370 specified that, in addition to meeting the requirements on the content and format of a citizen petition in § 10.30, a petition requesting modified requirements or an exemption from the subpart S requirements must:

- Specify the food or type of entity to which the modified requirements or exemption would apply (proposed § 1.1370(a));
- If the petition requests modified requirements, specify the proposed modifications to the subpart S requirements (proposed § 1.1370(b)); and
- Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health (proposed § 1.1370(c)).

We received no comments on this section and are finalizing it as proposed.

4. Public Availability of Information in a Citizen Petition (§ 1.1375)

We proposed that we would presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under 21 CFR part 20 (part 20) (FDA's regulations on public information) and will be made public as part of the docket associated with the petition (proposed § 1.1375).

We received no comments on this provision and are finalizing it as proposed.

5. Process for Citizen Petitions Requesting Modified Requirements or an Exemption (§ 1.1380)

We proposed (in § 1.1380) to establish a process for our handling of citizen petitions requesting modified requirements or an exemption from subpart S. Proposed § 1.1380(a) provided that, in general, the procedures in § 10.30 would govern our response to such a petition, and an interested person could submit comments on such a petition in accordance with § 10.30(d). Proposed § 1.1380(b) specified that, under § 10.30(h)(3), we would publish a notification in the **Federal Register** requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition. Proposed § 1.1380(c) provided that, under § 10.30(e)(3), we would respond to a petitioner in writing. If we granted the petition either in whole or in part, we would publish a notification in the **Federal Register** setting forth any modified requirements or exemptions and the reasons for them (proposed § 1.1380(c)(1)). If we denied the petition (including a partial denial), our written response to the petitioner would explain the reasons for the denial (proposed § 1.1380(c)(2)). Finally, proposed § 1.1380(d) specified that we would make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

We received two comments requesting changes to this section. As discussed in the following paragraphs, we are declining these requests and finalizing the provisions as proposed, with one minor change. The only change is that the proposed rule used the word ''notification'' in places where the final rule uses the word ''notice'' to refer to a type of document published in the **Federal Register**. This revision, which we have made throughout the document on our own initiative, was made to align subpart S with the current terminology regarding **Federal Register** documents, and does not change the meaning of these provisions.

(Comment 449) One comment recommends that we provide timeframes for review of petitions for modified requirements, exemptions, and waivers.

(Response 449) As stated in § 1.1380(a), in general the procedures set forth in § 10.30 govern FDA's response to a petition requesting modified requirements or an exemption. (The same is true for petitions requesting a waiver for a type of entity under § 1.1435(a).) This includes the timeframes set forth in § 10.30(e). We decline to codify different or more specific timeframes for review of petitions for modified requirements or exemptions, or for petitions requesting a

waiver for a type of entity. We also decline to codify specific timeframes for review of waiver requests for individual entities (see §§ 1.1415 and 1.1420).

We anticipate that the circumstances for each petition or waiver request will be unique and will likely result in wide variation in the time needed to thoroughly review and consider the petition or request. We will complete our review of such petitions and requests and issue responses as soon as possible given available Agency resources.

(Comment 450) One comment requests that we announce denials of petitions to the public through a **Federal Register** notice with a justification for the denial. The comment asserts that it is not sufficient to identify a petition as denied on a list on a website without including the justification for the denial, and that providing a rationale for denial would allow stakeholders to gain insight into FDA's decision-making process and potentially improve subsequent petitions.

(Response 450) We agree that stakeholders have a legitimate interest in understanding the rationale for a petition denial. In accordance with § 10.30(e)(3), we will place our response to the petitioner (which will include the rationale for the denial) in the public docket file for the citizen petition. We think that this procedure, combined with periodically updating the status of each petition in accordance with § 1.1380(d), will provide sufficient transparency regarding petition denials. Announcing all denials of petitions through a **Federal Register** notice would require additional resources that would not be justified in every case. That said, in keeping with § 10.30(e)(3), we may decide in certain cases that it is appropriate to announce a denial of a petition through issuance of a **Federal Register** notice.

6. Adopting Modified Requirements or Granting an Exemption on FDA's Own Initiative (§ 1.1385)

In proposed § 1.1385 we specified the procedures we would follow if, on our own initiative, we adopted modified requirements or granted an exemption from the traceability recordkeeping requirements. Proposed § 1.1385(a) provided that if we, on our own initiative, determine that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notification in the **Federal Register** setting forth the proposed modified requirements or exemption and the reasons for the proposal; the notification would establish a public docket so that interested persons may submit written comments on the proposal. Proposed § 1.1385(b) provided that, after considering any comments timely submitted, we will publish a notification in the **Federal Register** stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

We received no comments on this section and are finalizing it as proposed.

7. When Modified Requirements and Exemptions Become Effective (§ 1.1390)

Proposed § 1.1390 specified that any modified requirements that we adopt or any exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the **Federal Register**, unless otherwise stated in the notification. We received no comments on this section and are finalizing it as proposed.

8. Circumstances Under Which FDA Might Revise or Revoke Modified Requirements or an Exemption (§ 1.1395)

Proposed § 1.1395 specified that we may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health. We received no comments on this section and are finalizing it as proposed.

9. Procedures for Revision or Revocation of Modified Requirements or an Exemption (§ 1.1400)

We proposed (in § 1.1400(a)) that if we tentatively determine that modified requirements or an exemption should be revised or revoked, we will provide the following notifications:

- We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition (proposed § 1.1400(a)(1)); and
- We will publish in the **Federal Register** a notification of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notification will establish a public docket so that interested persons may submit written comments on our tentative determination (proposed § 1.1400(a)(2)).

Proposed § 1.1400(b) specified that after considering any comments timely submitted, we will publish notification in the **Federal Register** of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. Proposed § 1.1400(b) further stated that if we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in the notification.

We received no comments on these provisions and are finalizing them as proposed.

Q. Waiver Procedures (§§ 1.1405 to 1.1450)

In accordance with section 204(d)(1)(I) of FSMA, we proposed to establish a process for the issuance of a waiver of the subpart S requirements if we determine that application of the requirements would result in an economic hardship for an individual entity or a type of entity. We received comments seeking clarifications of and modifications to these provisions, to which we respond in the following paragraphs.

1. Circumstances Under Which FDA Will Waive Requirements (§ 1.1405)

Proposed § 1.1405 specified that we will waive one or more of the subpart S requirements when we determine that all of the following conditions are met:

- Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity (proposed § 1.1405(a));
- The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1405(b)); and
- The waiver will not otherwise be contrary to the public interest (proposed § 1.1405(c)).

We are finalizing this provision as proposed.

(Comment 451) One comment requests that we define ''significantly impair'' as used in the waiver provisions and provide examples of what might constitute significant impairment of our ability to rapidly and effectively identify recipients of a food under the specified circumstances.

(Response 451) We decline to formally define ''significantly impair.''

We anticipate a wide variety of circumstances that could lead to a request for a waiver, and we think it will be necessary to apply the three criteria set forth in § 1.1405 on a case-by-case basis. The use of the phrase ''significantly impair'' in § 1.1405(b) conveys that it is not necessary to demonstrate that the proposed waiver would have no effect at all on FDA's ability to trace any impacted foods. However, if the impact is significant, it would be grounds for denying the waiver request.

(Comment 452) One comment asks that we define ''economic hardship'' for purposes of the waiver provisions.

(Response 452) We decline to formally define ''economic hardship'' because the unique circumstances leading to a petition for a waiver on grounds of economic hardship may vary widely, and there are likely relevant circumstances that may arise that we cannot predict at the time of rulemaking. Under § 1.1405(a), the economic hardship for the individual entity or type of entity must be due to its unique circumstances. In the preamble to the proposed rule (85 FR 59984 at 60015), we stated that such circumstances might include, but are not limited to, issues related to unique business operations or geographical factors. We also stated that merely having relatively low revenue or relatively few employees would not ordinarily constitute an economic hardship sufficient to qualify for a waiver from the subpart S requirements. This is because the waiver process in § 1.1405 is not meant to substitute for the decisions we made regarding the exemptions for small entities, as reflected in § 1.1305(a) and (i), and § 1.1455(b)(3)(iii). In addition, we anticipate that we will typically grant waivers only for sustained or long-term circumstances, rather than short-term circumstances such as those some firms may experience during an economic downturn.

(Comment 453) One comment requests that we address in the preamble how we will consider the impact of waivers of requirements on entities in other parts of the supply chain.

(Response 453) Under § 1.1405(b), we will only grant a waiver if doing so would not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded (with respect to allergen labeling). In making this determination, we will consider the effect that the waiver would have on the entire supply chain, and thus on the traceability of the affected foods. We also note that, as discussed in Response 445, the final rule contains provisions to clarify the responsibilities of entities that receive food from suppliers to whom subpart S does not apply (which could include suppliers who are subject to a waiver).

(Comment 454) One comment suggests that in the current economic circumstances and pandemic we might receive widespread waiver requests based on economic hardship. The comment also maintains that at the same time, people recovering from COVID–19 might face increased sensitivity to foodborne illness.

(Response 454) We agree that we may receive a higher number of requests for waivers during an economic downturn, including, potentially, the circumstances brought on by the COVID–19 pandemic. (Though we note that, by the time entities must come into compliance with subpart S traceability requirements, the economic conditions brought on by the pandemic may have normalized.) In general, as stated in Response 452, we anticipate that we will typically grant waivers only for sustained or long-term circumstances, rather than short-term circumstances such as those some firms may experience during an economic downturn. Furthermore, under § 1.1405(b) we will only grant a waiver if doing so would not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded with respect to allergen labeling; and under § 1.1405(c) we will only grant a waiver request if the waiver will not otherwise be contrary to the public interest. In evaluating the impact of waivers on the public interest, we are cognizant of the fact that certain populations are particularly vulnerable to foodborne illness.

2. Mechanisms for Requesting a Waiver (§ 1.1410)

We proposed in § 1.1410 that we will consider whether to waive a requirement of subpart S on our own initiative or in response to the following:

- A written request for a waiver for an individual entity (proposed § 1.1410(a)); or
- A citizen petition requesting a waiver for a type of entity submitted under § 10.30 by any person subject to the requirements of subpart S (proposed § 1.1410(b)).

We are finalizing this provision as proposed.

(Comment 455) One comment asks that we define ''individual entity'' as to its meaning in the waiver provisions.

(Response 455) We decline to formally define ''individual entity.'' Individual entities requesting a waiver will be able to self-identify as an individual entity. Examples of individual entities include, but are not limited to, a single farm, packer, distributor, or RFE.

(Comment 456) One comment asks that we define ''type of entity.''

(Response 456) We decline to formally define ''type of entity.'' Entities of a particular type requesting a waiver will be able to self-identify as a ''type of entity.'' We note that, under § 1.1425(a), a petition requesting a waiver for a type of entity must specify the type of entity to which the waiver would apply. In order for a waiver to be evaluated and (if granted) carried out, the type of entity must be sufficiently delineated so that FDA can clearly identify the entities to which the waiver applies.

(Comment 457) One comment asserts that there should be public notice and comment for all waiver requests, regardless of how the waiver is sought. The comment maintains that establishing a process for consideration of waiver requests that does not allow for public comment is inconsistent with the FD&C Act and the APA. The comment asserts that section 416(d)(2) of the FD&C Act (21 U.S.C. 350e(d)(2)) requires the Secretary to publish waivers and any reasons for the waivers in the **Federal Register**. The comment maintains that by providing one process that requires public notice and comment and another that does not, we would receive requests that were not subject to public comment and would shield waiver decisions from public scrutiny.

(Response 457) Although § 1.1435 of the final rule provides for public notice and comment for waiver requests for a type of entity through publication of a **Federal Register** notice, we decline the request to provide for public notice and comment for waiver requests for individual entities. We note that section 416(d)(2) of the FD&C Act (cited by the comment) applies to requests for waiver from the requirements of FDA's regulation on sanitary transportation of foods; there is no comparable requirement (in either the FD&C Act or section 204(d) of FSMA) to publish in

the **Federal Register** waiver requests from the food traceability recordkeeping requirements in subpart S. We do not believe it is necessary or appropriate for information on an individual entity seeking a waiver based on economic hardship to be publicized through submission of a citizen petition and subsequent publication of a **Federal Register** notice, as individual entity waiver requests will focus on the unique economic circumstances of the individual entity seeking a waiver, which could necessitate the submission of confidential commercial or financial information. We also do not believe public comment is necessary for our review of such waiver requests. On the other hand, as stated in the preamble to the proposed rule (85 FR 59984 at 60015), for waiver requests that concern a type of entity, the fact that the waiver could apply to multiple parties, including persons unaware that the waiver request had been submitted, makes it appropriate to require that the request be submitted in a citizen petition and a notification of the request be published in the **Federal Register**.

3. Requesting a Waiver for an Individual Entity (§ 1.1415)

We proposed in § 1.1415 to specify that a person may request a waiver of one or more requirements of subpart S for an individual entity by submitting a written request to FDA that includes the following:

- The name, address, and point of contact of the individual entity to which the waiver would apply (proposed § 1.1415(a));
- The requirements of subpart S to which the waiver would apply (proposed § 1.1415(b));
- Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements (proposed § 1.1415(c));
- Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1415(d)); and
- Information demonstrating why the waiver would not otherwise be contrary to the public interest (proposed § 1.1415(e)).

On our own initiative, we have revised this provision to specify that a written request for a waiver for an individual entity must be submitted to FDA as described at *www.fda.gov.* Otherwise, we are finalizing this provision as proposed.

(Comment 458) One comment asks that we provide a clear process for what information and documentation an entity will be required to provide to have their waiver request approved. The comment maintains that the process should be flexible and not cumbersome because applicants are likely already facing economic hardship.

(Response 458) We agree that the process for requesting a waiver for an individual entity should be flexible and not cumbersome. We believe that § 1.1415 of the final rule, which adopts the waiver submission requirements set forth in proposed § 1.1415, adequately describes the information that persons seeking a waiver for an individual entity must submit to the Agency without prescribing the submission of particular documents or particular facts that may or may not be relevant to an individual entity's situation. As stated in the preamble to the proposed rule (85 FR 59984 at 60016), we anticipate that after we publish the final rule, we will establish an electronic mailbox to receive requests for waivers for individual entities. In addition, we expect to publish on our website information about how to submit materials to this electronic mailbox, as well as provide a physical FDA address to which waiver requests could be mailed.

4. Process for Request for a Waiver for Individual Entity (§ 1.1420)

We proposed in § 1.1420(a) that, after considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision. In proposed § 1.1420(b) we specified that any waiver for an individual entity that we grant will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response. We received no comments on these provisions and are finalizing them as proposed.

5. Citizen Petition for Waiver for Type of Entity (§ 1.1425)

We proposed in § 1.1425 to specify that, in addition to meeting the requirements on the content and format of a citizen petition in § 10.30, a petition requesting a waiver for a type of entity must:

- Specify the type of entity to which the waiver would apply and the requirements of subpart S to which the waiver would apply (proposed § 1.1425(a));
- Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements (proposed § 1.1425(b));
- Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1425(c)); and
- Present information demonstrating why the waiver would not otherwise be contrary to the public interest (proposed § 1.1425(d)).

We received no comments on these provisions and are finalizing them as proposed.

6. Public Availability of Information in Citizen Petition Requesting Waiver (§ 1.1430)

We proposed in § 1.1430 to specify that we will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 and would be made public as part of the docket associated with the petition. We received no comments on this provision and are finalizing it as proposed.

7. Process for Citizen Petition Requesting a Waiver (§ 1.1435)

We proposed in § 1.1435(a) to specify that, in general, the procedures in § 10.30 govern FDA's response to a petition requesting a waiver, and that an interested person may submit comments on a petition requesting a waiver in accordance with § 10.30(d). Proposed § 1.1435(b) would provide that, under § 10.30(h)(3), we will publish a notification in the **Federal Register** requesting information and views on a submitted petition requesting a waiver

for a type of entity, including information and views from persons who could be affected by the waiver if the petition were to be granted.

Proposed § 1.1435(c) stated that we would respond to a petitioner in writing under § 10.30(e)(3), as follows:

- If we grant a petition either in whole or in part, we will publish a notification in the **Federal Register** setting forth any requirements we have waived and the reasons for the waiver (proposed § 1.1435(c)(1)); and
- If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial (proposed § 1.1435(c)(2)).

Finally, proposed § 1.1435(d) specified that we will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

We received two comments that relate both to these provisions and to the similar provisions in § 1.1380 regarding the process for a petition requesting modified requirements or an exemption. Those comments are addressed above (see Section V.P.5 of this document). We are finalizing § 1.1435 as proposed.

8. Process for Granting Waivers on FDA's Own Initiative (§ 1.1440)

We proposed in § 1.1440(a) that if FDA, on its own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notification in the **Federal Register** setting forth the proposed waiver and the reasons for such waiver. The notification would establish a public docket so that interested persons may submit written comments on the proposal. Proposed § 1.1440(b) specified that after considering any comments timely submitted, we will publish a notification in the **Federal Register** stating whether we are granting the waiver (in whole or in part) and the reasons for our decision. Under proposed § 1.1440(c), any waiver for a type of entity that we grant will become effective on the date that notice of the waiver is published in the **Federal Register**, unless otherwise stated in the notification.

We received no comments on these provisions and are finalizing them as proposed.

9. Circumstances Under Which FDA May Modify or Revoke a Waiver (§ 1.1445)

We proposed in § 1.1445 to specify that we may modify or revoke a waiver if we determine that:

- Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies (proposed § 1.1445(a));
- The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1445(b)); or
- The waiver is otherwise contrary to the public interest (proposed § 1.1445(c)).

As discussed in the paragraphs below, we received one comment on this provision. We are finalizing this provision as proposed.

(Comment 459) One comment states that FDA should provide a citizen petition process for modifying and revoking waivers that allows presentation of data to the Agency for reconsidering waivers.

(Response 459) FDA's citizen petition regulation in § 10.30 provides standardized procedures for requesting that we take (or refrain from taking) an administrative action. While we expect that under most circumstances we would initiate any effort to modify or revoke a waiver, a person could submit a citizen petition in accordance with § 10.30(b) asking that we modify or revoke a waiver, and could include any data they wish to share with the Agency. Under § 10.30(d), any interested person could submit comments (including data) to the docket established for any such petition.

10. Procedures for Modification or Revocation of a Waiver (§ 1.1450)

As with procedures for requests for waivers, we proposed to establish different procedures for modifications and revocations of waivers for (1) individual entities and (2) types of entities. We proposed in § 1.1450(a)(1) to specify that if we tentatively determine that we should modify or revoke a waiver for an *individual entity,* we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. We further proposed that the notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked. Under proposed § 1.1450(a)(2), upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. The provision further stated that if we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

Proposed § 1.1450(b)(1)(i) specified that if we tentatively determine that we should modify or revoke a waiver for a *type of entity,* we will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition. Proposed § 1.1450(b)(1)(ii) specified that we will also publish notification in the **Federal Register** of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The provision further stated that the notification will establish a public docket so that interested persons may submit written comments on our tentative determination.

Proposed § 1.1450(b)(2) provided that, after considering any comments timely submitted, we will publish notification in the **Federal Register** of our decision whether to modify or revoke the waiver and the reasons for the decision. Proposed § 1.1450(b)(2) further stated that if we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in that notification.

We received no comments on these provisions and are finalizing them as proposed.

R. Records Maintenance and Availability (§ 1.1455)

We proposed to adopt several requirements concerning the maintenance and availability of records required under subpart S. In response to comments received and on our own initiative, we have made changes to some of these provisions, primarily those concerning records availability.

1. General Requirements for Records

We proposed to require that records be kept as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records (proposed § 1.1455(a)(1)). We also proposed to require that all records be legible and stored to prevent deterioration or loss (proposed § 1.1455(a)(2)).

On our own initiative, we have added to § 1.1455(a)(1) a statement that electronic records may include valid,

working electronic links to the information required to be maintained under subpart S, to make clear that entities may use electronic links (*e.g.,* to databases or websites) to meet their recordkeeping requirements under the rule.

We respond to the comments we received on proposed § 1.1455(a) in the following paragraphs.

(Comment 460) Many comments assert that the proposed rule creates a de facto requirement for firms to maintain their records electronically, which the comments assert is contrary to section 204(d)(1)(C) of FSMA. One comment maintains that retailers in particular would be unable to comply with the electronic sortable spreadsheet requirement (in proposed § 1.1455(b)(3)) unless their suppliers keep electronic records and the retailer has a system to accept and store that electronic data. Another comment maintains that Congress intended for this rule to require only paper records in order to protect farmers who may lack access to computers and other technology. One comment points to the volume of information required in the KDEs and the preamble discussion of a master data plan as evidence that paper records would be inadequate and that electronic records are therefore a de facto requirement of the rule. Some comments reference the quantity of traceability information required to be gathered and stored by firms of all sizes and maintains that the estimates for one-time capital investment in the Preliminary Regulatory Impact Analysis (PRIA) for the rule seems to imply that FDA assumes a firm will need to invest in technology. The comments note that section 204(d)(1)(G) of FSMA states that the recordkeeping requirements we adopt must, to the extent practicable, not require a facility to change business systems to comply with the requirements.

(Response 460) We do not agree that the proposed rule creates a de facto requirement for firms to maintain their records electronically, nor do we think that the rule violates section 204(d)(1)(C) of FSMA, which states that the rule shall not prescribe specific technologies for the maintenance of records. Under § 1.1455(a)(1) of the final rule, subpart S records may be maintained on paper, electronically, or as true copies. In certain circumstances when the public health is threatened, we may request that information about specific foods and specific date ranges (or traceability lot code ranges) be provided to us in an electronic sortable spreadsheet in accordance with § 1.1455(c)(3)(ii); but we believe that firms that maintain their records on paper will be able to create such a spreadsheet, using the information contained in their paper records, under those limited circumstances. Moreover, we note that § 1.1455(c)(3)(ii) does not prescribe a specific technology for creating the sortable spreadsheet.

Regarding FSMA section 204(d)(1)(G), although we recognize that there may be incentives or in some cases market pressures for entities to adopt electronic recordkeeping for traceability, and some entities may find it beneficial to invest in new technology to keep traceability records, the rule itself does not require entities to replace their paper-based systems with electronic records. Estimates of capital investment costs in section II.F of the FRIA assume that some (but not all) entities will choose to adopt new technologies or update their existing ones in light of the rule (Ref. 16). In particular, the capital investment cost estimates in the FRIA reflect a prediction that adoption of technologies for traceability will depend on a firm's size, industry, position in the supply chain, products, and existing traceability systems, as well as whether the firm decides to adopt an electronic recordkeeping system as a result of this rule.

(Comment 461) One comment refers to FDA's statements in the preamble to the proposed rule encouraging the use of electronic records for traceability and maintains that regulators take preambles seriously (as the comment contends has occurred with the produce safety regulation), which the comment asserts is problematic due to an unconstitutional lack of notice and arbitrary enforcement of requirements. The comment maintains that a rule or statute is unconstitutional when it fails to provide the regulated entity or person with fair notice of the compliance requirements and/or allows for arbitrary and discriminatory enforcement. The comment asks that we include paper recordkeeping options especially for farms that may not have access to electronic recordkeeping technology. The comment also recommends that we delete the electronic spreadsheet requirement and ensure that additional technology is not included as a requirement in the final rule or encouraged in the preamble to the final rule.

(Response 461) As stated in Response 460, the final rule does not require the use of electronic records. Although we continue to encourage all parts of the food industry to adopt electronic recordkeeping for traceability, firms are not required to do so, and we will not take any regulatory action against a firm for keeping required subpart S records in paper form. (Indeed, § 1.1455(a)(1) makes it clear that we could not take any such action.) With respect to the electronic sortable spreadsheet requirement in § 1.1455(c)(3)(ii) of the final rule, as discussed in Section V.R.3 of this document, this provision requires that information on certain FTL foods be provided to us in an electronic sortable spreadsheet format only in certain limited circumstances involving an outbreak investigation, a product recall, or some other public health threat; it does not require the maintenance of records in electronic form. We also note that the final rule includes exemptions from the sortable spreadsheet requirement (see § 1.1455(c)(3)(iii)), which we have included in response to comments arguing that smaller entities would have difficulty complying with this requirement. This includes an exemption in § 1.1455(c)(3)(iii)(A) for farms with average annual sales of $250,000 or less (see Section V.R.3 of this document).

(Comment 462) One comment asks whether paper records would also be required if a firm keeps records in electronic form.

(Response 462) If a firm keeps records in electronic form, it is not also required to keep paper versions of those records. Under § 1.1315(a)(1), a firm's traceability plan must include a description of the procedures the firm uses to maintain the required subpart S records, including the format and location of such records. When FDA makes a records request under § 1.1455(c), we will expect the records to be in the format described in the traceability plan. If the traceability plan states that the firm maintains its records electronically and the firm provides us with electronic records, we would not expect to also be provided with paper records.

(Comment 463) One comment requests clarity on what information firms will be required to made available to FDA vs. what must be shared with the supply chain.

(Response 463) All records required under the rule must be made available to the Agency upon request in accordance with § 1.1455. This includes the traceability plan that is described in § 1.1315, the records of CTEs that are described in §§ 1.1325 through 1.1350, and (under specified circumstances) the sortable spreadsheet that is described in § 1.1455(c)(3)(ii).

The only information that is required to be shared within the supply chain is the information for which this is explicitly stated in the rule.

Specifically, certain information must be provided to other entities in the supply chain by harvesters and coolers of FTL foods in accordance with § 1.1325(a)(2) and (b)(2) (see Section V.J of this document) and by shippers in accordance with § 1.1340(b) (see Section V.M of this document).

(Comment 464) Some comments urge us to provide a written request that includes the specific records that we request.

(Response 464) As further discussed below, we have concluded that in the exigent circumstances described in § 1.1455(c)(3), it may be necessary for us to make a records request by phone. Section 1.1455(c)(3)(i) specifies that if the request is made by phone, we will also provide the request to the firm in writing if asked to do so by the firm. For requests that are made in person—either under the exigent circumstances described in § 1.1455(c)(3) or during a routine inspection—we will work with the firm to ensure that the request is understood, including by providing the request in writing as needed.

2. Establishment and Maintenance of Records by Another Entity

We received several comments asking whether third parties may keep records on behalf of a covered entity. In response to the comments, we are adding a provision to the codified (in § 1.1455(b)) concerning establishment and maintenance of records by another entity, as discussed in the following paragraphs.

(Comment 465) One comment requests clarity on the ability of previous handlers of the food to maintain records on an entity's behalf with the understanding that the records must be accessible within 24 hours. Some comments express appreciation for FDA indicating in the preamble to the proposed rule that firms can enter into agreements with a third party to create records for them. One comment maintains that such agreements would be a viable option for entities that only hold FTL foods but do not own them. One comment asks if a shipper could maintain records of a product specifically grown for that shipper, or if both the grower and shipper had to maintain the records. Some comments request that we adopt a provision to accommodate agreements to keep records on behalf of entities subject to subpart S.

(Response 465) As stated in the preamble to the proposed rule (85 FR 59984 at 60004), we believe it is appropriate that persons subject to subpart S be allowed to enter into agreements with individuals or firms to create and keep the records they are required to maintain under the rule, including, but not limited to, records documenting KDEs for the CTEs the person performs. As we stated, this might entail firms hiring consultants or other outside entities to conduct their required recordkeeping, or relying on supply chain partners such as brokers or suppliers to establish and maintain records on their behalf. In response to comments requesting further clarity on this topic, § 1.1455(b) of the final rule specifies that a person subject to subpart S may have another entity establish and maintain records required under subpart S on that person's behalf, although the person subject to subpart S requirements is responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review. In addition, it should be noted that if a person covered by the rule has another entity establish and maintain required subpart S records on its behalf, the covered person must include information on the arrangement in its traceability plan in accordance with § 1.1315(a)(1).

In response to the question about shippers maintaining records of a product grown specifically for the shipper, we note that the final rule no longer has requirements for the CTE of growing. However, § 1.1455(b) allows for the flexibility to make arrangements for any entity to establish and maintain records on behalf of a covered entity, as described above. This could include, for example, an arrangement between a shipper (who may also be the initial packer) and a harvester under which the shipper maintains the required harvesting records under § 1.1325(a) on behalf of the harvester. If requested by FDA, it would still be the responsibility of the harvester to make the records available within 24 hours.

3. Record Availability (§ 1.1455(c))

a. Making Records Available Within 24 Hours of Request

We proposed to require that persons make all records required under subpart S available to an authorized FDA representative as soon as possible but not later than 24 hours after the request (proposed § 1.1455(b)(1)).

On our own initiative, we have added a clarification that records must be made available to an authorized FDA representative ''upon request.'' We also have added a requirement that, in addition to records required under subpart S, firms must make available any information needed to understand the records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records the firm provides correspond to the information required under subpart S. We conclude that it is more appropriate that this information be provided in response to our requests to review records under § 1.1455(c) rather than maintained as a part of a firm's traceability plan (formerly ''traceability program records''), as would have been required under proposed § 1.1315(a)(4).

In response to comments received, we have made other changes to proposed § 1.1455(b)(1) (finalized as § 1.1455(c)(1)), as discussed in the following paragraphs.

(Comment 466) One comment asserts that the proposed rule would permit FDA to request records only after a foodborne illness outbreak has occurred, limiting an entity's incentive to comply with the requirements of the rule and reducing FDA's ability to conduct an effective traceback in the event of an outbreak. The comment maintains that firms would be more likely to comply with the regulations if FDA were granted the authority to inspect records on a periodic basis. The comment further asserts that periodic inspections would help ensure the accuracy and efficiency of traceback investigations, which would improve public health, limit the scope of recalls, and limit unnecessary disposal of food.

(Response 466) The comment misunderstands the proposed rule, which stated (in proposed § 1.1455(b)(1)) that covered entities must make all records required under subpart S available to an authorized FDA representative as soon as possible but not later than 24 hours after the request. That provision was not limited to outbreak situations. Similarly, under § 1.1455(c)(1) of the final rule, FDA may request review of a firm's subpart S records at any time, regardless of whether we have reason to believe that the firm might have handled an FTL food suspected of being a source of a foodborne illness outbreak. This is in keeping with section 204(d)(1)(H) of FSMA, which states that this rulemaking must allow covered entities to maintain the required records at a central or reasonably accessible location provided that such records can be made available to FDA not later than 24 hours after the Agency's request.

We agree with the comment that periodic inspections of traceability records can have a positive impact on public health by ensuring that covered entities are appropriately maintaining the required records such that they will be available and complete when needed during a traceback investigation. As

discussed in Section V.U of this document, we expect to conduct routine records inspections to ensure that entities subject to the final rule are satisfying the rule's requirements.

We note that § 1.1455(c)(3) (discussed below) contains specific requirements that would only apply in the event of a foodborne illness outbreak, recall, or other public health threat. This includes the electronic sortable spreadsheet requirement set forth in § 1.1455(c)(3)(ii). Thus, covered entities would only be required to provide FDA with an electronic sortable spreadsheet during the circumstances described in § 1.1455(c)(3). During a routine inspection that does not meet the conditions described in § 1.1455(c)(3), a covered entity would not be required to provide FDA with an electronic sortable spreadsheet.

(Comment 467) Some comments ask that any request we make for traceability records maintained by a foreign entity and related to an imported food be communicated through the U.S. importer of the food. The comments express concern that we will place direct responsibility on foreign entities to comply with reporting obligations.

(Response 467) We decline this request. For the subpart S requirements to function as intended, all covered supply chain entities, both domestic and foreign, must maintain and provide traceability information as required under the rule. FDA may conduct onsite inspections of foreign entities to determine compliance with regulatory requirements, including those in subpart S, and we may communicate directly with foreign entities during our evaluation of inspectional outcomes or corrective actions. During an outbreak investigation involving an FTL food, we might seek to obtain information directly from foreign entities in the food's supply chain, through the U.S. importer of the food, or through other means. All entities in the supply chain who manufacture, process, pack, or hold the FTL food, whether foreign or domestic, will need to determine how they will maintain required records and make them available to us upon request (unless the entity is subject to an exemption). As previously stated, § 1.1455(b) of the final rule allows firms to have another entity establish and maintain subpart S records on their behalf, although covered firms remain responsible for ensuring that the records are provided onsite to us within 24 hours of our request for the records. Thus, foreign entities may enter into an agreement with their U.S. importer or another entity to maintain records on their behalf, while remaining responsible for compliance with applicable subpart S requirements.

(Comment 468) Several comments request that the rule allow 48 hours rather than 24 hours in which to make requested records available.

(Response 468) We continue to believe that in most cases 24 hours is an adequate length of time in which to make requested subpart S records available to us, and we note that this is in keeping with section 204(d)(1)(H) of FSMA, which states that this rulemaking must allow covered entities to maintain the required records at a central or reasonably accessible location provided that such records can be made available to FDA not later than 24 hours after the Agency's request. However, we recognize that additional time might be appropriate in certain situations, such as when we are requesting a particularly large volume of records. Therefore, § 1.1455(c)(1) of the final rule specifies that records must be made available to us within 24 hours after our request or within some reasonable time to which FDA has agreed. Similar language has been added to § 1.1455(c)(3), which addresses records requests that are necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health. As discussed below, in the circumstances described in § 1.1455(c), the 24-hour time period can begin with a remote request (*e.g.,* a request made by phone).

(Comment 469) Some comments ask who is responsible for providing records to FDA and who will receive records at FDA.

(Response 469) The covered entity who receives a request for records from FDA is responsible for providing the records they are required to maintain under the rule. It is possible that we might request records for a particular FTL food from multiple covered entities in the same supply chain. Regardless of whether or not this is the case, each entity of whom we request records is required to provide us with the records they are required to maintain under subpart S. We will provide the firm from which we request records with a point of contact for submitting the records to us, as we currently do when we request records from industry. In many situations the point of contact is the local FDA office, but in some cases in might be the offices of our regulatory partners, such as a State regulatory agency. In accordance with section 204(c) of FSMA, we intend to establish a product tracing system for the receipt of food traceability information, which could include an electronic portal for the submission of information to the Agency.

b. Offsite Storage of Records

We proposed that offsite storage of records would be permitted if such records can be retrieved and provided onsite within 24 hours of request for official review, and that electronic records would be considered onsite if they are accessible from an onsite location (proposed § 1.1455(b)(2)). We did not receive any comments on this provision and are finalizing it (in § 1.1455(c)(2)) as proposed.

c. Provision of Electronic Sortable Spreadsheet in Outbreak/Recall/Public Health Threat Situation

In § 1.1455(b)(3), we proposed to require, when necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, that entities must make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records they are required to maintain under subpart S, for the foods and date ranges specified in FDA's request. We also proposed that we would withdraw a request for such a spreadsheet when necessary to accommodate a religious belief of a person asked to provide such a spreadsheet.

In response to comments received, we have made several changes to these proposed requirements, including exempting certain small entities from the requirement to provide an electronic sortable spreadsheet, as discussed in the following paragraphs.

(Comment 470) Many comments state that producing and providing an electronic sortable spreadsheet to FDA within 24 hours would be prohibitively difficult for entities of all sizes. One comment maintains that compiling location data into an electronic sortable spreadsheet in 24 hours is particularly burdensome. One comment maintains that the 24-hour deadline could result in data errors. Some comments urge us to create a mechanism by which industry

can request additional time to make the information available, particularly if the records request is large; alternatively, these comments ask that we consider prioritizing what information might be made available to us most quickly for a large request. Some comments recommend either removing the requirement entirely or providing more time to provide the spreadsheet. One comment asks that we consider exercising enforcement discretion regarding this requirement when entities make a good faith effort to comply in a timely manner.

(Response 470) As discussed in the preamble to the proposed rule (85 FR 59984 at 60018), we believe that the electronic sortable spreadsheet requirement will be one of the most effective ways to improve the speed and efficiency of our traceback efforts during a foodborne illness outbreak or other threat to public health. We will only request an electronic sortable spreadsheet when we conclude that obtaining the information in this format is necessary to help us prevent or mitigate a foodborne illness outbreak, assist in implementation of a recall, or otherwise address a threat to the public health, and we will only request information on the FTL foods that may be associated with the outbreak, recall, or other threat to public health.

We believe 24 hours generally is a reasonable timeframe in which to provide a requested electronic sortable spreadsheet given the limited circumstances, limited scope, and urgent nature of these requests. Such spreadsheets can be created using software that is readily available and commonly used for other general business purposes. However, in some circumstances we agree it may be appropriate to provide a firm with additional time to make the electronic sortable spreadsheet available to FDA. For a large records request, for example, a firm that does not maintain records electronically may need to manually enter a considerable amount of information into such software to create an electronic sortable spreadsheet. We agree that it may be reasonable for FDA to extend the 24-hour timeframe in such circumstances, for some or all of the information we request. Therefore, § 1.1455(c)(3) of the final rule specifies that, as under § 1.1455(c)(1), the information requested in these exigent circumstances must be made available to us within 24 hours or within some reasonable time to which FDA has agreed. In determining what timeframes are reasonable, we will consider the specific circumstances, including an entity's effort to comply in a timely manner.

However, we recognize that some smaller entities may be less likely to have the resources to produce the traceability information requested in these exigent circumstances in an electronic sortable spreadsheet format. Therefore, we are exempting certain smaller entities, including certain smaller farms, RFEs, restaurants, and other entities, from the requirement to provide the requested information in an electronic sortable spreadsheet. To make clear what information must be included in an electronic sortable spreadsheet while specifying that certain smaller entities may provide this information in a different form, § 1.1455(c)(3)(ii) provides that except as specified in § 1.1455(c)(3)(iii) and (iv), when the information FDA requests under § 1.1455(c)(3) is information a person is required to maintain under §§ 1.1325 through 1.1350 (*i.e.,* records of CTEs), the person must provide the information in an electronic sortable spreadsheet, along with any other information needed to understand the information in the spreadsheet. Under § 1.1455(c)(3)(iii), a person may provide the information we request under § 1.1455(c)(3) in a form other than an electronic sortable spreadsheet if they are:

- A farm whose average annual sum of the monetary value of their sales of RACs and the market value of RACs they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (§ 1.1455(c)(3)(iii)(A));
- An RFE or restaurant with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (§ 1.1455(c)(3)(iii)(B)); or
- A person (other than a farm, RFE, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (§ 1.1455(c)(3)(iii)(C)).

Entities not required to make the requested information available to us in an electronic sortable spreadsheet format must provide the information in a different form, such as paper records or electronic records that are not compiled in a sortable spreadsheet. For firms that are not exempt from the electronic sortable spreadsheet requirement in § 1.1455(c)(3)(ii), we intend to provide guidance and technical assistance to help entities comply, including potentially providing an electronic template for entering information into a sortable spreadsheet format.

(Comment 471) One comment requested flexibility for the requirement to provide electronic records to the FDA for firms that, for religious reasons, do not use electronic recordkeeping.

(Response 471) As indicated in proposed § 1.1455(b)(3), we agree that it is appropriate to accommodate the religious beliefs of persons asked to provide an electronic sortable spreadsheet. Therefore, the final rule specifies that we will withdraw a request for an electronic sortable spreadsheet under § 1.1455(c)(3)(ii), as appropriate, to accommodate a religious belief of a person asked to provide such a spreadsheet (§ 1.1455(c)(3)(iv)).

(Comment 472) One comment states that the electronic sortable spreadsheet requirement in proposed § 1.1455(b)(1)(3) violates section 204(d)(1)(E) of FSMA, which states that the recordkeeping requirements for FTL foods must not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business. The comment maintains that because the electronic sortable spreadsheet would have to be provided within 24 hours of request, some firms might be concerned with their ability to assemble such a spreadsheet in that timeframe and might therefore consolidate their records daily to be prepared for the possibility of a request, thereby creating duplicate records.

(Response 472) We do not agree that the electronic sortable spreadsheet requirement necessitates the creation and maintenance of duplicate records. FDA may request an electronic sortable spreadsheet containing information on certain FTL foods in the limited exigent circumstance specified in § 1.1455(c)(3). Firms are not required to prepare an electronic sortable spreadsheet daily or to otherwise consolidate or duplicate records in preparation for such a request. While we encourage firms to prepare for having to respond to a request for an electronic sortable spreadsheet under § 1.1455(c)(3)(ii), including maintaining their records in an organized manner to facilitate the preparation of such a spreadsheet, we do not anticipate that firms will choose

to maintain their subpart S records in one manner and then duplicate those records each day to be prepared for a spreadsheet request from FDA.

(Comment 473) One comment asks what information each firm will receive from FDA (*e.g.,* during an outbreak investigation) to use for looking up the records they must include in their electronic sortable spreadsheet. Some comments suggest that our implementation of the rule should limit the scope of information requested and the number of requests.

(Response 473) Under § 1.1455(c)(3), when necessary to facilitate an outbreak investigation, assist in a recall, or otherwise address a threat to the public health, FDA will specify the particular FTL foods for which we need to review CTE/KDE records, focusing on particular dates on which the food was handled and/or particular traceability lot codes of such foods. Our request will make clear the specific foods and the date ranges (or traceability lot codes) for which we seek required traceability information. We will strive to tailor the information request as much as possible so that firms can focus their efforts on the most relevant information. As discussed below, we have concluded that in the exigent circumstances described in § 1.1455(c)(3), it may be necessary for us to make a records request by phone. Section 1.1455(c)(3)(i) specifies that if the request is made by phone, we will also provide the request in writing upon the firm's request; however, the firm must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request. For requests that we make in person, we will work with the firm to ensure that the request is understood, including by providing the request in writing as needed.

(Comment 474) Several comments ask that we clarify how we will request an electronic sortable spreadsheet containing the required information. Some comments ask whether we will make the request verbally or in writing. One comment asks that we clarify how an electronic sortable spreadsheet containing the information we request may be made available to FDA.

(Response 474) We have revised the proposal to specify that our request for information under § 1.1455(c)(3) of the final rule may be made in-person or remotely (*e.g.,* by phone) by an authorized FDA representative. In addition, § 1.1455(c)(3)(i) specifies that if our request for the information specified in § 1.1455(c)(3) is made by phone, we will also provide the request in writing upon request; however, the requested information must be provided within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request. This is the case for any information we request under the exigent circumstances described in § 1.1455(c)(3), even if we are not requesting that the information be provided in an electronic sortable spreadsheet (*e.g.,* if the entity is exempt from the electronic sortable spreadsheet requirement under § 1.1455(c)(3)(iii)).

We are currently considering various mechanisms by which electronic sortable spreadsheets, as well as digitized records and other requested information, can be made available to FDA. Approaches under consideration include sending requested information to a dedicated email box or through an online reporting mechanism, such as a web-based portal to allow for submission of traceability information that we might create in accordance with section 204(c) of FSMA (see Response 522). A request for records under § 1.1455(c)(3) will specify how the information may be shared with FDA. In addition, we expect to issue communication on how firms may make electronic sortable spreadsheets and records (whether in paper or electronic form) available to FDA.

(Comment 475) Some comments ask that we clarify when the 24-hour deadline associated with the electronic sortable spreadsheet requirement begins.

(Response 475) Under § 1.1455(c)(3) of the final rule, the 24-hour period (or other reasonable time to which FDA has agreed) in which the requested information must be provided begins when we issue the request, whether we do so in person or remotely (*e.g.,* by phone).

(Comment 476) Some comments assert that use of electronic spreadsheets might compromise data quality and impede analysis. The comments suggest that we specify a structured data format such as Extensible Markup Language (XML) or JavaScript Object Notation (JSON) to maintain accuracy and data integrity during large-scale information exchange.

(Response 476) We do not agree that use of an electronic sortable spreadsheet will adversely affect the quality of firms' data or our ability to analyze the data. Although there is a potential for human error for firms that input information from paper records into an electronic spreadsheet, we do not believe this will be a particularly difficult or complex process, and any accuracy concerns will be far outweighed by the benefits of having access to comprehensive information in a sortable manner, considerably enhancing our ability to analyze the data more quickly and effectively. As discussed in Response 400, one of the KDEs that we may request as part of the electronic sortable spreadsheet is the reference document type and number for a given CTE. This information will allow us to refer back to the original reference document (whether paper or electronic) where the information was maintained, which may help reconcile any data errors that may occur in the spreadsheet.

We agree that structured data formats promote data accuracy and integrity, especially during large-scale information exchange. We will take this into consideration as an option as we work to develop a range of methods for providing the data required in the electronic sortable spreadsheet to FDA.

d. English Translation of Records in Another Language

We proposed in § 1.1455(b)(4) that upon FDA request, a person subject to the rule must provide within a reasonable time an English translation of records maintained in a language other than English. On our own initiative, we are adding language to clarify that proposed § 1.1455(b)(4) (which is finalized as § 1.1455(c)(4)) refers only to records required under subpart S. We are otherwise finalizing the provision as proposed.

(Comment 477) One comment asserts that we made assumptions that downplay the complexity of the supply chain in putting together supply chain examples. The comment asserts that we assumed any required KDEs would be in English or easily understood as information passes through the supply chain, and maintains that some foods on the FTL, particularly seafood, move through many countries where English is not the first language.

(Response 477) For the purposes of creating supply chain examples, we chose to provide examples in which all the KDEs were maintained in English. However, covered entities may keep records required under subpart S in any language, provided that, in accordance with § 1.1455(c)(4) of the final rule, the entity can make available to us within a reasonable time an English translation of subpart S records that are maintained in another language. Records in a language other than English have to be translated into English only if we request such a translation. We recognize that the fact that subpart S records may be maintained in any language may necessitate that firms work with their supply chain partners to ensure that information provided (such as by shippers to their customers) is readily

understood, but the need to understand information from other supply chain entities exists regardless of traceability recordkeeping requirements.

4. Record Retention

We proposed to require, except as specified otherwise in subpart S, that persons subject to the rule maintain records containing the information required by subpart S for 2 years from the date the person created the records (proposed § 1.1455(c)). We are finalizing this provision at § 1.1455(d), with one minor edit as described below.

(Comment 478) One comment recommends that FDA require only the program records to be maintained for 2 years. The comment suggests that all other traceability records should only be maintained for 1 year.

(Response 478) We decline to make this change. As stated in the preamble to the proposed rule (85 FR 59984 at 60018), although a highly perishable food might pose a risk to consumers for only a few weeks, illnesses caused by a contaminated food can be linked retrospectively to past illnesses through whole genome sequencing (WGS) and other evidence months or even years after the food was sold. Exposure and consumption information collected from illness cases can be compared to information from past cases of illness with the same WGS pattern, and having access to traceability records for the food for up to 2 years after the records were created could greatly aid our investigation into an illness outbreak involving the food. In addition, reviewing food production records up to 2 years old could help us determine whether a current foodborne illness outbreak was part of a long-standing contamination problem with a food or firm. There are also some foods on the FTL with a long shelf life, such as various frozen seafood products. Therefore, § 1.1455(d) of the final rule requires that, except as specified otherwise in subpart S (*e.g.,* records maintained by an RFE or restaurant that is subject to the partial exemption in § 1.1305(j) because they purchase food directly from a farm), persons subject to the rule must maintain records containing the information required by subpart S for 2 years from the date the entity created or obtained the records. (On our own initiative, we added the reference to records ''obtained'' to reflect that in some situations firms may rely on records they receive from others rather than creating the records themselves.)

5. Electronic Records

We proposed to specify that records that are established or maintained to satisfy the requirements of subpart S and that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the requirements of part 11 (21 CFR part 11), which concern electronic records and signatures (proposed § 1.1455(d)). We further proposed that records that satisfy the requirements of subpart S, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11, if not otherwise exempt. We did not receive any comments on these provisions and are finalizing them (at § 1.1455(e)) as proposed.

6. Use of Existing Records and Multiple Sets of Records

We proposed to require that persons subject to the rule do not need to duplicate existing records (*e.g.,* records kept in the ordinary course of business or maintained to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by subpart S (proposed § 1.1455(e)). We further proposed that a covered person may supplement any such existing records as necessary to include all of the information required by subpart S. Finally, we proposed that persons do not have to keep all of the information required by subpart S in one set of records, but they must indicate the different records in which the information is kept in accordance with proposed § 1.1315(a)).

In § 1.1455(f) of the final rule, we are finalizing the provisions on the use of existing records as proposed. On our own initiative, we have moved the provision on the use of more than one set of records to a new paragraph, § 1.1455(g), and revised it to align with changes we are making regarding traceability plans in § 1.1315. Therefore, § 1.1455(g) specifies that a person subject to subpart S does not have to keep all of the information required by this subpart in a single set of records; however, the person's traceability plan must indicate the format and location of the records the person is required to keep under the subpart, in accordance with § 1.1315(a)(1).

(Comment 479) Several comments request that FDA allow firms to leverage existing records.

(Response 479) We agree with the comments. Under § 1.1455(f) of the final rule, firms may use existing records they keep for other purposes to meet the requirements applicable to them under subpart S, provided those records contain the required information.

(Comment 480) One comment urges us to coordinate with other government and non-governmental agencies to identify existing practices and records that might also satisfy traceability requirements.

(Response 480) As stated in Response 536, FDA coordinates with State and other Federal agencies, where appropriate, in conducting its traceability operations. However, persons subject to the rule are responsible for keeping and providing the records required under subpart S. As previously stated, § 1.1455(f) allows firms to use records they keep in accordance with other regulations or for any other purposes to meet their applicable recordkeeping requirements under the final rule.

7. Public Disclosure

We did not propose requirements related to public disclosure but have added § 1.1455(h) to the final rule in response to comments.

(Comment 481) One comment asserts that FDA has a duty to protect from the disclosure of a company's trade secret or confidential commercial information under section 414(c) of the FD&C Act and questions whether we will be able to prevent disclosure if a Freedom of Information Act (FOIA) request is made for information related to subpart S. The comment requests that FDA explain how we intend to protect information from disclosure under FOIA.

(Response 481) FDA protects confidential information from disclosure in accordance with all applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and part 20. Consistent with other FSMA regulations, we have added § 1.1455(h), which states that records obtained by FDA in accordance with subpart S are subject to the disclosure requirements under part 20. This provision makes clear that traceability records that are provided to FDA under subpart S are subject to the information disclosure requirements in part 20, including, but not limited to, provisions protecting against the public disclosure of information concerning trade secrets and commercial or financial information that is privileged or confidential (see 21 CFR 20.61).

S. Consequences of Failure to Comply (§ 1.1460)

We proposed to codify in subpart S certain FSMA provisions related to the consequences of failing to comply with these traceability recordkeeping requirements. Section 204(j)(1) of FSMA

amends section 301(e) of the FD&C Act (21 U.S.C. 331(e)) to make it a prohibited act to violate any recordkeeping requirement under section 204 of FSMA (except when such violation is committed by a farm). We therefore proposed, in § 1.1460(a), to specify that the violation of any recordkeeping requirement under section 204 of FSMA, including the violation of any requirement of subpart S, is prohibited under section 301(e) of the FD&C Act, except when such violation is committed by a farm.

Section 204(j)(2) of FSMA amended section 801(a) of the FD&C Act (21 U.S.C. 381(a)) by adding paragraph (a)(4), which states that FDA shall refuse admission to an article of food if it appears from examination of samples of the food or otherwise that the recordkeeping requirements under section 204 of FSMA (other than the requirements under section 204(f), which concern FDA requests for information from farms under certain circumstances, and which are not addressed in this rulemaking) have not been complied with regarding such article. We therefore proposed, in § 1.1460(b), to specify that an article of food is subject to refusal of admission under section 801(a)(4) of the FD&C Act if it appears that the recordkeeping requirements under section 204 of FSMA (other than the requirements under section 204(f)), including the requirements of subpart S, have not been complied with regarding such article.

Although we are finalizing these provisions as proposed, in the following paragraphs we respond to comments regarding actions FDA might take in response to the commission of prohibited acts under § 1.1460(a) and comments on implementation of the refusal of admission provision in § 1.1460(b).

1. FDA Response To Commission of a Prohibited Act

(Comment 482) Several comments ask that we specify the types of consequences that could result from failing to comply with the FTL traceability requirements. One comment asks whether we will follow a tiered approach to imposing consequences that progresses from issuing a warning letter, to levying a fine, to issuing a stop sale order. One comment recommends that we levy fines for producers that do not comply with the regulation. One comment requests clarification regarding the consequences of non-compliance by RFEs. One comment asks whether a State agency with an established produce safety program may determine the consequences for farms that fail to comply with subpart S.

(Response 482) Under § 1.1460(a) of the final rule, the violation of any recordkeeping requirement under section 204 of FSMA or subpart S (except when such violation is committed by a farm) is a prohibited act under section 301(e) of the FD&C Act. While we intend to work to educate industry before and while we regulate to assist industry in understanding and coming into compliance with the subpart S requirements, there are various actions the Federal government may take if an entity commits a prohibited act under section 301(e) of the FD&C Act. Depending on the nature of the violation, it is generally FDA's practice to give individuals and firms an opportunity to take prompt and voluntary corrective action before we initiate an enforcement action. We may issue advisory action letters, which include Untitled and Warning Letters, to notify firms of violations and to prompt voluntary compliance. When voluntary compliance is not forthcoming, the Federal government may bring a civil action in Federal court to enjoin persons who commit a prohibited act. The Federal government may also bring a criminal action in Federal court to prosecute persons who commit a prohibited act. (FDA does not have the authority to impose fines for violations of section 204 of FSMA or subpart S.) As appropriate, FDA may hold multiple entities responsible for the failure to maintain traceability records in accordance with subpart S.

As discussed in Section V.U of this document, we are in the process of developing our compliance strategy for the traceability rule. We plan to work with our State, Local, Tribal, and Territorial (SLTT) and other regulatory partners to implement efficient enforcement of the rule, including coordinating actions or deferring to each other when a particular agency is best situated to act swiftly to protect consumers. We are still determining how we will work with our SLTT and other regulatory partners in the implementation and enforcement of the rule.

2. Refusal of Admission

(Comment 483) One comment expresses support for proposed § 1.1460(b) and asserts that any seafood offered for importation by an importer that cannot meet the traceability requirements of proposed § 1.1330(a)(2) (which were the proposed first receiver requirements relating to the harvesting of a food) should not be allowed entry into the United States. The comment maintains that there have been many instances in which a foreign shrimp exporter has been incapable of identifying the source of shrimp packaged for export, and the comment contends that FDA has identified this inability to trace imported seafood back to its source as a significant threat to the health of U.S. consumers. In contrast, one comment maintains that there seem to be harsher penalties for foreign entities than domestic entities that fail to comply with the rule, including the fact that imported food may be refused entry under proposed § 1.1460(b). The comment asks that FDA be mindful of its obligations under the World Trade Organization (WTO) to ensure that foreign entities are not held to different standards than those applicable to domestic firms.

(Response 483) As previously stated, § 1.1460(b) incorporates into subpart S section 801(a)(4) of the FD&C Act, which states that FDA shall refuse admission to an article of food if it appears from examination of samples of the food or otherwise that the recordkeeping requirements under section 204 of FSMA (other than the requirements under section 204(f)) have not been complied with regarding such article. The ability to refuse admission to a food under section 801(a)(4) of the FD&C Act is one of the tools Congress gave FDA to help ensure compliance with subpart S. Other tools available to FDA include those related to the prohibited act in section 301(e) of the FD&C Act (as referenced in § 1.1460(a)), as discussed in Response 482. As discussed in Section V.U.3 of this document, we believe the final rule is consistent with U.S. international trade obligations, including those under the WTO, because the same traceability recordkeeping requirements that apply to foreign entities also apply to domestic entities.

(Comment 484) One comment urges us not *to* require importers to ensure their supply chains are fully compliant with the rule as a condition of importation of their food. The comment asks whether we intend to check traceability records or conduct tracebacks as a condition of importation of their food.

(Response 484) Importers that do not physically possess food on the FTL are not subject to subpart S requirements. The final rule does not require importers of FTL foods to verify that entities in their supply chain are in compliance with the subpart S requirements as a condition of importation. However, importers may wish to be aware of whether their suppliers are subject to, and in

compliance with, subpart S requirements because under section 801(a)(4) of the FD&C Act, an article of food is subject to refusal of admission if it appears that the requirements under subpart S have not been met for that food (see § 1.1460(b)). We are still determining our approach to enforcement of the subpart S requirements and the appropriate circumstances regarding refusal of admission for non-compliance with the rule.

(Comment 485) One comment expresses concern that an overly wide range of foods may become subject to a refusal of admission under proposed § 1.1460(b). The comment maintains that if a problem is detected in only one of many factories within the same company, it would not be reasonable to automatically reject all the foods from that company.

(Response 485) The refusal of admission authority in section 801(a)(4) of the FD&C Act (which is referenced in § 1.1460(b)) applies to apparent non-compliance with the recordkeeping requirements under section 204 of FSMA (including subpart S), not any other FDA regulations. We agree that in general it would not be appropriate to deny admission to all foods from a company when a single factory associated with that company fails to meet applicable subpart S requirements for one or more FTL foods, particularly if the company works to address the noncompliance in a timely manner. Under section 801(a)(4) of the FD&C Act, an article of food is subject to refusal of admission if it appears—either from examination of the food or otherwise—that the subpart S requirements have not been complied with. If a company has a history of non-compliance with subpart S at one or more of its locations, including a failure to come into compliance after subpart S violations were brought to the company's attention, we would consider this history in deciding whether to refuse admission to some or all of the company's FTL foods.

(Comment 486) Some comments ask that we revise proposed § 1.1460(b) to provide a means for a foreign supplier's shipment to gain entry following an admission refusal. The comments suggest that importers could remedy a violation by verifying corrective actions taken by a foreign supplier.

(Response 486) We decline to codify a procedure for requesting termination of a refusal of admission under § 1.1460(b). To the extent that the comment is asking about procedures for removal of food from detention without physical examination (DWPE) under an import alert due to non-compliance with the subpart S recordkeeping requirements, existing procedures are likely to be applicable. An article of food may be subject to refusal and the food and covered entity placed on DWPE because information indicates the appearance of a violation of an applicable FDA regulation (such as subpart S). Our decision to remove a food and covered entity from an import alert is based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future entries will be in compliance with the relevant requirements. FDA import alerts often provide information about obtaining removal from the import alert, in particular how to submit information that resolves the appearance of a violation. If we place any food and covered entity that failed to comply with subpart S on import alert, we plan to provide information in the import alert about removal from the alert. Depending on the nature of the violations at issue, we might specify that we will review traceability records from the covered entity responsible for the violation(s) of subpart S before granting removal. However, such a review might not always be necessary.

(Comment 487) One comment requests that we create a unique violation code for food entry lines refused at the border in accordance with proposed § 1.1460(b). The comment also asks that we establish a unique charge code to facilitate the public's ability to monitor our enforcement of the new traceability requirements as applicable to imported foods.

(Response 487) As stated in Section V.U.4 of this document, we are developing our compliance and enforcement strategy for entities that fail to comply with subpart S. It is likely that we will establish a new charge code in FDA's import system for processing entries to identify food that is refused entry in accordance with section 801(a)(4) of the FD&C Act and § 1.1460(b). The publication of an import alert relating to violations of subpart S would then include this charge code, along with a description of the applicable laws and regulations. We currently publish an Import Refusal Report (IRR) on those products for which we determined to refuse admission, including the charge information that identifies the reason for Agency actions.

T. Updating the FTL (§ 1.1465)

In accordance with section 204(d)(2)(B) of FSMA, we proposed in § 1.1465 to establish procedures for updating the FTL to designate new foods on the list and remove foods from the list when appropriate. We received several comments on the proposed requirements for updating the FTL, to which we respond in the following paragraphs.

1. Procedure for Updating the FTL

We proposed in § 1.1465(a) that when we tentatively conclude, in accordance with section 204(d)(2) of FSMA, that it is appropriate to revise the FTL, we will publish a notice in the **Federal Register** stating the proposed changes to the list and the reasons for those changes and requesting public input on the proposed changes. We proposed in § 1.1465(b) that after considering any information and views submitted on the proposed changes to the FTL, we will publish a notice in the **Federal Register** stating whether we are making any changes to the list and the reasons for the decision. We also proposed that if we revise the FTL, we will publish the revised list on our website. We are finalizing these procedures in § 1.1465 as proposed.

(Comment 488) Many comments suggest that updating the FTL should take place on a scheduled timetable to ensure that FDA takes into account changes in product safety, food safety improvements, current risk of foods, and consumer dietary changes, and to ensure that the FTL reflects the most recent science and knowledge from outbreaks. The comments also maintain that updating the FTL on a regular schedule would provide predictability to the food industry to prepare for potential changes to the FTL. The comments suggest a range of possible timeframes for updating the FTL, from quarterly to every 5 years.

(Response 488) As part of our administration of the FTL, we will periodically review data and other information relevant to the seven criteria for commodity-hazard pairs in the RRM–FT, including the consideration of food safety improvements across commodities. We will also determine whether we should add new or revised commodity-hazard pairs to the Model. We agree with the comments that we should update the FTL on a consistent basis. Therefore, we have determined that we intend to update the FTL approximately every 5 years, subject to available resources. We conclude that this 5-year timeframe would allow for the time needed to update the RRM–FT with new data and information, develop a proposed revised FTL and accompanying materials, publish a notice in the **Federal Register** stating the proposed changes to the FTL and the reasons for these changes,

review comments from the public on the proposal, and publish a second notice in the **Federal Register** stating whether we are making any changes to the FTL and the reasons for the decision, as set forth in § 1.1465. As part of this process and before proposing any changes to the FTL, we intend to provide stakeholders with a mechanism to submit relevant data for our consideration as part of our update to the RRM–FT.

For the initial update to the FTL following the publication of the final rule, we will take into consideration the compliance date for the final rule when deciding when to begin the process outlined above.

We agree with the comments that adopting a regular schedule for updating the FTL will provide consistency and help stakeholders be aware of any possible changes to the FTL. However, if substantial new data or information critical to public health emerges, we may decide to review the RRM–FT and the FTL more frequently than every 5 years. An example of such information might be the occurrence of multiple unrelated foodborne illness outbreaks involving a food not on the FTL within the same year. Conversely, we may also update the RRM–FT with new data and information and determine that no changes are needed to the FTL. In that case, we will inform the public that the RRM–FT was updated and the FTL has not changed.

(Comment 489) Many comments request that we update the FTL through notice and comment rulemaking. Some comments assert that the APA requires that the FTL be updated through rulemaking because the FTL defines the scope of the rule, has substantive effects on industry, and acts as a regulation.

(Response 489) Congress explicitly spoke to the process for updating the FTL, and § 1.1465 is in keeping with what Congress provided. Section 204(d)(2)(B) of FSMA states that FDA may update the FTL to designate new foods and to remove foods that are no longer deemed necessary for inclusion, provided that each such update to the list is consistent with the requirements of section 204(d) and notice of the update is published in the **Federal Register**. Section 1.1465 of the final rule incorporates into subpart S the requirement to provide notice of an update of the FTL in the **Federal Register**. In accordance with § 1.1465(a) and (b), when we tentatively conclude that it is appropriate to revise the FTL, we will publish a notice in the **Federal Register** stating the proposed changes and the reasons for those changes and requesting public input, after which we will review comments from the public and publish a second notice in the **Federal Register** stating whether we are making any changes to the FTL and the reasons for the decision. We conclude that this process is in keeping with section 204(d)(2)(B) of FSMA and will give stakeholders sufficient opportunity to provide input on any potential changes to the FTL.

(Comment 490) Several comments request that stakeholders be able to provide input into the development of the FTL. Some comments express interest in engaging with FDA to ensure the most recent data is available in developing the FTL. Many comments request that we develop a process by which stakeholders can request that a food be removed from or added to the FTL. One comment asks that we update the FTL upon a request from stakeholders, including industry, regulators, or public health officials.

(Response 490) As described in Section V.B of this document, we solicited and considered public input into the development of the RRM–FT, which provides the basis for identifying the foods included on the FTL. As discussed in Response 488, we intend to update the FTL approximately every 5 years, subject to available resources. This process will include updating the RRM–FT with new data and information, developing a proposed revised FTL and accompanying materials, and, if we tentatively conclude that it is appropriate to revise the FTL, following the procedures set forth in § 1.1465. As part of this process and before proposing any changes to the FTL, we intend to provide stakeholders with a mechanism to submit relevant data for our consideration as part of our update to the RRM–FT. When updating the RRM–FT, we will use the most recent data available, depending on availability of data sources.

We decline to create a process for stakeholders to request that we update the FTL. We believe that the approach of updating the FTL approximately every 5 years, subject to available resources, is more appropriate considering the time and resources that are needed for this process. We believe that the process set forth in § 1.1465 will provide stakeholders sufficient opportunity to provide input on any changes to the FTL. If we were to set up a process for stakeholders to request updates to the FTL, it would introduce uncertainty about the frequency of updates and potentially necessitate the use of significant resources. To the extent that the comments are suggesting a process under which individual foods would be evaluated for addition to, or removal from, the FTL, we note that when updating the RRM–FT, we want to consistently apply new data and information across all commodities, rather than conducting analyses of individual foods, to help ensure the integrity of the RRM–FT and our analysis.

(Comment 491) One comment recommends that we convene expert panels with representation from the food industry to advise the Agency on updating the FTL.

(Response 491) At present we do not intend to convene expert panels to help update the FTL. We intend to update the FTL approximately every 5 years, subject to available resources, following the process described in Response 488. As part of that process and before proposing any changes to the FTL, we intend to provide stakeholders with a mechanism to submit relevant data for our consideration as part of our update to the RRM–FT. We believe that this opportunity to submit relevant data, combined with the opportunity to submit comment on proposed changes to the FTL as described in § 1.1465(a), will provide all stakeholders, including different parts of the food industry, sufficient opportunity to provide input.

(Comment 492) A few comments request that we develop a system for farmers to know which foods are under consideration for being added to the FTL. The comments maintain that this would allow farmers to factor in this information when making planting decisions.

(Response 492) As previously stated, we intend to update the FTL approximately every 5 years, subject to available resources. This should enable stakeholders, including farmers, to become aware of any new foods under consideration for being added to the FTL. Further, § 1.1465(c) (discussed below) specifies that any additions to the FTL will become effective 2 years after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice. We believe this is sufficient time for entities to ensure they are ready to comply with the rule for any new foods on the FTL.

(Comment 493) Several comments ask that we release to the public the risk scores for commodity-hazard pairs and data used in the Model for each food that is added to or removed from the FTL when it is updated in the future.

(Response 493) When we update the FTL, we will publish a notice in the **Federal Register** stating whether we are making any changes to the list and the reasons for the decision, in accordance with § 1.1465(b). We also intend to make available the commodity and

commodity-hazard pair risk scores and additional information to provide the public with a clear understanding of why certain foods are on the FTL.

(Comment 494) Many comments ask that we clarify how foods can be added to and removed from the FTL, as well as the factors we will consider when reanalyzing the FTL and the scientific basis to support updates to the FTL.

(Response 494) As discussed in Response 5, to determine which foods should be included on the FTL, we developed a risk-ranking model for food tracing based on the factors that Congress identified in section 204(d)(2)(A) of FSMA. To determine whether any foods should be added to or removed from the FTL, we intend to use the same approach we used when developing the initial FTL for the proposed rule. This includes use of the same factors specified in section 204(d)(2)(A) of FSMA as operationalized in the RRM–FT. We will update the RRM–FT with new data and information based on the criteria and approach outlined in the Methodological Approach Report.

In the future, as additional data streams, risk assessment methods, and computational methods arise, we may decide to modify how we implement the factors in section 204(d)(2)(A) of FSMA into a risk-ranking model. However, we do not anticipate developing a new model every 5 years.

(Comment 495) Some comments ask that we exercise enforcement discretion for a food that we have proposed to remove from the FTL for the period of time that the proposal is pending notice and comment. The comments assert that unless we are seeking records for such a food to address a threat to the public health under proposed § 1.1455(b)(3), we should not enforce the recordkeeping requirements because the proposal to remove the food demonstrates that we no longer consider it to pose a high risk.

(Response 495) We do not intend to exercise enforcement discretion as suggested, although we may consider the status of these foods as we prioritize limited inspection resources. In accordance with § 1.1465(a), when we tentatively conclude that it is appropriate to remove a food from the FTL, we will publish a notice in the **Federal Register** stating the proposed removal and the reasons for the change, and requesting information and views on the removal. Submitted comments may provide data or information that could change our mind about removing the food from the FTL. Any deletions from the FTL would become effective as soon as FDA updates the FTL, which would happen only after we had considered any information and views submitted on the proposed removal, and after we had published a notice in the **Federal Register** stating our decision to remove the food from the list (see § 1.1465(b) and (c)).

(Comment 496) A few comments urge us to ensure the FTL is updated based on the most recent available data. One comment asks how we will address data gaps in updating the Model and the FTL.

(Response 496) When updating the RRM–FT, we will use the most recent data available, depending on availability of data sources. For example, while we will use the most recent version of NHANES data available, those data reflect events from a few years before the public availability of the data based on how NHANES releases their data. As described in the Methodological Approach Report (Ref. 10), we scored the seven criteria in the Model based on available data, both quantitative and qualitative. If quantitative data was not available for a certain criterion, the criterion was scored based on qualitative data, which sometimes included expert elicitations. We plan to take a similar approach in the future.

(Comment 497) A few comments maintain that as food safety technologies improve and adoption of them increases, and if risks decrease, we should seek to decrease the number of foods on the FTL.

(Response 507) As discussed in Response 498, we will periodically review data and other information relevant to the seven criteria for commodity-hazard pairs in the RRM–FT. This could include the consideration of food safety improvements across commodities and information on any new technologies that may affect food safety for specific commodities or industries. Updating the Model might result in foods coming off the FTL, but that would depend on any changes we might make to the Model as well as the risk scores of the foods based on the data in the Model.

2. Timeframe for Implementation of FTL Changes

We proposed in § 1.1465(c) that when FDA updates the FTL, any deletions from the list will become effective immediately, while any additions to the list will become effective 1 year after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice.

(Comment 498) Many comments request that when a food is added to the FTL, entities be given 2 years, rather than just 1 year, before firms that manufacture, process, pack, or hold this food must be in compliance with the rule. The comments maintain that 2 years are needed to allow entities handling foods added to the FTL sufficient time to update their recordkeeping practices and make any relevant changes to their supply chains. The comments also maintain that supply chains for new foods added to the FTL will need the same transition time as the supply chains associated with foods on the first iteration of the FTL. Some comments maintain that some products may have a shelf life of more than 12 months, so that it would take longer than 1 year to go through any old product inventory in the supply chain.

(Response 498) We agree that more than 1 year may be needed for firms to revise or update their traceability operations when new foods are added to the FTL, and we believe that 2 years will generally provide sufficient time in which to take these actions and come into compliance with the rule with respect to the added foods. Therefore, we have revised § 1.1465(c) to specify that any additions to the FTL will become effective 2 years after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice. Section 1.1465(c) further states that any deletions from the FTL will become effective as soon as FDA updates the FTL.

Although we do not anticipate that it would occur frequently, there may be situations in which we decide that the 2-year timeframe for the effective date of additions to the FTL should not apply. For example, in the case of an urgent public health concern related to a particular food that is added to the FTL, we might determine it is necessary to require firms handling that food to maintain and provide subpart S records sooner than 2 years. Conversely, if coming into compliance with subpart S within 2 years may be especially challenging for firms handling a particular food, we may determine that more time is needed for that industry to come into compliance. Any differences in the effective date from the standard 2-year timeframe would be stated specifically in the **Federal Register** notice announcing the revised FTL.

We do not intend to conduct our first update to the FTL until after the initial compliance date for the final rule. This will allow industries with foods currently on the FTL to work towards compliance without concern about changes to the FTL before implementation. We describe our

process for updating the FTL in Response 488.

We recognize that the final rule provides 3 years from the rule's effective date for firms to come into compliance, as discussed in Section VI of this document. We have concluded that it is appropriate for this initial compliance period to be longer than the 2 years we are providing in § 1.1465(c) for additions to the FTL to become effective. Many of the traceability systems that will be operationalized in advance of the first compliance date will be in place when the FTL is updated. Therefore, we have determined that 2 years for any new additions to the FTL will be sufficient.

(Comment 499) One comment raises concerns about the impact of changes to the FTL on small farmers, which the comment asserts have less time and fewer resources than larger entities to come into compliance with the rule.

(Response 499) We agree that some small farms might have fewer resources for traceability recordkeeping than some larger entities, although they also might handle fewer FTL foods than larger firms. As previously discussed, the final rule exempts some small farms from subpart S and adopts other exemptions that might apply to some smaller farms or certain FTL foods from these farms. As stated in Response 498, when we update the FTL, any additions to the list will not become effective until 2 years after we publish the revised list, so any smaller farms that are subject to the rule would have 2 years to prepare for compliance with subpart S with respect to the foods that have been added to the FTL. We believe this will provide sufficient time even for smaller entities to come into compliance with the rule regarding the FTL foods they handle.

U. Other Issues

We received comments on several other matters related to the rule, including traceability technology and standards, international trade concerns, outreach and training, and implementation and enforcement of the rule. We respond to the comments in the following paragraphs.

1. Traceability Technology and Standards

(Comment 500) Some comments maintain that entities would have to update their traceability systems to maintain and share the required KDEs. The comments further assert that this would have a financial impact on entities shipping FTL foods, as they will have to invest in technology to produce information whose format might not be compatible with that used by their customers. One comment asserts that this need to purchase technology would have an impact across the entire food industry but would especially affect small businesses, contrary to the directive in section 204(d)(1)(E) of FSMA that the traceability recordkeeping requirements be scale-appropriate and practicable for facilities of varying sizes and capabilities. One comment asserts that examples of sending tracing information to customers provided in the preamble to the proposed rule and at public meetings assume use of technology that may not be widely adopted in the seafood industry. One comment maintains that the proposed rule would force many companies to move to EDI ASNs, which the comment contends would be expensive to set up, validate, and maintain for businesses with thousands of suppliers. The comments ask that we modify the proposed rule to allow firms to comply with limited or no access to such technology.

(Response 500) The final rule does not require covered entities to adopt new technologies to meet their subpart S requirements. While we recognize that some firms may want to invest in certain technological tools or systems, not all firms want to or are financially able to do so. Therefore, the final rule provides firms with considerable flexibility in how they can meet their requirements, including the ability to keep records in paper or electronic form and to use existing records to the extent that they contain required information (see § 1.1455(a) and (f)). We recognize that covered entities vary widely in their traceability procedures and practices, and that coming into compliance with subpart S might have a greater financial impact on certain entities, especially smaller ones. Consequently, the final rule fully exempts certain smaller entities from subpart S and exempts others from the requirement to provide an electronic sortable spreadsheet containing requested traceability information in certain circumstances.

(Comment 501) Several comments suggest that traceability will be improved by the use of digitization and electronic records. One comment maintains that technologies can help address issues raised by farmers and food processors, including by easing the burden for small farms, reducing the burden of duplicative recordkeeping requirements by different regulatory bodies, and protecting against unnecessary exposure of trade secrets. One comment contends that the use of electronic records for traceability could reduce the scope of recalls and result in improved consumer confidence in producers. One comment asserts that the continued use of paper records may hinder information sharing or compromise accuracy during outbreak investigations. Some comments ask that the rule require electronic recordkeeping for traceability to facilitate sharing of data and information, while other comments assert that use of electronic records should be voluntary. Several comments ask that we encourage the use of electronic recordkeeping. On the other hand, some comments support the fact that all-digital systems are not required, and some assert that it will take years for some entities, even some larger ones, to adopt electronic recordkeeping.

(Response 501) As stated in the preamble to the proposed rule (85 FR 59984 at 60017), although we strongly encourage all entities in the supply chain to adopt electronic recordkeeping for traceability, we recognize that not all firms have systems in place to maintain and provide information in electronic form, and that adopting such systems to meet subpart S requirements could be burdensome for some firms. Therefore, the rule allows persons subject to subpart S to keep required records in either paper or electronic form (see § 1.1455(a)). Under FDA's New Era of Smarter Food Safety initiative, we will continue to explore ways to encourage entities to voluntarily adopt tracing technologies and harmonize tracing activities to support end-to-end traceability throughout the food safety system. Additional information on this initiative can be found in FDA's New Era of Smarter Food Safety Blueprint (Ref. 18).

(Comment 502) One comment expresses concern that the proposed rule will be challenging for companies that rely on paper records, particularly small companies, due to the volume and type of KDEs required. The comment maintains that their direct suppliers can meet some of the proposed requirements but they may be challenged in collecting and passing along their suppliers' information due to the digitization effort required, particularly with respect to bulk ingredients received from distributors. The comment states that coordination by the industry is required to achieve the goal of rapid traceability under the rule.

(Response 502) As previously stated, firms are not required to keep their records in electronic form or to digitize records they received in paper form. However, we recognize that firms that maintain records electronically may incur costs in digitizing information they receive in paper records, and that

procedures to identify and document FTL ingredients, regardless of whether or not they are in bulk form, might involve coordination with suppliers. We encourage coordination and communication by industry to ensure supply chain traceability for FTL foods and for entities to work with their supply chain partners to send and receive records to meet the requirements of subpart S. One option for coordinating and communicating the required traceability information to be shared between firms would be through contractual agreements often associated with commercial POs. By using options such as this, firms can clarify the KDEs that must be provided.

(Comment 503) One comment asks that we address what systems firms should use to receive, store, and access digital traceability records. The comment also requests that we clarify how we will receive records from small businesses, including how we will secure the data and mitigate company privacy concerns.

(Response 503) As previously stated, the rule does not prescribe specific technologies for records maintenance or communication with subsequent recipients or the Agency. For those firms wishing to keep subpart S records in electronic form, there are several systems and technologies they might consider using to help them meet their requirements under the rule. We will review firms' subpart S records when they are made available upon the request of an authorized FDA representative in accordance with § 1.1455(c) of the final rule. We intend to develop materials addressing how firms can provide records and electronic sortable spreadsheets to us. As discussed in Section V.R of this document, in response to concerns about maintaining the confidentiality of traceability information provided to FDA, we are adding a provision (§ 1.1455(h)) specifying that records we obtain in accordance with subpart S are subject to the disclosure requirements in part 20 of FDA's regulations, which include provisions concerning the non-disclosure of trade secrets and commercial or financial information that is privileged or confidential.

(Comment 504) One comment maintains that the proposed rule does not discuss the importance of data sharing among supply chain partners and focuses too narrowly on data collection between the covered entity and FDA. The comment asserts that sharing data and records is most widely and commonly facilitated using digital data-sharing standards such as GS1's GDSN for product information (Trade Item Data), EDI for transactional data, and GS1's EPCIS for physical event data. The comment asks FDA to highlight widely used marketplace standards for digital data sharing, such as GDSN, EDI, and EPCIS, in any FDA guidance that may accompany the final rule.

(Response 504) We disagree that the rule does not acknowledge the importance of data sharing among supply chain partners. In fact, we recognize that such information sharing is vital to ensuring effective and efficient traceability. It is for this reason that the framework of the rule includes requirements outlining the specific KDEs for the different CTEs in the supply chain, and specifying which KDEs must be provided to an entity's supply chain partners (for example, by shippers to receivers). As previously stated, although we encourage firms to use available technologies to facilitate their sharing of information with supply chain partners, the rule does not require the use of electronic records and does not prescribe any specific technologies for records maintenance or sharing. Therefore, firms may use any system or standards that help them meet their requirements to keep and provide information under subpart S. We might consider addressing how firms might use existing systems and standards to meet subpart S requirements in future guidance for industry.

(Comment 505) Some comments recommend that the rule address the use of product barcodes as a traceability tool. One comment suggests that we select a barcode type such as GS1–128 that would allow for distribution hubs and other locations to apply for numbers. Some comments request recognition that their implemented system for lot-level tracking using a GS1–128 barcode applied to the shipping container would meet the subpart S requirements. One comment asserts that firms are using different barcodes and different dating systems, and contends that there must be some type of standard for the traceability rule to be effective. One comment states that the proposed rule does not address the importance of capturing product identities physically on food products for robust food traceability in conjunction with sharing traceability data. The comment maintains that automatic identification and data capture (AIDC) tools, such as barcodes and radio-frequency identification (RFID) tags, which capture food product identities and other pertinent data affixed to the physical object, play a vital role in ensuring congruence between traceability data exchanged and events in food supply chains, and asks FDA to recognize AIDC standards and encourage the use of AIDC tools in any guidance accompanying the final rule.

(Response 505) While we recognize the utility of product barcodes and that having industry adopt standards for their use could enhance traceability, section 204(d)(1)(C) of FSMA prohibits us from prescribing specific technologies for the maintenance of records, while section 204(d)(1)(G) specifies that, to the extent practicable, the regulations must not require a facility to change business systems to comply with the requirements. Because the food industry has already developed and adopted the use of various data carriers, if we were to require use of a specific data carrier for any of the KDEs passed from shipper to receiver, a significant number of firms would have to replace their current systems (including firms that currently use paper-based systems). Moreover, if we were to require the use of a specific data carrier or to structure the rule around a specific carrier or type of technology, we would run the risk of having the rule become outdated as new technologies are developed. We have therefore opted to allow for significant flexibility in how firms choose to comply with the rule. We will consider the usefulness of issuing materials that address the use of existing technologies, including product barcodes, for the maintenance and sharing of traceability information.

(Comment 506) One comment asks that we recognize the utility of serial shipping container codes (SSCC) to complement batch/lot level tracing of food products and include the SSCC in any guidance accompanying the final rule. The comment maintains that use of an SSCC aids in tracing the path of a food product in a traceback situation, working in conjunction with batch/lot level identification and without necessitating item-level serialization.

(Response 516) 506) We recognize that the use of SSCCs can be a helpful tool for improving traceability, and firms may wish to use them together with the required traceability lot codes. While SSCCs are not required under subpart S, we encourage the use of any tools that will improve a firm's procedures for traceability and support the maintenance and sharing of the required traceability records under the final rule.

(Comment 507) Several comments ask that we consider requiring the use of globally unique product identifiers (*e.g.,* GS1 GTIN, GS1 GLN, unique resource locators (URL), universal unique identifiers (UUID)), assigned according to recognized industry standards (*e.g.,*

GS1, American National Standards Institute (ANSI), International Organization for Standards (ISO)), encoded into machine-readable data carriers (*e.g.,* 1D and 2D barcodes, RFID, or internet-of-things devices (IoT)) and attached to traceable objects, to facilitate electronic capture of globally unique traceability lot codes and associated KDEs.

(Response 507) We recognize that the use of globally unique product identifiers can be a helpful tool for improving traceability, and firms may wish to use them in establishing required traceability lot codes, including by encoding and attaching them as described in the comments. However, we are not making this a requirement under the final rule. We recognize that while some firms and systems may use these specific standards, not all firms and systems maintain and provide information in this way, and we want to allow sufficient flexibility for firms to maintain and provide the required KDEs based on their preferred systems. Therefore, the rule does not require traceability lot codes to be globally unique, nor does it require them to be encoded into machine-readable data carriers and attached to traceable objects. We believe that the traceability lot code for an FTL food combined with the product description and other required KDEs should be sufficiently unique for our traceability purposes during an outbreak investigation, and we believe there are a variety of ways that firms can provide the required KDEs to their supply chain partners.

(Comment 508) One comment recommends that we require the use of case-level GTINs to identify the originator or brand owner of the food. Another comment suggests that the primary information needed for traceability is the lot number of the food, the identification of the product such as the GTIN, and contact information for the entity that assigned the lot number. The comment asserts that additional descriptors about the food are unnecessary if a GTIN is available.

(Response 508) We recognize that GTINs can be a helpful tool for improving traceability, and firms may wish to use them as part of their traceability systems. However, we do not think it is appropriate to require their use. As discussed above, we have designed the rule to be flexible so that firms may use a range of methods or standards to comply.

As discussed in Section V.C of this document, we believe that the KDEs we are requiring in the final rule are all necessary to ensure efficient and effective traceability of FTL foods. Regarding the comment that additional descriptors about the food are unnecessary if a GTIN is available, we recognize that some of the required KDEs, such as elements of the product description that may be contained within the GTIN trade item identification, may be linked to a GTIN in a database. When this is the case, firms would not need to maintain that information separately, provided they meet the requirements of the rule relating to those data elements (*e.g.,* by maintaining the information for 2 years in accordance with § 1.1455(d); and by providing the product description, as defined, to FDA upon request in accordance with § 1.1455(c), and to immediate subsequent recipients in accordance with § 1.1340(b)).

(Comment 509) One comment requests that the final rule focus on permissioned access to data throughout the supply chain using data standards such as GS1 Digital Link and ISO/IEC 20248:2018 Digital Signature Meta Data Structure, together with AIDC.

(Response 509) The final rule permits (but does not require) the use of permissioned access to data, for example in the context of shippers providing required KDEs to receivers under § 1.1340(b). As discussed above, we have designed the rule to be flexible so that firms may use a range of methods or standards to comply.

As discussed in Response 412, the final rule establishes the concept of the traceability lot code source reference, which is an alternative method through which information on the traceability lot code source could be made available to FDA while protecting the confidentiality of that information. Various methods for offering permissioned access to data, such as those described in the comments, could be used in this context. For example, a shipper of an FTL food may choose to use a web address in a QR code or a GS1 Digital Link as a traceability lot code source reference that they provide to the recipient of the food. Such a web address may employ reasonable security measures, such as only being accessible to a government email address, provided the Agency has access to the information at no cost and without delay.

(Comment 510) One comment suggests that FDA work with producers to create a software program that would allow them to track and share traceability data. The comment suggests that the software could be in Excel or a unique software program.

(Response 510) We intend to develop materials with examples on how firms can maintain and share with supply chain entities information required under subpart S. As part of FDA's New Era of Smarter Food Safety initiative, we sponsored a Low- or No-Cost Tech-Enabled Traceability Challenge (Ref. 30) to encourage the development of low- to no-cost traceability solutions to help enable food operations of all sizes to participate in traceability efforts in a scalable, cost-effective way. However, at present we do not plan to develop a software program for use by persons subject to the rule.

(Comment 511) Some comments request that we establish a single digital system or de-centralized database such as blockchain for storage of traceability information to simplify implementation, help producers obtain initial licensing rights, speed investigations and recalls, provide data uniformity, reduce manual data entry, and support the adoption of 2D QR codes linked to KDEs and CTEs to ease data communication. One comment asserts that lack of a single system for transaction data storage creating seamless electronic interoperability among many disparate and highly competitive entities has been a significant challenge for implementation of drug product tracing under the Drug Supply Chain Security Act (DSCSA) and would present a similar challenge for food traceability. On the other hand, one comment maintains that a single method for collecting all food supply chain data or a single repository for holding and sharing such information is neither feasible nor desirable.

(Response 511) We do not believe it is necessary or appropriate to establish a single system or database to achieve the rule's purpose of facilitating traceability of FTL foods. Participating in such a system or database could be costly or otherwise infeasible for some covered entities because it would require electronic recordkeeping, and mandating participation in such a system or database may be inconsistent with section 204(d)(1)(C) and (E) of FSMA. We believe that the rule can achieve its intended goal of improving the traceability of FTL foods without requiring participation in a single electronic records system or database.

(Comment 512) One comment asserts that although the proposed rule defines discrete CTEs, it does not require companies to indicate the CTEs in data submissions to FDA, which the comment maintains could be a critical aid for interpreting the data quickly. The comment asserts that EPCIS includes classifications of events to help

users and software tools quickly interpret the structure of data contained within the event.

(Response 512) The rule requires covered persons to keep KDEs for particular CTEs involving an FTL food, and we may request that persons make subpart S records for particular FTL foods available to us in a manner that indicates the particular CTE to which maintained KDEs apply. We anticipate that grouping KDEs by CTE would be the most efficient and effective way for firms to provide us with information on specific FTL foods. We also note that under § 1.1455(c)(3)(ii), we may request that firms provide to us in an electronic sortable spreadsheet the information they are required to keep under the CTE requirements in §§ 1.1325 through 1.1350, for the foods and date ranges or traceability lot codes specified in our request.

(Comment 513) One comment asserts that although the proposed exemptions for small entities will help reduce the pressure on small operations that currently have limited financial or technological resources, ultimately market demands, access to premium pricing, and other initiatives will require a more comprehensive traceability rule in the future with a focus on digitization.

(Response 513) The final rule is intended to allow for traceability across the supply chain in a technologically neutral way, while providing certain exemptions (including for some small entities) for the reasons described in Section V.E of this document. The rule does not mandate digitization for the reasons discussed in Response 460. However, we recognize the importance of digitization in traceability, and under our New Era of Smarter Food Safety initiative we will continue to explore ways to encourage all entities in the supply chain to adopt tracing technologies and harmonize activities to support end-to-end traceability throughout the food safety system, including enabling food producers of all sizes to participate in a scalable, cost-effective way. We do not currently have plans to issue a more comprehensive or digitally focused traceability rule in the future. We intend to focus on helping covered entities come into compliance with the final rule and then assessing the effectiveness of the subpart S requirements.

(Comment 514) One comment compares this rule with the DSCSA, which outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. The comment maintains that the DSCSA achieves its traceability goals through unique (serialized) product identifiers applied to all packages and homogeneous cases of covered products. The comment contends that the lot-level traceability envisioned by the proposed rule would not enable the same level of specificity as serialization. As an example, the comment describes a situation in which multiple deliveries of the same traceability lot code of a food to the same recipient would yield ambiguous results when trying to match a specific food in inventory at that recipient to a specific reference record and associated KDEs, such as date of receipt. The comment maintains that if food cases and items were serialized, it would be possible to link a specific case of food to a reference record and associated KDEs.

(Response 514) We believe the comment's comparison of the DSCSA to subpart S is inapt because the goals and requirements of the provisions differ. The DSCSA is intended, in part, to protect consumers from exposure to drugs that may be counterfeit, diverted, stolen, or otherwise unfit for distribution. While serialization is an important tool for detecting counterfeit, diverted, or stolen packages or homogenous cases of drugs, lot-level traceability for foods is important to determine if contamination found in one package of a traceability lot of food could be present in another package from the same traceability lot or other lots of food from the same traceability lot code source and to help meet the goal of preventing or mitigating foodborne illness outbreaks as a result of contamination. Moreover, in contrast to the DSCSA, section 204(d)(1)(L)(iii) of FSMA prohibits requiring product tracing of FTL foods to the case level. Consequently, the final rule is designed to facilitate lot-level tracing of FTL foods, rather than tracing to the case level.

(Comment 515) Many comments urge FDA to adopt existing global standards. One comment encourages us to adopt a digital traceability standard to minimize data capture and sharing errors, despite the initial costs to small growers and distributors. The comment maintains that without universal adoption of such a standard, effective food supply chain traceability will not be possible. Several comments assert that FDA has successfully partnered with a consensus-based standards group for the implementation of other healthcare laws, such those regarding unique device identifiers and the DSCSA. Several comments assert that GS1 sets forth a comprehensive set of standards that is widely used in the food industry, and the comments ask that FDA require or recommend the use of GS1 standards in meeting subpart S traceability requirements. Some comments assert that we have proposed requirements that are similar to but different from GS1 standards, and the comments maintain that these differences could create confusion and inefficiencies. One comment states that industry has worked with GS1 to establish a common language and standards for communication of product data among trading partners and has taken steps to use these standards to create a process for traceability with the PTI. The comment maintains that building on this existing platform would avoid confusion and provide a sound foundation for the implementation of the rule. Some comments recommend the use of EPCIS standards, maintaining that they would bring alignment with currently accepted taxonomy and enable more rapid adoption of new traceability requirements.

One comment maintains that the final rule should accommodate different ''data sharing architectures'' within supply chains, including architectures that do not allow all actors to have access to full product pedigrees. The comment asserts that GDST interoperability standards are designed to enable rapid and direct verification of traceability data. The comment further states that the seafood industry uses multiple data sharing practices or architectures, some of which eschew sharing of all product pedigree information with all supply chain actors. The comment asserts that GDST's approach to interoperability through standardized CTEs/KDEs and data standards conducive to digital linking would provide a robust means of achieving the outcome-based results mandated by the rule while respecting the diversity of data sharing architectures necessary to the current business realities of the seafood sector. Therefore, the comment recommends that we include a reference to the use of GDST standards for information required under the rule for seafood.

One comment maintains that although blockchain has been raised as a possibility for ensuring interoperability, it would be unrealistic to expect many supply chain entities who still use paper records to be able to install and operate a technology like blockchain within 2 years. On the other hand, one comment asserts that a platform with blockchain characteristics and the support for records and transactional information to fit various production systems may minimize any data gaps and could lower barriers to entry or

other challenges that may decrease diversification. One comment suggests that BlockApps would provide a network blockchain-backed solution for traceability in the agriculture industry. One comment asserts that any business process that uses fielded data involving entities, actions, and interplay needs modeling of the data and associated relationships, and requests that FDA develop entity relationship diagrams for the proposed rule.

(Response 515) Although we acknowledge the benefits to enhanced traceability that many of the systems and technologies discussed in the comments might provide, as previously stated we have decided to make subpart S technologically neutral. We think this approach provides firms with maximal flexibility, allows for changing approaches as new technology is developed, and is in keeping with Congress's intent as expressed in section 204(d) of FSMA. Under the final rule, firms may use any traceability standards or approaches that suit their needs (including paper records) as long as they enable firms to keep and provide the information specified under applicable subpart S requirements. However, we intend to participate in traceability governance and harmonization efforts with international regulatory counterparts, including in bodies such as GS1, as part of the New Era for Smarter Food Safety initiative.

(Comment 516) Some comments assert that FDA has the statutory authority to recognize GS1 and other ''voluntary consensus standards'' under the National Technology Transfer and Advancement Act (NTTAA) (Pub. L. 104–113) and OMB Circular A–119, which the comments describe as requiring federal agencies to use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.

(Response 516) Although we agree that firms may use GS1 and other standards to facilitate compliance with their subpart S requirements, we are not prescribing specific standards for the maintenance or transmission of information required under subpart S. Regarding the NTTAA and OMB Circular A–119, we note that this rule does not establish government-unique standards in lieu of voluntary standards. Rather, we are not prescribing *any* specific technological standards for the maintenance and transmission of required traceability information. The approach we have taken is consistent with the Agency's options under the framework of the NTTAA and OMB Circular A–119, as well as the requirement in section 204(d)(1)(C) of FSMA that FDA not prescribe specific technologies for the maintenance of records.

(Comment 517) One comment asserts that FDA should adopt category-specific (*e.g.,* field-grown leafy greens, seafood) global data standards to meet subpart S requirements, and asks that we convene meetings and technical working processes to develop these category-specific global standards.

(Response 517) To the extent that the comment asks us to adopt category-specific electronic data standards for use in subpart S, we decline to do so for the same reasons we decline to adopt specific electronic data standards more generally (see Response 515). However, we regularly participate in working groups and workshops that are engaged in the development of standards for traceability, which often discuss standards that are specific to certain commodities. We intend to continue participating in these efforts and providing relevant input as needed.

(Comment 518) A few comments ask FDA to recognize approaches such as the PTI, which the comments maintain goes beyond the requirements of the rule and includes lot-level tracing via a barcode with a GTIN and lot number. The comments request that firms that are following other programs such as the PTI be considered compliant with the requirements in the final rule.

(Response 518) Although conducting traceability operations consistent with the PTI or a similar program might help firms meet many applicable subpart S requirements, we will not regard such firms to be in compliance with those requirements simply because they follow such a program. The PTI and other programs were not designed to ensure compliance with subpart S, which is not yet in effect. Firms will need to ensure they are in compliance with applicable subpart S requirements by the compliance date regardless of their participation in the PTI or other traceability programs.

(Comment 519) Several comments ask that FDA not regard the proposed rule as a component of the Agency's New Era of Smarter Food Safety initiative. The comments assert that the technology-enabled traceability envisioned under the New Era initiative will not be possible until data harmonization and interoperability standards are in place. Some comments maintain that the rule would prematurely incorporate recordkeeping requirements that reflect New Era capabilities without considering criticisms of the initiative itself. One comment asserts that the rule should not be used as a vehicle to promote the agenda of the New Era and, as a result, push smaller, limited-resource firms out of the food industry. Some comments maintain that there are significant challenges to overcome before the digital end-to-end traceability system for all foods envisioned in the New Era initiative can be achieved, including continued industry reliance on paper recordkeeping and significant diversity in electronic recordkeeping systems in use. However, one comment requests that we continue to assist regulated entities in electronic data migration, tracking, and management under the New Era initiative.

(Response 519) As noted in our New Era of Smarter Food Safety Blueprint (Ref. 18), the final rule will serve as the foundation for much of our traceability work because it will harmonize the KDEs and CTEs needed for enhanced traceability. We believe that establishing this foundation for traceability will allow stakeholders in the supply chain to adopt and leverage digitally enabled technologies, foster improved data sharing, and introduce approaches that greatly reduce the time it takes to identify the origin of a contaminated food tied to an outbreak and/or recall. Although the rule does not require the use of electronic tracing records, we intend to work collaboratively with the food industry, including through the New Era of Smarter Food Safety initiative, to explore ways to encourage firms to voluntarily adopt tracing technologies and ways to harmonize tracing activities, which will support interoperability across a variety of technology solutions, working towards outcomes that are achievable for all sectors.

(Comment 520) Several comments urge FDA to work with industry to define best practices and develop standards for interoperability that will facilitate effective, secure data sharing among all entities in the supply chain. Several comments urge us to adopt standards for language and data structure to help ensure that food traceability systems are interoperable, allowing for swift and accurate exchange of information throughout the supply chain. Some comments assert that although we have specified the information we believe is essential for effective traceability, failing to specify the language/terminology to be used and the structure/format for the retention and exchange of data would impair or even prevent effective traceability. One comment asserts that adopting a standard format would reduce human transcription errors, reduce database costs, and help prevent trade barriers.

One comment asserts that the proposed rule appears not to recognize the necessary standardized data structures for rapid and effective food traceability and recall; the comment recommends the use of standards for both globally unique product identifiers and data structures (or syntax). The comment maintains that with such standards, once a product is uniquely identified, the data can be pieced together or structured in a specific order that conveys the history of that product and how it is transformed and moves through complex supply chains. But the comment maintains that globally unique identification is lost if this structure or syntax is garbled, just as the syntax is lost if the product lacks globally unique identification.

Some comments maintain that, given the diversity in the food supply chain, interoperability is necessary for achieving scalability, lowering adoption costs, and preventing the exclusion or elimination of smaller supply chain participants. One comment asserts that to ensure continued market access for small producers, the technology for traceability must be accessible for all types of operations, and open source and cost-effective solutions should be promoted. One comment suggests that FDA encourage food traceability technology providers to develop solutions that will add little or no overhead so food retailers of all sizes can participate in a technologically based food safety system. One comment asserts that being overly prescriptive in the rule could impede technological evolution and the efficiency with which the rule is implemented; therefore, the comment suggests that we provide additional guidance on options for appropriate digital solutions to ease the burden of compliance and aid successful implementation.

Some comments recommend that, consistent with GS1 standards, FDA should better define the need for both data and data structure in its final rule and acknowledge their shared importance in achieving interoperability and traceability across the supply chain. One comment maintains that although adoption of a universal traceability standard would cause hardship for several entities in the food supply chain, particularly small growers and even some small distributors, hardships would be borne across the supply chain and consumers would share in that cost. One comment maintains that providing support or a platform for electronic submissions that is secure, interoperable, and not limited in regard to regions, products, or otherwise may mitigate issues for scalability across complex supply chains and decrease the ambiguity of exemptions while addressing issues of technology implementation and data liability.

(Response 520) As previously stated, the final rule provides flexibility to entities subject to subpart S regarding the format and manner in which required information is kept and provided to subsequent recipients. However, we recognize the importance of interoperability of standards and systems for food traceability to be conducted at an optimal level. We believe that establishing the KDE/CTE requirements for FTL foods in the final rule is a necessary first step in achieving standardization and interoperability between tracing systems. As previously stated, we intend to explore ways to encourage firms to voluntarily adopt tracing technologies and harmonize tracing activities, which should enhance interoperability and traceability throughout the supply chain.

(Comment 521) Some comments express support for FDA-industry dialogue or partnerships to develop interoperability standards.

(Response 521) As previously stated, through the New Era of Smarter Food Safety initiative and other efforts, we intend to explore ways to encourage firms to voluntarily adopt tracing technologies and to harmonize tracing activities to foster interoperability. We welcome all opportunities to work with the food industry and others to achieve these goals.

(Comment 522) Several comments ask that we share information regarding the systems we will use to receive, store, and access traceability records required under the rule. The comments also ask for information on the interoperability of technology systems between FDA and small businesses, expressing concerns regarding the security and privacy of data submitted to the Agency.

(Response 522) In accordance with section 204(c) of FSMA, we are in the process of developing a product tracing system that would allow information to be provided to FDA in a secure way and in a variety of formats similar to other FDA systems that allow industry to provide information to us. As we progress in the development of this system, we will keep stakeholders informed on the details of the system, including options for data formats and sharing the required records and electronic sortable spreadsheet with FDA. In addition, with respect to the concerns about the security and privacy of data we receive from industry, as previously stated, § 1.1455(h) of the final rule specifies that records we obtain in accordance with subpart S are subject to the disclosure requirements in part 20, which include, among other things, provisions regarding the non-disclosure of trade secrets and commercial or financial information that is privileged or confidential.

2. Labeling Issues

(Comment 523) Some comments request clarification on whether we will provide standards for labels or specify package labeling practices or label printing standards to ensure data integrity and quality. One comment encouraged us to require a lot code on consumer pre-packed products in accordance with the Codex General Standard for Labeling Prepackaged Foods, section 4.6.

(Response 523) The rule does not establish labeling requirements for FTL foods, and in particular does not prescribe standards for labels or labeling that might include KDE information for FTL foods, including traceability lot codes. For example, although shippers of FTL foods are required to provide certain information, including the traceability lot code, to the immediate subsequent recipient of the food, the rule does not require that the information be stated on the label or package of the product.

(Comment 524) Some comments suggest that we include requirements for food labels to facilitate traceability. One comment asserts that for food safety and insurance concerns, all products must be labeled in a way that is easily traceable to the producer. The comment suggests that this may be achieved in a variety of ways, such as through the use of twist ties, bags, food grade stickers, and labels on produce or on customer order forms. One comment maintains that label requirements should include at least the lot code, pack date, and brand of the product. One comment asserts that to allow for adequate tracing, firms must be required to label all ingredients. The comment maintains that permitting companies to group many ingredients into spices and natural flavors can make it impossible to conduct traceback when issues arise. One comment asserts that it is important that FDA remain technology-neutral and not place undue requirements on specific data carried within labels and packaging, but instead retain flexibility for advances in the means to associate unique identification with corresponding event data in the database. The comment therefore encourages us to discuss and approve technology-neutral and ever-evolving methods of complying with the recordkeeping requirements, but not to

specify how or where data are stored in data carriers.

(Response 524) Although the rule includes requirements to provide certain information to receiving entities in the supply chain, it does not prescribe the form in which this information must be provided. We conclude that it is not necessary for the rule to require that traceability information be placed on food labels to ensure adequate traceability of FTL foods. Nevertheless, firms may use product labels to provide information required under subpart S to their supply chain partners if that suits their business practices.

3. U.S. International Obligations and Standards

(Comment 525) One comment maintains that the proposed rule would establish higher standards than those in the Codex Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System (CAC/GL 60–2006) (Ref. 31), and requests that we provide justification of the necessity of requiring higher levels in accordance with Article 3.3 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The comment asserts that although Article 6 of the Codex Principles for Traceability requires that exporting countries not be required to replicate the traceability/product tracing tools used by the importing country, the proposed rule would require exporting countries to adopt the same traceability standards as those used in the United States. The comment also maintains that while Article 12 of the Codex Principles for Traceability specifies that a traceability tool should be able to identify where the food came from and where it was sent, the proposed rule would go beyond one step forward/one step back tracing by requiring that traceability lot codes assigned at food origination be linked to the KDEs in all CTEs. In addition, the comment asserts that under Article 16 of the Codex Principles for Traceability, a food inspection and certification system within which a traceability tool is applied should not be more trade restrictive than necessary; under Article 17, application of the traceability tool should be practical, technically feasible, and economically viable; and under Article 19, a traceability tool should be implemented when appropriate on a case-by-case basis. The comment maintains it is often unknown at the earliest point in the food chain whether foreign agricultural and fishery products eventually will be exported to the United States. But the comment asserts that under the proposed rule, all the stakeholders throughout the food chain must use the same traceability lot code even for products with only a slight possibility of being exported to the United States, which the comment contends would require all stakeholders to entirely update their traceability systems currently in place, resulting in practically, technically, and economically difficult situations.

(Response 525) We believe the rule is consistent with CAC/GL 60–2006. When developing our proposed rule and in considering comments when finalizing this rule, we took into account the Codex Principles for Traceability. To the extent that the rule adopts a more stringent standard than the Codex Principles for Traceability (CAC/GL 60–2006), the more stringent approach is limited to achieve the U.S. level of food safety protection and is based on principles of science and risk. We do not agree that the rule's recordkeeping requirements are in conflict with Article 12 because the rule's more extensive recordkeeping specifications are limited in their application and justified by risk. Specifically, these requirements apply only to foods on the FTL, which we developed using the RRM–FT in accordance with the risk-based factors specified in section 204(d)(2)(A) of FSMA. Also, the rule provides flexibility to domestic and foreign facilities in that it does not dictate any specific product or technology that persons subject to the rule must use to comply with its requirements.

In addition, the rule's recordkeeping requirements are consistent with Article 6 of the Codex Principles for Traceability, and we do not agree with the comment that the rule requires exporting countries to adopt the same traceability standards as those used in the United States. Rather, the rule places additional recordkeeping requirements on specific persons who manufacture, process, pack, or hold foods on the FTL only if the food will be offered for sale in the United States. Food imported into the United States must comply with all applicable FDA requirements; the new traceability requirements would be no different. We believe that foreign entities are able to anticipate whether their products will be exported to the United States, and we note that several existing FDA regulations (such as those concerning produce safety, preventive controls for human food, egg safety, and seafood HACCP) apply to food that is imported into the United States. Because most of the entities that manufacture, process, pack, or hold foods on the FTL also perform activities that would be covered by one or more of these existing regulations (if the food is to be exported to the United States), we believe that these entities will already have procedures in place to identify whether or not their products will be exported to the United States. As discussed in Responses 103 and 335, we believe that U.S. importers will work with their foreign suppliers to help ensure there is an understanding of the potential for foods on the FTL to be exported to the United States and the traceability information required for these products.

Further, we believe the rule is consistent with our international trade obligations because it is consistent with the Codex Principles for Traceability and, to the extent that the rule adopts a more stringent standard than the relevant Codex guidelines, the more stringent approach is limited to achieve the U.S. level of food safety protection and is based on principles of science and risk. For high-risk foods, the rule sets a higher standard of protection and includes additional requirements. This approach is consistent with relevant trade obligations, and the more stringent approach that it takes is scientifically justified based on public health concerns associated with the foods subject to the rule, *i.e.,* the foods on the FTL. We developed the FTL using our RRM–FT, which uses a semiquantitative, multicriteria decision analysis risk-ranking approach that is consistent with the factors specified in section 204(d)(2)(A) of FSMA for use in designating the foods that will be subject to the additional traceability recordkeeping requirements of the final rule, and which is operationalized with data relevant to those factors. Using the results of the RRM–FT, we identified foods to be placed on the FTL, which lists the foods for which additional traceability records are required under the final rule. This is consistent with Article 18 of the Codex Principles for Traceability, which recommends countries take into account the assessed food safety risks of food products, as well as Article 19, which states that a traceability tool should be implemented, when appropriate, on a case-by-case basis.

The requirements we are establishing are necessary for the protection of human, animal, or plant life or health, and are consistent with our international trade obligations, including that the regulatory requirements are not more trade restrictive than necessary to achieve the level of food safety protection FDA has established for U.S. consumers (see also Article 16 of the Codex Principles for Traceability). The traceability

recordkeeping requirements in the final rule help FDA rapidly and effectively identify recipients of certain foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death, are tailored to apply to only high-risk foods offered for sale in the U.S. market, and apply both to domestic and foreign firms. When developing the final rule, we also carefully considered the costs of compliance, as recommended by the Codex guideline, and we have provided flexibility in how firms may meet the rule's requirements. In addition, we recognize that meeting the rule's requirements may be especially burdensome for entities with limited resources, which is why the rule provides certain types of small entities with a full or partial exemption.

(Comment 526) One comment, noting that part 5 (''Traceability'') of Canada's Safe Food for Canadians Regulations (SFCR) has tracing requirements for fresh produce, suggests that we work together with the Canadian Food Inspection Agency (CFIA) to standardize requirements on tracing to reduce the burden on the fresh produce industry.

(Response 526) We will continue our close cooperation with our colleagues at the CFIA. As discussed in Response 479, § 1.1455(f) of the final rule states that entities do not need to duplicate existing records so long as those records contain the information required by subpart S, and entities may supplement any such existing records as necessary to include only the specific information required by subpart S that is not already contained in their existing records. Thus, any records that entities maintain to comply with part 5 of the SFCR can be used to meet the requirements of subpart S, if those records contain or are amended to contain the required information.

(Comment 527) One comment asserts that the competent authorities from other countries will not support the rule and will reciprocate with equally burdensome rules that will be different and create another unintended hurdle for U.S. firms that export products to those countries.

(Response 527) As we have done throughout this entire rulemaking process, we intend to continue to work closely with our international regulatory counterparts, including working toward harmonizing approaches to traceability internationally. While we received comments from several countries that expressed concerns about certain aspects of the rule, such as how records should be maintained by supply chain entities, the role of importers, and the proposed compliance date, they nonetheless expressed support for the rule overall. Principally, we will continue to work with our regulatory counterparts in Codex and in other international fora to promote food safety by using efficient and effective global supply chain traceability measures, while minimizing the regulatory burden on exporters, to the extent practicable.

(Comment 528) One comment, referencing the requirement in section 204(d)(1)(K) of FSMA that FDA take into account international trade obligations in developing the proposed recordkeeping requirements, asserts that because the majority of the seafood consumed in the United States is globally sourced, the rule will have a major impact on U.S. trading partners.

(Response 528) This final rule applies equally to domestic and foreign firms that manufacture, process, pack, or hold FTL foods intended for distribution in the United States. In certain industries, such as seafood, where the majority of the product consumed in the United States is imported, we recognize that many foreign firms will be affected. When proposing the rule and in considering comments before finalizing the rule, consistent with 204(d)(1)(K) of FSMA, we have taken into account international trade obligations and, as stated earlier, we believe the subpart S requirements are consistent with our international trade obligations. Also, as discussed earlier, the final rule provides flexibility in how firms comply with the requirements and affords a partial or full exemption to certain small entities, including foreign small entities.

(Comment 529) One comment maintains that because data collection and maintenance require manpower, resources, and time, the requirement to collect and maintain detailed information may negatively impact trade and present a particular burden for small farms and businesses. To address these concerns, the comment suggests that we narrow the rule to require only records related to food safety concerns. For example, the comment suggests that information about raw material sources and suppliers should be adequate, while the quantity of material received may not be directly relevant to food safety and should not be required.

(Response 529) Subpart S will enhance food safety by ensuring that covered entities maintain and provide information that will promote fast and effective traceability in response to foodborne illness outbreaks. As discussed in Sections III.C and V.C.5 of this document, in response to comments, the final rule includes several changes to streamline and better define the KDEs required for each CTE. The KDEs specified in the rule contain information that is essential for adequate traceability. With respect to the quantity of food received, we believe this information is important to record (regardless of whether the food is a raw material) because it helps us understand the amount of food we might need to locate in traceback and traceforward efforts when conducting an outbreak investigation or recall. We recognize that meeting the rule's requirements may not be feasible for certain entities with limited resources, which is why the rule affords certain entities a full or partial exemption.

4. Implementation and Enforcement

a. General

(Comment 530) Several comments encourage FDA to adopt an ''educate while we regulate'' approach to enforcing the final rule, asserting that the rule is complex and will require much time and effort to come into compliance. Some comments express appreciation that we took this approach with other food safety regulations implemented in accordance with FSMA, such as the produce safety regulation, and request that we take a similar approach with this rule. One comment asserts that inspections that are educational in nature will encourage the development of a positive food safety culture. One comment asserts that meeting the requirements will be a significant undertaking for all covered entities, but particularly for smaller growers and producers. One comment maintains that our implementation of the rule will require further cooperation with industry and asserts that creating more interconnected recordkeeping systems will require time, resources, guidance, and patience.

(Response 530) Consistent with our approach for other FSMA regulations, including those on produce safety, preventive controls for human and animal food, FSVP, and intentional adulteration, we intend to take the approach of educating before and while we regulate. We recognize that significant outreach, education, and technical assistance will be essential to facilitating industry's understanding of the rule. This approach of educating before and while we regulate aligns with the Agency's New Era of Smarter Food Safety blueprint (Ref. 18), which envisions ongoing collaboration and dialogue between FDA and industry to enhance food traceability, support the food safety system, and improve food safety culture.

We are currently considering the best approach for structuring and conducting

records inspections under this rule. Once the compliance date arrives, we expect to conduct routine records inspections to ensure that entities subject to subpart S are satisfying the basic requirements. Routine records inspections primarily will focus on understanding an entity's subpart S recordkeeping practices, identifying any gaps in compliance, and achieving compliance through prompt voluntary corrective actions if we observe deficiencies. In exigent circumstances (*e.g.,* foodborne illness outbreaks, recalls, or other food safety emergencies), we may request specific subpart S records from covered entities to facilitate a traceback or traceforward operation. As with other FSMA regulations, we may consider taking appropriate compliance or enforcement action to address non-compliance when necessary to protect the public health.

We recognize that complying with these traceability recordkeeping requirements may pose challenges for many persons subject to the rule, particularly smaller entities and entities in sectors of the supply chain that we do not regularly inspect. Section 204(h) of FSMA requires FDA to issue an SECG within 180 days of promulgation of the final rule to assist small entities, including farms and small businesses, in complying with the requirements of subpart S. We also expect to provide additional information to stakeholders about the rule, and to engage in outreach, education, and technical assistance to assist the affected sectors of the food industry. In response to comments regarding the length of time needed to come into compliance with the rule, we have extended the compliance period we initially proposed by 1 year, to 3 years after the effective date of the final rule (see Section VI of this document).

We have engaged with stakeholders throughout this rulemaking process and will continue to do so as firms prepare to come into compliance. Concurrent with issuance of the proposed rule, we provided information and supplementary materials on our website, such as information on exemptions, key terminology, supply chain examples, and a pre-recorded webinar discussing the proposed requirements. In accordance with section 204(d)(4) of FSMA, we held three public meetings during the comment period to provide persons in different regions an opportunity to comment. During these public meetings we discussed the Agency's commitment to educate industry before and while we regulate, in line with our overall approach to implementing FSMA. In addition to outreach and guidance we intend to provide (see Section V.U.5 of this document), we note that FDA's TAN is a resource for covered entities with questions related to this rule. Inquiries are answered by FDA information specialists or SMEs who provide a central source of information to support industry understanding and implementation of FSMA standards. The TAN staff have compiled answers to frequently asked questions on the proposed rule (available on our website) and will continue to respond to questions now that we have issued the final rule.

(Comment 531) One comment maintains that the proposed rule seems similar to the FSVP regulation in that it can be monitored using document-based records requests. The comment asks that we publish a list of required records like the checklist the Agency published for FSVP.

(Response 531) The ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements'' document to which the comment referred is a list of records required under the FSVP regulation, organized by sections of that rule, to help importers determine the records they are required to maintain under that regulation (Ref. 32). The FSVP regulation requires importers to verify that foods they import into the United States have been produced in a manner that meets applicable U.S. food safety standards, and requires importers to conduct a hazard analysis, supplier verification, and other activities, in addition to maintaining required records. In contrast, subpart S is entirely focused on the maintenance and provision of records relating to traceability. As previously stated, we intend to issue an SECG in accordance with section 204(h) of FSMA, as well as other materials to assist covered entities in understanding their obligations under subpart S. We anticipate that these materials will specify the KDEs and other records (such as a traceability plan) that entities are required to maintain and provide under subpart S, though the structure of these materials may differ from the FSVP document to which the comment refers.

(Comment 532) One comment asserts that penalizing distributors for non-compliance with the recordkeeping requirements in subpart S would not help FDA conduct effective and timely traceback investigations.

(Response 532) As previously stated, we are developing our compliance and enforcement strategy for the final rule. While any strategy we adopt will include taking compliance or enforcement action when needed to correct problems that put consumers at risk, it will also include actively supporting education and technical assistance efforts for persons subject to the rule. Where appropriate, regulatory actions we take in response to violations of subpart S, whether by distributors or any other type of entity subject to the rule, will be aimed at gaining compliance through voluntary corrective actions, as has been the case with our implementation of other FSMA regulations. As previously stated, we plan to educate industry before and while we regulate to assist firms in understanding the rule. We intend to use our standard regulatory inspection tools, including discussing violations at the time of our review of records, to inform covered entities of violations of the rule as they are observed and to provide firms with a reasonable opportunity to comply.

(Comment 533) One comment requests that we clarify who may be held responsible if a traceback investigation fails during an outbreak.

(Response 533) During an outbreak investigation, our objective is to obtain information as quickly as possible to help identify the source of contamination and remove potentially contaminated product from the marketplace. To effectively implement the final rule, it is important that all supply chain entities subject to subpart S comply with the applicable requirements of the rule. If we encounter non-compliance with subpart S during the course of a traceback investigation, we will consider the specific circumstances of the case in deciding whether to take compliance or enforcement action. Some of the factors we look at in making this decision include whether the entity took prompt, voluntary corrective action when given the opportunity to do so, and whether the entity has a history of non-compliance.

b. Jurisdictional Issues and Coordination With Other Regulatory Authorities

(Comment 534) Some comments ask how we will coordinate with other federal agencies that share jurisdiction over seafood and use existing data systems to facilitate supply chain transparency and food traceability. The comments recommend that we enter into agreements with our federal partners to identify best practices and coordinate seafood oversight and inspection programs. The comments also suggest that we ensure interoperability between agency data

systems so that any data the seafood industry submits to the various systems is accessible to all federal agencies responsible for seafood oversight.

(Response 534) We agree that coordination with other federal agencies, where appropriate, is important to effective regulation of seafood. FDA has a Memorandum of Understanding (MOU) with the National Marine Fishery Service's Seafood Inspection Program in NOAA (Ref. 33), which includes recognizing our mutual regulatory responsibilities and sharing information on regulatory priorities. As we proceed with implementation of subpart S, we will continue to collaborate with NOAA and other federal agencies on data and information sharing and integrating systems as appropriate.

(Comment 535) Some comments ask that we clarify which regulatory authorities are responsible for compliance and enforcement activities regarding the rule. The comments assert that the subpart S requirements overlap with other regulations and implicate other regulatory authorities besides FDA, such as State agencies. Some comments request that we clarify the jurisdictional boundaries between FDA and State agencies and ensure coordination of inspections under the regulation to avoid overburdening farms and first receivers. One comment asks whether subpart S records will be inspected by FDA investigators or FDA-credentialed State investigators. Some comments recommend that we place primary responsibility on State agencies to conduct oversight and enforcement activities at produce farms. These comments also request adequate training and funding for State agencies if we expect subpart S to be enforced during routine inspections of farms. Some comments assert that we will need to partner with State and local regulatory agencies to conduct oversight activities for growers and retailers, adding that it would be unfair and potentially counterproductive to the goals of the regulation if we limited our activities to the food facilities we typically inspect.

(Response 535) We currently are considering the best approach for structuring and conducting inspections for compliance with the subpart S recordkeeping requirements, including the roles that FDA and State investigators should play. We recognize many entities may prefer that traceability rule inspections be conducted as part of an inspection for compliance with other regulatory requirements, such as the regulations on produce safety or preventive controls for human food, and we anticipate that we might seek to take this approach. Regarding RFEs and restaurants, we expect that we will work with our SLTT partners to consider mechanisms for conducting routine traceability records checks.

With respect to inspections of farms, FDA has a Cooperative Agreement Program (CAP) with State agencies for implementing the produce safety regulation (referred to as the ''State CAP''). Not all 50 States participate in inspections of farms under the CAP, and in those States that do not, FDA is responsible for inspections. We also are responsible for inspecting foreign farms, and we lead inspections of sprout growers. Incorporating review of traceability records into regular produce safety regulation inspections is one option for inspecting for compliance with subpart S. This could be accomplished, for example, by adding traceability inspections to the State CAP for produce and providing additional funding to the States to do this work. As we have done with regard to the produce safety regulation, we likely would offer training on the subpart S requirements to State regulators as appropriate to the inspection model. Even if a State CAP includes regulatory oversight and inspectional responsibilities, we might still be involved with compliance and enforcement. However, if a State CAP does not exist or a program does not include regulatory oversight, we would be responsible for conducting inspections and carrying out compliance and enforcement activities.

(Comment 536) Some comments recommend that we work with State and Federal authorities to clarify the roles during foodborne illness investigations. These comments assert that the federal government should build on existing cooperative relationships to ensure the efficient enforcement of the subpart S requirements. The comments recommend that we develop codes to clarify responsibilities and to assist with enforcement and oversight by State regulators.

(Response 536) Our SLTT and other regulatory partners play an important role in helping to ensure food safety in the United States. We routinely work with our regulatory partners to address activities affecting the safety of food, and we intend to continue to leverage existing partnerships and agreements as we implement the subpart S requirements. We will work with our regulatory partners to clarify oversight responsibilities, consider whether additional codes are necessary, reduce redundancy, and consider all tools that will promote effective implementation of the rule.

c. Retail

(Comment 537) Some comments encourage us to conduct enforcement activities at the points of the supply chain where food products are provided to consumers; other comments request clarification on how we will monitor compliance at the retail level. Some comments assert that problems with traceability have historically arisen when foods are sold by restaurants, retailers, and on e-commerce platforms, which are entities that often have not been subject to previous FDA oversight. Some comments assert that enforcing the requirements at the ''last mile'' will improve traceability for products with short shelf-lives.

(Response 537) Under § 1.1345 of the final rule, RFEs and restaurants will be required to maintain KDEs as receivers of FTL foods unless they meet the criteria for an exemption from subpart S. Being able to trace an FTL food quickly through the supply chain from the point of service is a key purpose of the rule, and having access to the traceability lot code for a food at the end of the supply chain is critical to achieving that goal. We are considering several approaches to regulatory oversight at the retail level, including partnering with SLTT and other regulatory officials to conduct routine traceability records checks. As previously stated, we plan to educate industry before and while we regulate to assist firms, including RFEs and restaurants, in understanding the rule. We recognize the complexities of regulation at retail, and we intend to fully leverage our partnerships to help RFEs and restaurants understand and comply with the rule.

(Comment 538) Some comments ask that we provide State and local agencies with resources to address the financial burden associated with oversight of RFEs if we expect those agencies to educate RFEs regarding the subpart S requirements and conduct monitoring and enforcement activities. Some comments ask when we will provide training for investigators and whether FDA investigators and state-credentialed investigators will receive the same training.

(Response 538) We expect to build on our existing collaboration efforts and mechanisms with SLTT officials in the development of tools and training for use by inspectors and investigators. We appreciate the concerns about the potential resource needs associated with oversight, industry education, and staff training with our SLTT partners. We

will consider obtaining additional funding for our regulatory partners through various mechanisms, such as grant programs. We anticipate that FDA and State investigators, as well as other partners conducting inspections, will receive joint training and education on the subpart S requirements using existing training programs.

d. Regulatory Parity

(Comment 539) Some comments ask us to administer the regulation equally across all segments of the food supply chain. The comments also request that we not focus our regulatory oversight activities solely on domestic entities that may already be familiar with traceability. The comments maintain that doing so would be unfair and could adversely affect the rule's ability to achieve one of its principal goals, that of ensuring faster product traceability during outbreaks.

(Response 539) The final rule applies to all persons who manufacture, process, pack, or hold FTL foods, unless an exemption applies, including both persons in the United States and those in other countries. As with all of our FSMA-related enforcement efforts, we intend to apply our oversight resources for the traceability recordkeeping requirements in a risk-based manner, placing greater emphasis on violations that are more likely to result in harm to the public health. There are likely to be both domestic and foreign firms that will be considered higher priorities for oversight because of factors such as having a poor compliance history or handling a high volume of foods that pose significant safety risks. Although there are some differences in our enforcement tools and approaches for domestic and foreign entities, we will conduct our subpart S oversight activities in a manner that furthers the goals of the regulation without unfairly focusing on either domestic or foreign firms.

(Comment 540) Some comments express concern that we will enforce the requirements against entities located in foreign countries and assert that, while all entities should follow the regulation, we should only hold U.S. importers directly responsible for violations.

(Response 540) We do not agree. Foreign entities covered by subpart S are responsible for complying with the portions of the rule that apply to them, based on the CTEs they perform. As discussed in Response 260, importers might not be subject to the rule, depending on whether they manufacture, process, pack, or hold any FTL foods; and if they are subject to the rule, they are only responsible for complying with the portions of the rule that apply to them, based on the CTEs they perform. The rule is not structured to hold an importer responsible for a violation that was committed by a different entity, such as a foreign supplier.

When we encounter non-compliance with subpart S, either during a routine investigation or during an outbreak investigation, we will generally provide an opportunity for prompt, voluntary corrective action, as discussed in Response 482. Decisions about enforcement action—whether against a foreign or domestic entity—will be made on a case-by-case basis.

5. Outreach and Training

As discussed in the following paragraphs, several comments request that FDA conduct outreach efforts and provide guidance, training, and funding to help entities subject to subpart S understand and comply with the rule.

a. Outreach and Training Efforts

(Comment 541) Many comments ask that we provide education, training, and technical assistance to help industry, including particular sectors of industry (*e.g.,* farms, RFEs, wholesale operations, and small and medium-sized firms generally), comply with the new traceability recordkeeping requirements for FTL foods. Some comments assert that educating industry will be vital because the rule will not be effective without industry's strict adherence to the new requirements. Several comments assert that small and medium-sized businesses, including farms, are likely to be adopting traceability systems for the first time and will therefore require training and technical assistance from FDA to help them comply with the rule. One comment maintains that because the rule introduces new terms (*e.g.,* ''key data element,'' ''critical tracking event''), compliance will require education and training. One comment maintains that any introduction of new terminology has consequences to industry and can be especially disruptive to small businesses that lack resources necessary to undergo extra training and hire consultants, and that may have a more limited capacity to adapt and implement new procedures. The comment asserts that the introduction of new requirements disproportionately benefits the largest producers because implementation requires investment in outside experts and management systems, adding that this is particularly concerning when new terms and rules are introduced without education, training, and support for small producers and independent retailers.

(Response 541) We agree with the comments on the importance of conducting outreach to ensure that all sectors of the supply chain are aware of the traceability recordkeeping requirements for FTL foods, as well as providing education to help farms and firms come into compliance with the new requirements. To that end, we are developing communications and educational materials covering all aspects of the rule to assist covered entities of all types, sizes, and levels of traceability expertise. As previously stated, these educational materials will include an SECG setting forth in plain language the subpart S requirements to assist small entities, including farms and small businesses, in achieving compliance. Although we do not agree that this rule benefits larger firms to the disadvantage of smaller ones, we understand that smaller firms may need additional assistance in understanding and implementing some aspects of traceability that larger firms may already have adopted.

(Comment 542) Some comments maintain that education and training is especially important for firms that have not been subject to other regulations adopted in accordance with FSMA. One comment states that it will be a challenge to identify all entities subject to the rule to ensure they receive appropriate education because the rule covers some entities that are not subject to other FSMA requirements, such as ''qualified facilities'' under the produce safety regulation. Some comments suggest that outreach during implementation is essential because companies are at different stages of implementation of traceability recordkeeping due to various factors, including customer demand, compliance with trading partners, and other regulations.

(Response 542) We agree that it will be particularly important to provide education and training to firms that have limited experience with other FSMA regulations and to firms that do not already have robust traceability systems, as well as firms that operate internationally and therefore might also be subject to traceability requirements of foreign countries that may differ from this rule. We also agree that it would be challenging for us to reach all covered entities directly. Therefore, we will extensively engage public and private entities such as State departments of agriculture, industry trade groups, and other stakeholders to share communications and outreach materials for the rule. Although we have tried to

align the subpart S requirements as much as possible with traceability systems, procedures, and terminology already used by industry, we realize that some firms keep different records and provide different tracing information to their customers, which heightens the importance of clearly explaining and illustrating the requirements in the final rule. Again, we intend to extensively engage with public and private entities to share information on the traceability regulations in a timely fashion to assist both domestic and international firms during implementation.

(Comment 543) Some comments suggest that FDA provide training for the entire industry, including foreign firms, because new requirements differ from firms' current procedures and practices and from regulations in foreign countries. Some comments maintain that outreach to foreign firms is important because the compliance status of many U.S. businesses will depend on these firms, and that without such outreach the burden to educate, develop digital capabilities, and promote compliance will fall to industry. Some comments ask that we provide resource materials in multiple languages to help educate the international community about the rule.

(Response 543) We agree there is a need to conduct outreach to foreign entities that will be subject to the subpart S requirements. Among other things, we intend to provide resource materials in multiple languages, work through entities such as the USDA Foreign Agricultural Service and interested embassies to provide outreach to covered foreign entities, and work through associations that serve the U.S. importer and U.S. agent communities, since they may be in dialogue with their foreign suppliers about the requirements of the rule.

(Comment 544) One comment maintains that proper lot code stewardship throughout the supply chain is a departure from current business practices that will require targeted education and training to achieve.

(Response 544) We agree. Given the importance of traceability lot codes in the subpart S requirements, we anticipate that assignment, maintenance, and provision to customers of traceability lot codes will be a key focus of education and training efforts regarding the rule.

(Comment 545) One comment asks that we provide a timetable for the provision of training and resources to ensure compliance.

(Response 545) We will begin to provide resource materials as soon as the final rule issues and will continue to do so up to and after the compliance date. We will try to provide as much outreach and training to covered entities as possible before the compliance date, and thereafter we will continue to engage with industry to promote a full understanding of the rule.

b. Guidance Documents, Templates, and Other Written Materials

(Comment 546) Several comments ask that we provide industry with guidance, forms, spreadsheets, and other written materials to aid understanding of, and compliance with, the traceability recordkeeping requirements in the final rule. Several comments request that we issue a guidance document on the requirements; some comments ask that the guidance include model traceability information to demonstrate how to implement the rule. Some comments ask that we provide more examples and real-life scenarios in the preamble to the final rule or in guidance. Some comments request that we provide examples of the KDEs that would be required at each step in the supply chain for frozen fish products, for both wild-caught and farm-raised fish. One comment suggests that we identify appropriate SMEs for each FTL food to help develop implementation guidance.

(Response 546) We agree that communication, training, and educational materials should take multiple forms and include industry-specific examples and real-life scenarios. We intend to develop an array of materials, taking into consideration the suggestions provided in the comments.

(Comment 547) One comment asks that we consider issuing guidance to link the traceability code with ultimate point of consumption data, such as shopper cards or credit card information. The comment maintains that being able to link a lot of a food with customer information is useful in limiting the scope of recalls, feasible given current practices, and would further protect public health by improving the ability to notify any impacted entities.

(Response 547) We do not believe guidance on the use of consumer data is necessary because the rule does not require firms to keep information on sales to consumers and does not require maintenance of records linking traceability lot codes for FTL foods received from manufacturers or distributors with sales of such food to consumers. However, we recognize that individual RFEs and restaurants might choose to use customer data (*e.g.,* data obtained from a membership card) to help with outbreak investigations and recall implementation. In general we encourage firms to consider adopting traceability practices that go beyond the requirements of subpart S, if such practices are suited to the firm's specific circumstances.

(Comment 548) Several comments request that we develop and make available templates for records that firms might use to maintain and send traceability information required under the rule. Several comments ask that we develop an electronic spreadsheet that firms could use to record the KDEs for the relevant CTEs for their FTL foods, as well as to meet the requirement in proposed § 1.1455(b)(3) to provide information in an electronic sortable spreadsheet in certain circumstances. The comments maintain that the availability of such a template would help FDA know where to look for critical information in an investigation and would provide guidance to firms as to what records they must keep under the rule. One comment asserts that the Leafy Greens Pilot completed in 2020 demonstrated the critical importance of template review and stakeholder education to maximize efficacy. Some comments ask that we develop spreadsheet templates that include examples of supply chains of different lengths and levels of complexity. One comment maintains that having examples for each FTL food category would be valuable to industry, as the supply chain realities for cantaloupes would be quite different than those for deli salads or finfish. This comment suggests that we issue a template that demonstrates how traceability lot codes are preserved alongside other adjacent business-relevant coding that may still be required for the effective operation of certain supply chains. One comment maintains that having an official template could influence software and business process design, including enterprise resource planning, traceability system design, and sourcing and procurement practices. One comment suggests that we provide electronic reporting templates that acknowledge the current digital reality, particularly regarding what it means to ''establish and maintain records.'' One comment requests that we provide sample forms and spreadsheets specifically for use by farms. One comment suggests that templates would be helpful in demonstrating third-party logistics companies' role in traceability.

(Response 548) While we do not intend to issue an ''official'' template for an electronic sortable spreadsheet or any other document that all firms must use to meet subpart S requirements, we

understand that many firms might like to see examples of forms and formats they might use to comply with the rule, and we intend to make such examples available as part of the resource materials for compliance with the rule.

(Comment 549) Some comments ask that we update the supporting materials for the proposed rule that we had posted on our website, while other comments ask that we incorporate into the final rule our responses to ''Frequently Asked Questions'' (FAQs) about the proposed rule (which we also have posted on our website).

(Response 549) We have updated the materials on our website. We have addressed many issues raised in the FAQs in the preamble to the final rule, and we expect to continue to update our website as we develop additional materials (such as the SECG) and as we receive questions about the final rule.

(Comment 550) One comment asks that we test the assumptions made in the PRIA and develop a return on investment (ROI) model with representative company types/sizes that we would provide to industry as a cost calculator to help encourage compliance with the rule.

(Response 550) Although we have analyzed the benefits and costs of the rule in the FRIA (Ref. 16), it is not appropriate or feasible for FDA to develop an ROI model for persons subject to subpart S. Firms subject to the rule might wish to consider conducting their own ROI analyses to determine what approach (*e.g.,* purchasing new software vs. updating current traceback SOPs) is most appropriate for their firm as they come into compliance with the rule.

c. Coordination of Training Efforts

(Comment 551) Several comments recommend that we coordinate training efforts with industry associations, universities, and/or State and local regulatory authorities. For example, one comment suggests that, similar to the Produce Safety Alliance that has supported educational efforts for the produce safety regulation, FDA should establish a ''Traceability Alliance'' in partnership with land grant institutions and their extension services to ensure that stakeholders have an appropriate level of education on traceability to successfully implement the rule. The comment suggests that we collaborate with non-governmental partners, industry associations, and non-profit technical organizations to assess industry educational needs and develop educational content to support the rule. Some comments suggest that we work with industry experts to assess current practices, infrastructure, and needs, as well as develop and disseminate implementation guidance. One comment asserts that FDA followed this approach in its development and use of the CORE Network. One comment offers to work with FDA and stakeholders to develop tools to facilitate understanding and implementation of the requirements, particularly to help less digitized and smaller-scale supply chain entities. One comment expresses support for FDA's ongoing work with the leafy greens industry and encourages similar work with the seafood, shell egg, and dairy/cheese industries. One comment suggests that we coordinate with cooperative extension services at the State level, the USDA's National Organic Program, and farm advocacy groups to develop sample materials and trainings. Regarding seafood, one comment suggests that we work with the National Sea Grant College Program of NOAA to develop outreach compliance programs for unloading docks and fish houses.

(Response 551) We recognize the importance of partnerships in ensuring wide distribution and sufficient specificity of training and educational resources. We are currently developing our outreach and education approach, including consideration of partnerships with industry associations, universities, and/or federal, state, and local agencies on such efforts as appropriate. We will work to ensure that training materials and dissemination are suited to the needs of the various types of entities covered by this rule.

(Comment 552) Some comments criticize the regulation for not addressing recall modernization. The comments ask that we provide guidance to industry on how to manage product recalls and request clarification on what data we will provide to help industry implement a product recall during a food safety incident. The comments also recommend that we collaborate on recalls with the direct-to-consumer and curbside delivery segments of the supply chain to learn about emerging business trends and potential food safety impacts regarding consumer-level food traceability.

(Response 552) While this rulemaking does not address recall modernization directly, we are working on this issue through other initiatives. For instance, the New Era of Smarter Food Safety Blueprint (Ref. 18), which outlines the approach we will take over the next 10 years to build on the work the Agency has done to implement FSMA, contains a section on ''Recall Modernization within Core Element 2: Tech-Enabled Traceability.'' Our goals for this initiative include developing best practices guidance on various consumer notification practices for different business models to facilitate product recalls.

d. Resources for Outreach and Training

(Comment 553) Several comments request that we provide funding for outreach, education, and training efforts. One comment requests that we provide adequate resources to SLTT agencies to address the financial burden they will incur by providing educational, compliance, and enforcement activities regarding the rule for RFEs. One comment states that the education and outreach efforts conducted regarding the produce safety regulation have highlighted how important funding for education efforts is to the adoption of food safety practices. Some comments ask that we extend the existing CAP programs, including the Local Food Safety Collaborative and Native American Tribal Cooperative Agreement, to identify and educate small entities likely to be affected by the new traceability regulation, and to consider proposing and establishing a unique CAP for the regulation with the goal of developing appropriate programming to reach small and very small businesses. One comment expresses support for a program, similar to the On-Farm Readiness Reviews conducted by the National State Departments of Agriculture, that would help growers prepare for compliance with the rule. One comment requests that we provide funding to educational organizations to help growers become oriented to, aware of, and compliant with the rule, and recommends that we engage in this effort with existing national educational curricula organizations such as the Food Safety Preventive Controls Alliance and the Produce Safety Alliance. One comment suggests that we work with other U.S. agencies to provide resources to help industry comply. One comment maintains that while the rule is forward-thinking and important, it presents possible unfunded mandates.

(Response 553) We are committed to working with our SLTT partners to address the resource needs associated with implementing the traceability final rule, including with respect to outreach, training, and enforcement. We are committed to providing guidance, education, and technical assistance to SLTT partners and will consider new and existing channels in an effort to lessen the burden associated with administering the rule. We also intend to work with other federal agencies as

needed to enhance education and outreach efforts.

(Comment 554) One comment asserts that because most entities affected by the rule are small and medium-sized firms, the need for additional investment to aid compliance with the rule skews toward these firms. The comment suggests that because farmers often have little ability to negotiate higher prices for their commodities, FDA should work with industry and Congress to find ways to offset costs of compliance. One comment suggests that additional funding from Congress is needed to implement the rule, and that funding in the form of subsidies could also help producers, suppliers, and retailers be more compliant in tracing efforts.

(Response 554) We carefully considered costs of compliance when developing the rule and have attempted to provide maximum flexibility to persons subject to the rule to meet applicable requirements. We also have concluded that meeting the requirements of the rule may not be feasible for some entities, so we have adopted exemptions for certain types of small entities. We cannot comment on efforts in Congress to provide funding for producers, suppliers, retailers, and other entities to improve their traceability capability.

e. Funding for Equipment and Technology

(Comment 555) Several comments ask that we provide financial assistance to help entities subject to the rule purchase equipment (such as scanners), software, and training needed to comply with the rule. Some comments suggest that many farms and food producers may discover that they need to invest in alternate technology systems to meet the recordkeeping requirements. One comment maintains that if the electronic sortable spreadsheet is an integral part of FDA's approach to improved traceability, the Agency should provide funding for education for computer literacy and adoption of digital recordkeeping practices, or provide a 24-hour, third-party technical assistance service to help farms comply. One comment asks if we will provide financial assistance and training or grants to help firms purchase new equipment as part of the New Era for Smarter Food Safety initiative. Some comments suggest that we follow the model established by Canada, under which British Columbia Traceability Funding Programs refund up to 70 percent of investments that firms need to make to comply with Canadian traceability requirements.

(Response 555) FDA is not in a position to provide financial assistance to help covered entities purchase or upgrade equipment they might choose to use to comply with the rule. Nevertheless, we are exploring ways to assist firms in adopting tracing technologies and harmonizing tracing activities, such as the previously mentioned Low- or No-Cost Traceability Challenge, in which we encouraged stakeholders to develop traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end user. We will continue to search for and highlight these and other approaches to help provide economical options for traceability.

6. Grocery Returns

(Comment 556) One comment expresses concern that because of advanced traceability, grocery returns may need to be eliminated to ensure accurate traceability, but doing so would result in more food waste going into landfills.

(Response 556) Sales or shipments to consumers are not covered by the rule, so we do not anticipate that grocery returns will be impacted by the rule.

7. Performance Metrics

(Comment 557) One comment asks that we identify metrics to measure the success of the food traceability rule. The comment suggests that expert panels and industry could use the metrics to understand how the rule is impacting public health and what foods should be included on the FTL.

(Response 557) As we have done for other FSMA rules, we will consider appropriate performance metrics for the subpart S regulation as part of our implementation of the rule.

(Comment 558) One comment states that all parties should feel that proprietary or otherwise sensitive company information can be protected in the data collection and submission process, and suggests that FDA provide a direct portal and set of application programming interfaces for submission of data, along with a list of approved third parties to facilitate compliance with the proposed rule, based on open and interoperable standards.

(Response 558) As discussed in Response 412, we have made changes to the final rule to address concerns about disclosure of proprietary or sensitive information, in particular by including an option to provide receivers of FTL foods with a traceability lot code source reference instead of the traceability lot code source itself. We are developing a portal for submission of traceability information to us, which will protect the confidentiality of the information provided. We do not intend to ''approve'' or assess the capability of third parties who might perform recordkeeping or information transmission on behalf of entities subject to subpart S requirements.

VI. Effective and Compliance Dates

In the proposed rule, we proposed that the final rule would become effective 60 days after the date on which the rule is published in the **Federal Register**. We also proposed that the compliance date for all persons subject to the subpart S recordkeeping requirements would be 2 years after the effective date of the final rule.

We received no comments opposing the proposed effective date for the final rule. As proposed, the final rule will become effective 60 days after the date on which the rule is published in the **Federal Register**. However, in response to comments received, we are revising the compliance date to 3 years after the effective date of the final rule, as discussed in the following paragraphs.

(Comment 559) Many comments request that we extend the proposed 2-year compliance period after the effective date of the rule to other timeframes, including 3, 4, or 5 years after the effective date. The comments maintain that extending the compliance date would allow covered entities time to understand the requirements of the rule, purchase or update tracing technology, train staff, coordinate with supply chain partners, and establish or update recordkeeping systems. One comment maintains that a 3-year compliance date would be appropriate because it is the timeframe that the smallest covered entities had to comply with the final rule on preventive controls for human food. Comments requesting a 4-year compliance period or longer emphasize that data standardization would be time-consuming, including the time needed to invest in new technology systems, convert from paper to electronic, and ensure that foreign suppliers also have adequate systems. One comment maintains that a public-private partnership may be necessary to oversee data standardization, which would take time to establish. Several comments assert that 2 years is not enough time given all the preparation needed to comply but did not specify an alternative timeframe.

(Response 559) We agree that persons subject to the rule should have additional time to come into compliance with the subpart S requirements. Therefore, we are revising the compliance date for all covered entities

to 3 years after the effective date of the final rule. We believe this 3-year timeframe appropriately balances the public health gains through traceback efficiencies we expect to achieve through implementation of this rule against the need for covered entities to have adequate time to come into compliance with the new traceability requirements. The overwhelming majority of comments on the compliance date request more than 2 years to come into compliance, maintaining that they will need to work with suppliers to understand how information will be sent to them, possibly switch from paper to electronic records and/or purchase new equipment and software, redesign tracing systems to capture information that current systems do not, and work with foreign suppliers to ensure they understand the requirements for keeping and providing necessary records. Given the need for these activities, among others, to occur, we are persuaded that compliance in a 2-year timeframe would be challenging. Therefore, while the 3-year timeframe does postpone the anticipated public health gains from the rule by a year, we conclude that this postponement is justified. However, given the public health benefits expected from adoption of the new traceability requirements, we do not believe it would be appropriate to extend the compliance date beyond 3 years.

FDA believes the 3-year compliance timeframe allows an appropriate amount of time for firms to conduct activities necessary for them to come into compliance. Covered entities can work with supply chain partners in the 3-year timeframe to understand how information will flow forward through the supply chain and work out any needed written agreements or protocols for how information will be shared among entities, such as between harvesters/coolers and those performing initial packing. The additional year beyond the proposed 2-year compliance date will extend the time in which industry can establish or make any changes to tracing systems and make decisions around purchasing new equipment—activities that cannot begin until there is an understanding of the requirements of the final rule. The additional year will also allow time for the development of software and related products aimed at facilitating compliance with the rule, which multiple technology companies have expressed an interest in developing. It is possible that the 3-year timeframe will mean that some of the costs for technology solutions will be reduced compared to a 2-year compliance date, given the additional development and implementation time. The 3-year timeframe will also allow for time for any collaboration that industry might decide to undertake, to consider how they want to share information with each other; we will consider how we might assist industry with such efforts.

The 3-year compliance period will also allow more time for us to develop and disseminate outreach and training materials to stakeholders, including webinars focused on various industry segments and materials specifically targeted to smaller covered entities. As we have done with the previous FSMA rules, we plan to provide a variety of outreach and training materials for this final rule. For all of the aforementioned reasons, we believe that a compliance date 3 years after the effective date (which itself is 60 days after the date of publication of the final rule) strikes the right balance between achieving traceback efficiencies as quickly as possible and allowing sufficient time for covered entities to come into compliance with the new tracing requirements.

(Comment 560) Several comments request that the compliance date occur after FDA has issued all relevant guidance documents related to the rule so that covered entities can fully comply with regard to their own covered foods and also work with foreign suppliers.

(Response 560) We will work to issue any guidance documents related to this rulemaking as expeditiously as possible. However, the process for issuing both draft and final guidance documents can be lengthy, and the timing is often beyond our control. Therefore, we are unable to ensure that all relevant guidance documents related to the rule will be issued before the compliance date. However, we note that section 204(h) of FSMA requires us to issue an SECG not later than 180 days after promulgation of this final rule. The SECG will set forth, in plain language, the requirements of subpart S, with the goal of assisting small entities, including farms and small businesses, in complying with these new requirements.

(Comment 561) Several comments request that the compliance dates be phased in by business size. These comments state that extra time would be needed for small businesses to become educated about the rule and make investments, or seek assistance to make investments, in personnel and technology to come into compliance. Some comments suggest that small businesses be given 4 years to comply and all other businesses be given 3 years. Other comments suggest that certain categories of covered entities would need additional time to come into compliance, including the following: (1) importers who may need extra time to work with foreign suppliers; (2) retailers who may need additional time because they are at the end of the supply chain, and therefore need time to understand how information will come to them from a variety of sources and create systems to maintain the information; (3) grower/packers who may need extra time to adopt new technology and distributors who may need time to understand how suppliers will be providing information and develop appropriate interoperable technology systems; and (4) the seafood industry, which might need additional time to develop software, conduct training activities, and translate materials due to the global nature of the seafood supply chain. One comment suggests that those entities that establish traceability lot codes should have to comply initially, and then entities that only ship and/or receive FTL foods should have a later compliance date; the comment maintains that this would provide that the nodes that will be producing most of the data would have to comply first. The comment further suggests that entities that establish traceability lot codes and have 500 or more employees should be expected to comply within 2 years, while smaller businesses that establish traceability lot codes and have fewer than 500 employees could be afforded an additional year. Finally, the comment suggests that entities that solely receive and ship products be allowed another year after that to come into compliance.

(Response 561) We decline to phase in the compliance date for the subpart S requirements by business size or type of covered entities. In the preamble to the proposed rule (85 FR 59984 at 60020), we explained that we could more effectively and efficiently implement the new requirements by having all covered persons come into compliance by the same date. Subpart S operates via a chain of information being maintained and passed forward through covered entities in the supply chain. If an entity in a supply chain did not provide the required information to their customer, the chain would be broken and the rule would operate less efficiently; this would be particularly true if the entities assigning the traceability lot codes had to comply first, but subsequent supply chain members were not yet required to pass the information forward through the supply chain. Even if the compliance

dates were staggered based on the type of food (such as the delayed compliance date for seafood that was suggested in the comments), we anticipate that complications would arise for entities that handle both FTL seafood and other FTL foods (or multi-ingredient foods with seafood ingredients), as well as fairness concerns from other industries that face challenges similar to those faced by the seafood industry.

Staggering compliance dates would delay the benefits of the rule gained through efficient traceback until all covered entities reached their respective compliance date. Staggering the compliance dates would also make efficient implementation of the rule more challenging for covered entities, and might introduce additional complications and questions about who is required to comply when, and what ''compliance'' looks like when the compliance date has not yet arrived for a firm's supply chain partners. One of the reasons we are adding a year to the compliance date timeframe is to give covered entities more time to work together to understand how information will be shared under the rule; staggering the compliance dates would make that collaboration more difficult because covered entities would be at different stages in their compliance dates.

(Comment 562) One comment suggests that retailers and other covered entities should not be made to comply until FDA has partnered with industry to conduct pilots related to interoperability and public-private data sharing, such as testing approaches to implementing industry-wide traceability so that it is clear what covered entities need to do to successfully comply with the rule. Similarly, several comments suggest that because of the complexity of the rule and confusion about the scope and intended operation of the rule, we should implement the rule in phases by commodity, beginning with an initial test or pilot phase for the highest-risk commodities such as (according to the comments) leafy greens or some produce items. The comments suggest that compliance with the rule for all other commodities on the FTL would follow after experience has been gained with the initial commodities. The comments maintain that this initial phase would allow FDA and industry to establish traceability for the highest-risk commodities, while assessing whether the system will work as intended or whether further refinements need to be made before a second phase of implementation.

(Response 562) We decline to delay the compliance date until pilot implementation tests have been conducted or to begin with a pilot phase with certain commodities. As discussed in Response 559, we are adopting a 3-year compliance date for all covered entities, and we believe that this time period will be sufficient for covered entities to successfully comply with the rule. While we may conduct pilot programs, any such programs are likely to happen during the 3-year compliance period. We conclude that delaying the compliance date for an indeterminate amount of time while pilots are conducted is not appropriate given the anticipated public health benefits to be gained through traceback efficiencies.

(Comment 563) Several comments request that the compliance dates be phased in by node in the supply chain. These comments suggest that because downstream entities cannot comply until upstream entities send them information, the first compliance dates should be for the upstream entities, with downstream entities, particularly those handling product with a longer shelf life, assigned a later compliance date or given enforcement discretion until they have an opportunity to understand what type of information they will be receiving. One comment suggests that this would be similar to how FDA is implementing the DSCSA, and recommends that the Agency be guided by the DSCSA's stepwise approach and long implementation timeframe in establishing compliance dates for the food traceability rule. This comment asserts that because the food industry has fewer resources to devote to regulatory compliance than the pharmaceutical industry, the food industry should be allowed a longer time to comply with the tracing requirements. Some comments, which also reference the DSCSA, recommend a phased approach to implementation of subpart S that begins by focusing on the most significant gaps in the subpart J recordkeeping requirements.

(Response 563) We decline to stagger the compliance date for the subpart S requirements by node in the supply chain. While it is true that information must flow ''down'' the supply chain to enable downstream entities to obtain information they must keep under the rule, we do not agree that this means the compliance dates for this rule should be staggered by nodes. The supply chains that are affected by subpart S vary greatly in terms of their length, complexity, and the types of activities they involve. An entity such as a distributor might be the first covered entity in the supply chain for some of the FTL foods they handle (*e.g.,* for produce that was grown on an exempt farm), while simultaneously being in the middle of a chain of covered entities for other FTL foods they handle. There are also many covered entities that perform multiple CTEs with respect to the FTL foods they handle, including different CTEs for different FTL foods. Because of this variation and complexity in supply chains, it would be difficult to identify the nodes that would be subject to different compliance dates, and we anticipate that any effort to stagger compliance dates based on supply chain nodes would generate significant questions from stakeholders about their obligations for each compliance date. As discussed in Response 565, we recognize that when the compliance date arrives, there will be FTL foods in various stages of distribution, including on store shelves, for which there may not be complete tracing records, due to the fact that the product was produced before the compliance date. We will not expect these products to have subpart S records associated with them if the foods were already in distribution before the compliance date.

Regarding the comments suggesting a phased approach to implementation of subpart S that begins by focusing on the most significant gaps in the subpart J recordkeeping requirements, we note that both farms and restaurants are excluded from subpart J (see § 1.327(a) and (b)). To the extent that the comments are recommending that subpart S compliance or implementation should begin with farms and restaurants before requiring compliance by other supply chain entities, we do not think such an approach would be feasible. As discussed in Response 561, subpart S operates via a chain of information being maintained and passed forward through covered entities in the supply chain. If farms and restaurants were required to comply with the rule before other supply chain entities, this chain would be broken and implementation of the rule would be more challenging.

In the DSCSA, Congress specified different times (*e.g.,* 4, 6, or 7 years after the date of enactment) by which some requirements would have to be met by different types of entities, while other requirements generally would have to be met by all entities at the same time. Furthermore, DSCSA requirements concerning the interoperable, electronic tracing of product at the package level would go into effect 10 years after the date of enactment. While this type of staggering may be appropriate in the drug tracing context, we decline to adopt it here for the reasons explained above. Regarding the argument that the food industry should be given a longer time to comply with subpart S than the

drug industry is being given to comply with the DSCSA, we do not think the comparison is apt. The DSCSA requires tracking to the individual drug package and homogenous case level with consequent labeling requirements, and also requires interoperable, electronic product tracing at the package level. Subpart S, by contrast, requires lot-based recordkeeping that is in line with current industry best practices, and provides flexibility for individual entities to decide how they will keep and provide the relevant records, including whether or not they will choose to adopt electronic recordkeeping. We therefore think that a shorter compliance timeframe for subpart S is appropriate.

(Comment 564) Some comments ask that we consider a phased approach to implementation that extends the compliance date for the electronics or table spreadsheet requirements in proposed § 1.1455(b)(3) to 4 years after the effective date of the final regulation. One comment argues that this two-phased approach would give covered entities time to adopt new terminology and make substantial changes to current systems. The comment suggests that the first phase of implementation would consist of entities bringing their records into compliance with the rule, such that, within 2 years of the effective date of the final rule, all covered entities would be required to establish and maintain the records required by the rule and these records would be available to FDA upon request. The comment maintains that this phased approach would provide covered entities sufficient time to work with their supply chain partners and develop the recordkeeping systems necessary to comply with the rule, while giving FDA access to tracing records in the proposed timeframe. The comment suggests that in the second phase of implementation, beginning 4 years after the effective date of the final rule, firms would have to comply with the requirement to produce information required by the rule in an electronic sortable spreadsheet. The comment maintains that a phased approach is preferable because it allows firms to get their traceability systems in place before developing a system able to deliver an electronic sortable spreadsheet to FDA within 24 hours.

(Response 564) We decline to adopt a separate, extended compliance date for the electronic sortable spreadsheet requirement in § 1.1455(c)(3)(ii). The majority of the tracing information required under subpart S will be in the KDE records kept on FTL foods as they are initially packed or transformed and then shipped and received at various nodes in the supply chain. Firms will only be required to provide the electronic sortable spreadsheet when we conclude that obtaining the information in this format is necessary to help us prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to the public health. Thus, the spreadsheet is not a routine record, but it will be a very helpful document to FDA during an outbreak or other public health threat, and it will be critical to achieving the public health gains anticipated for this rule. We believe allowing 3 years for all covered entities to establish their tracing protocols and records, including for generation of the electronic sortable spreadsheet, strikes an appropriate balance between public health and feasibility. However, we acknowledge that there is concern about producing the electronic sortable spreadsheet, including that this could be especially challenging for smaller entities who may have fewer resources and who may be more likely to use paper-based tracing systems. Therefore, the final rule provides exemptions for certain smaller entities from the electronic sortable spreadsheet requirement as specified in § 1.1455(c)(3)(iii).

(Comment 565) Some comments ask that we clarify that the tracing records are not required until after the compliance date. The comments also note that it might take some time for downstream entities to begin receiving tracing records from their suppliers, and there will be products in inventory after the compliance date that were produced and received before the compliance date. Some comments request that we implement staggered compliance dates starting with entities at the beginning of the supply chain and exempt products already in commerce. Other comments ask us to exercise enforcement discretion for downstream entities who are unable to comply with the final rule because they do not have the required information from their suppliers.

(Response 565) As discussed in Response 561, we decline to implement staggered compliance dates. We affirm that records required under subpart S will not have to be maintained until the compliance date. Furthermore, we recognize that it will take time for downstream covered entities in supply chains of FTL foods to receive the tracing records required under the rule for covered products and that, in the meantime, there will be FTL foods on store shelves and in stages of distribution for which there may not be complete tracing records, due to the fact that the product was produced before the compliance date. This may be of particular concern for FTL foods with a long shelf-life, such as peanut butter. We will not expect these products to have subpart S records associated with them if the foods were already in distribution before the compliance date. As the compliance date approaches, we will determine whether it is necessary to provide further clarification on our position regarding these products.

(Comment 566) Some comments recommend that we encourage industry to adopt the requirements earlier and engage those companies that do so in a collaborative recall investigation process that benefits public health. These comments assert that such engagement could be used without regulatory action involving participating industry, absent any wrongdoing, and would incentivize early industry adoption of the additional recordkeeping practices and there by improve traceback investigations before the requirements take effect. One comment requests that any collaborative recall process have clearly defined roles and responsibilities for fact-finding and types of data sharing needed, as well as confidentiality during the investigation process.

(Response 566) We decline to establish a formal process to recognize early adopters of the tracing requirements in this subpart. However, we encourage industry to adopt subpart S practices as soon as practicable, and we agree that implementation before the compliance date will further benefit public health. As previously stated, we will consider how we might assist industry with any collaborative efforts they might decide to undertake regarding information sharing among supply chain partners to comply with the rule.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has designated this final rule as an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small firms may incur annualized costs that exceed 1 percent of their annual revenue, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in an expenditure in at least one year that meets or exceeds this amount.

This final rule will allow FDA and industry to more rapidly and effectively trace food products that cause illnesses back through the food supply system to the source and forward to recipients of the contaminated product. This rule will only apply to foods FDA has designated for inclusion on the FTL and foods that contain listed foods as ingredients that remain in the same form (*e.g.,* fresh) in which they appear on the list. By allowing faster identification of contaminated foods and increasing rates of successful tracing completions, the rule results in public health benefits if foodborne illnesses directly related to those outbreaks are averted. This might also lead to more efficient use of FDA and industry resources needed for outbreak investigations by potentially resulting in more precise recalls and avoidance of overly broad market withdrawals and advisories for covered foods.

The primary public health benefits of this rule are the value from the reduction of foodborne illnesses and deaths because records required by the rule are likely to reduce the time that a violative or contaminated covered food product is distributed in the market. Benefits from this rule are generated if the following two conditions hold: (1) a foodborne outbreak occurs and (2) the traceability records required by this rule help FDA to locate a commercially distributed violative product quickly and accurately and to ensure it is removed from the market.

While the primary benefits from the rule are the value of the reduction of foodborne illnesses and deaths, we also examine non-health related benefits. Non-health related benefits of this rule will be from avoiding costs associated with conducting overly broad recalls and market withdrawals that affect products that otherwise would not need to be withdrawn or recalled. Although recalls of rightly implicated foods come with necessary costs, overly broad recalls that involve loosely related or unrelated products can make overall recalls unnecessarily costly. The costs of a broad recall or market withdrawal include lost revenues from unimplicated products plus expenses associated with notifying retailers and consumers, collection, shipping, disposal, inventory, and legal costs.[1] There are no benefits from removing unimplicated products from the market. Benefits from avoiding overly broad recalls may be realized only when recalls are initiated in response to an FDA public health advisory.

It is possible, but not certain, that both of these categories of benefits could be experienced to the extent quantified in table 2 and the underlying regulatory impact analysis. On the other hand, it is also possible that a given instance of baseline contamination would lead to a very broad recall (that could be narrowed by the final rule) or to illnesses (that could be avoided due to the final rule) but not both.

Additional benefits of the rule may include increased food supply system efficiencies, such as improvements in supply chain management and inventory control; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions by consumers; reduction of food waste; and other food supply system efficiencies due to a standardized approach to traceability, including an increase in transparency and trust and potential deterrence of fraud (Ref. 16 (Refs. 1, 2)).

This rule will impose compliance costs on covered entities by increasing the number of records that are required for covered food products. Entities that manufacture, process, pack, or hold covered foods will incur costs to establish and maintain a traceability plan and traceability records. Some firms may also incur initial and recurring capital investment and training costs for systems that will enable them to keep, maintain, and make available to other supply chain entities (and to us upon our request) their traceability records. Moreover, firms will incur one-time costs of reading and understanding the rule.[2]

Table 2 summarizes the costs and benefits of the final rule. At a 7 percent discount rate, 20-year annualized costs range from about $63 million to $2.3 billion, with a primary estimate of $570 million per year. At a 3 percent discount rate, annualized costs range from about $53 million to $2.3 billion, with a primary estimate of $551 million per year. The present value of costs with 7 percent discounting over 20 years (not shown in table 2) ranges from about $0.7 billion to $24.6 billion, with a primary estimate of about $6 billion. The present value of costs with 3 percent discounting over 20 years (not shown in table 2) ranges from about $0.8 billion to $33.7 billion, with a primary estimate of $8.2 billion.

We estimate public health benefits using several case studies of outbreak tracebacks for four pathogens associated with illnesses caused by covered foods.[3] We calculate these benefits based on an estimated 83 percent reduction of traceback time resulting from the requirements of this rule. At a 7 percent discount rate over 20 years, the annualized monetized health benefits of the rule range from $59 million to $2.2 billion with a primary estimate of $780 million (table 2). At a 3 percent discount rate over 20 years, the annualized monetized health benefits range from $61 million to $2.3 billion with a primary estimate of $810 million. The present value of health benefits with 7

[1] For example, in an undifferentiated product recall, a single firm's investment in traceability may be ineffective when competitors and partners have not instituted a traceability system. This is problematic because, for example, in the event of an undifferentiated leafy greens outbreak, issuing a broad recall could be unavoidable, at least until the implicated product is identified and removed from the market. In situations where the recalled products are insured, targeted recalls will help prevent unnecessary recalls of insured products, which may have long-term consequences to retailers from increases in their insurance rates due to imprecise recalls.

[2] The information flows brought about by the rule may prompt new protective actions—for example, in farming, manufacturing, or cooking processes—that could also have costs. We have not quantified these potential costs, but they would likely correlate with the realization of the health and longevity benefits of this rule.

[3] This approach has a tendency toward underestimation of the total public health benefits because these four pathogens do not represent the total burden of all FTL-associated illnesses. However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both FTL-associated illnesses and benefits. We cannot scale up to 100 percent because our estimates of the percentage of illnesses potentially avoided with improved traceability depend on data specific to each pathogen. We describe our methods in detail in FRIA section II.E.1, Public Health Benefits from Averted Illnesses. In short, these four pathogens may account for roughly 95 percent of the total dollar value of the illnesses for which traceability might be an effective preventive measure.

percent discounting over 20 years (not shown in table 2) ranges from about $0.6 billion to $23.7 billion, with a primary estimate of $8.3 billion. The present value of health benefits with 3 percent discounting over 20 years (not shown in table 2) ranges from about $0.9 billion to $34.5 billion, with a primary estimate of $12.0 billion.

We estimate (non-health) benefits from avoiding overly broad recalls and market withdrawals. At a 7 percent discount rate over 20 years, these annualized monetized benefits range from $233 million to $1.8 billion with a primary estimate of $575 million (table 2). At a 3 percent discount rate over 20 years, these annualized monetized benefits range from $242 million to $1.8 billion with a primary estimate of $596 million. The present value of benefits from avoiding overly broad recalls with 7 percent discounting over 20 years (not shown in table 2) ranges from about $2.5 billion to $18.8 billion, with a primary estimate of $6.1 billion. The present value of these benefits with 3 percent discounting over 20 years (not shown in table 2) ranges from about $3.6 billion to $27.3 billion, with a primary estimate of $8.9 billion.

TABLE 2—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE ($MILLIONS)

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Benefits:							
Annualized Monetized Millions$/year	$780 810	$59 61	$2,238 2322	2020 2020	7% 3%	20 years ... 20 years ...	Monetized health benefits from an estimated 83% improvement in traceback time for four pathogens. Additional (non-health) benefits of avoiding overly broad recalls range from $233 million to $1.8 billion, with a primary estimate of $575 million (at 7% discount rate) and from $242 million to $1.8 billion, with a primary estimate of $596 million (at 3% discount rate).
Annualized Quantified							
Qualitative	Additional potential benefits include increased food supply system efficiencies; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions; reduction of food waste; and other efficiencies from a standardized approach to traceability.						
Costs:							
Annualized Monetized Millions$/year	570 551	63 53	2,323 2,267	2020 2020	7% 3%	20 years ... 20 years ...	A portion of foreign costs could be passed on to domestic consumers. We estimate that up to $50.5 million in annualized costs (7%, 20 years) to foreign facilities could be passed on to domestic consumers.
Annualized Quantified							
Qualitative	.....	.....	.....	.....	.....	.....	Costs of farming-, manufacturing- or cooking-related actions that, as a result of new information flows, address risks of foodborne illness.
Transfers:							
Federal Annualized Monetized Millions$/year.							
From/To	From:			To:			
Other Annualized Monetized Millions$/year.							
From/To	From:			To:			
Effects:							
State, Local or Tribal Government: No significant effect. Small Business: Potential impact on small entities that are currently not keeping traceability records described by the rule. Wages: N/A. Growth: N/A.							

We have developed a comprehensive economic analysis document that assesses the impacts of the final rule and includes the Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis (Ref. 16). The full analysis of economic impacts is available in the docket for this final rule and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impacts

We previously considered the environmental effects of this rule, as stated in the preamble to the proposed rule (85 FR 59984 at 60025). We stated that we had determined, under 21 CFR

25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. We received comments on our tentative determination that this rule is categorically excluded from the requirement to prepare an EA or an EIS; we respond to these comments in the Categorical Exclusion Memorandum for this rulemaking (Ref. 24). We conclude that we have not received any new information or comments that would affect our previous determination.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section with an estimate of the reporting and recordkeeping burden associated with the final rule. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Establishment, Maintenance, and Availability of Records; Traceability Records for Certain Foods—OMB Control No. 0910–0560—Revision.

Description: The new regulations will establish recordkeeping requirements applicable to certain foods, to help effectively and rapidly identify recipients of a food to prevent or mitigate a foodborne illness outbreak. These recordkeeping requirements are intended to strengthen public health protections by documenting the movement of foods throughout the supply chain, enabling FDA to identify the source of contaminated foods and aid in the removal of contaminated products from the market. The regulations also help implement statutory provisions governing high-risk foods. Access to and utilization of traceability records better enables FDA to respond to and contain threats to the public health introduced through foods on the Food Traceability List (FTL) (''listed foods'').

Description of Respondents: Respondents to the information collection are persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act (FSMA) (*i.e.,* the FTL).

In the following paragraphs, we describe and respond to the comments pertaining to the proposed information collection.

(Comment 567) Some comments suggest that the estimate of entities that will be affected is too narrow because it includes only those entities that manufacture, process, pack, or hold listed foods or foods containing a listed food as an ingredient. The comments maintain that, in practice, the new requirements will likely affect entities handling *all* foods because covered entities will be required to revise their recordkeeping systems to comply with the rule, and it would be more time- and energy-intensive to maintain two sets of recordkeeping systems (one for listed foods and one for non-listed foods). The comments assert that covered entities will expand their recordkeeping systems to all foods they handle, which in turn will require that their suppliers comply with the rule for the foods they provide to covered entities, whether FTL foods or not (making those suppliers also likely to adopt the rule's requirements for all foods). One comment asserts that the estimates should consider nearly every entity along the food supply chain except the consumer.

(Response 567) We regard recordkeeping by firms that do not handle covered foods, but that might choose to adopt traceability practices consistent with their business partners who do, as usual and customary and therefore assume no burden for this activity. When certain practices prove optimal on business grounds, or when large firms—including those not subject to the rule—exert influence over supplier practices via market power, practices might converge over time for reasons other than regulatory compliance. Moreover, as documented in the 2012 IFT traceability pilot project (Ref. 1), firms with widely varying traceability practices already conduct business with each other while serving the traceability demands of downstream customers and industry initiatives without resulting convergence among the entities with regard to those traceability practices. Because the rule does not prescribe specific technologies for records maintenance and KDEs required under subpart S mostly consist of information already commonly communicated between business partners, we expect supply chains to continue to accommodate widely varying traceability practices.

Concerning firms that handle both covered and non-covered foods, we do not believe implementation of KDE recordkeeping for non-covered foods would affect our estimates. First, our assumptions regarding new equipment, software, services, training, and procedures—which we acknowledge might necessarily displace existing systems rather than operate in parallel with them—considers these to be fixed costs with respect to the number of foods handled. Second, we estimate the variable costs of recordkeeping as labor, and we do not believe in general that requiring an employee to perform an action for certain foods creates a need to perform that action for all other foods. We would thus not attribute to the rule the additional labor cost of performing traceability recordkeeping on all other foods.

As noted in the FRIA, after consideration of the comments, we examined more recent data sources on covered entities and modified our estimate of the entities that will be affected by the rule. We have adjusted the total number of respondents downward by approximately 100,000, consistent with the updated data sources and our decision to exempt additional entities from the rule. While we expect that it will be possible for businesses to keep the requisite records just for FTL foods, we will continue to evaluate this aspect of the information collection in future updates.

(Comment 568) Some comments state that the estimated time and cost to read and understand the rule is too low. One comment asserts that the estimate of 3.3 hours for each respondent to read and understand the new recordkeeping requirements is an immense understatement. The comment stated that the proposed rule was 55 three-column pages in the **Federal Register** and includes multiple cross-references to FSMA and existing FDA regulations, and there were three full-day public meetings and multiple supplemental materials to help stakeholders understand the rule, including a revision to the FTL and an FAQ document. Other comments assert that the estimate of 3.3 hours is perhaps the amount of time it would take to simply read the proposed rule, but it fails to account for the need to consider the rule's implications and how it would affect a particular entity. Some comments maintain that more than 1 person per covered entity will need to read and understand the rule, that as many as 10 or more people might read the rule, and that the time needed to understand the rule is far more than 3.3 hours. One comment asserts that the estimate should be increased to a minimum of 10 hours, which would roughly triple employee costs. The comment bases this assertion in part on their estimate that reading and

understanding the ''supplemental examples'' we posted in February 2021 took 4 to 6 hours.

(Response 568) Our basis for the estimated time to read and understand the rule remains consistent with methods used in previous FDA analyses and assumes an existing understanding of applicable regulations already effective under FSMA. However, we did increase the amount of time we attribute to reading and understanding the recordkeeping requirements from 3.3 hours to, on average, 16.8 hours, as both the final codified text and particularly the preamble to the final rule are longer than the proposed rule text. This estimate is an average over all firms, and now includes an assumption that in small firms one employee will read the rule and in large firms three employees will read the rule. The estimated average sum of the time spent reading and understanding the rule at each firm is 16.8 hours.

With regard to the number of respondents, we account for multiple employees reading the rule at larger companies. While many small firms might not in fact read the full text of the preamble of the final rule and associated provisions of the Code of Federal Regulations (instead learning about the rule from simplified explanations via trade associations and publications), we assume that one employee will read the rule at small firms and that three employees will read the rule at large firms. Note also that we consider reading costs alone in Section II.F.2 (''Reading and Understanding the Rule'') of the FRIA to be separate from the costs to identify FTL products and plan for compliance, which we estimate in Section II.F.5.b (''Traceability Plan'') of the FRIA.

(Comment 569) Some comments maintain that the estimated one-time set-up costs are far too low. Some comments assert that while the proposed rule estimates that most entities (other than distribution centers and warehouses) will be required to maintain records for 1,000 FTL lots, the comments anticipate they will handle far more than 1,000 lots. One comment estimates that for its products containing nut butters alone (*i.e.,* not accounting for other ingredients potentially on the FTL), the firm handles more than 9,000 FTL lots per year. One comment asserts that because many if not most entities process numerous lots of hundreds of different SKUs each year, these entities will be required to establish and maintain records for far more than 1,000 FTL lots. The comment also asserts that even FDA's higher estimate for warehouses (48,333 lots annually) is still far too low. One comment maintains that entities other than distribution centers and warehouses will handle many thousands of food traceability lots (not just 1,000) on an annual basis, depending on their size, while distribution centers and warehouses likely will handle millions of such lots (not just 190,000).

(Response 569) To gain a better understanding of industry's possible adoption of new practices and systems in response to the rule and to better inform our estimates of the number of traceability lots handled by various covered entities by entity size and category, we contracted with consultants (the Eastern Research Group (ERG)) to elicit input from an external panel of industry experts (Ref. 34). We have incorporated their input in Section II.F.5 (''Traceability Plan'') of the FRIA, in which we estimate the costs of planning new procedures to comply with the final rule. In particular, our estimates now differentiate between small and large establishments. In most industry categories, our primary estimates of FTL lots undergoing initial packing, first land-based receiving, shipping, and transforming are now 800 to 900 lots for small establishments and 1,400 to 5,500 lots for large establishments. For lots received by warehouses, distribution centers, restaurants, and non-restaurant retailers, our primary estimates are now 1,500 to 4,600 lots for small establishments and 3,100 to 28,600 lots for large establishments.

(Comment 570) Some comments state that the time and cost estimates for training for the rule are far too low. One comment asserts that although FDA projects that only a portion of firms will incur training costs and that such firms will need to conduct an average of 2 hours of training regarding an average of 3 records, because of the rule's complexity and the fundamental changes to current recordkeeping practices that would be required under the proposed rule, firms will need to conduct ongoing, company-wide trainings to ensure compliance. One comment asserts that under third-party auditing programs that members are currently involved in, they have a minimum of 8 to 10 hours of training per employee (which does not include annual retraining, verification, and any travel costs associated with training). Based on these assertions, the comments maintain that we should significantly increase the estimate of the training time and costs. One comment asserts that training estimates did not account for the significant volume of employees who will require training and the time needed to train them. The comment maintains that time required to train employees will vary depending on their role, and that larger retailers will have several hundred associates to train, while tens of thousands of employees will require training when they are onboarded. The comment estimates that training costs range from $15,000 to nearly $3 million. One comment asserts that firms will have annual training costs, not just a one-time cost. The comment further maintains that annually training employees on the requirements will take 5 hours of each employee's time, and that an annual review, commonly required by auditors, would need to be conducted, all adding to costs.

(Response 570) In the PRIA, we assumed that training would be a one-time cost to train only a limited number of current employees on the new requirements and traceability practices. We also assumed that, for training new employees, some outdated training content will be replaced with training related to this rule, thus not incurring an additional training cost for those new employees. We note that comments did not provide additional data in support of alternative estimates. However, after reviewing the comments on our estimates of training costs, we determined a need for and sought additional data and information to improve our estimates. We contracted with consultants to survey a panel of external industry experts to further inform training costs to various covered entities based on their size and baseline industry practices (Ref. 34). In Section II.F.4 of the FRIA, we estimate the number of trainees for entities of different sizes across different industry sectors based on input by the expert panel. We now differentiate between small and large establishments across different industry categories. In general, hours stayed roughly the same or slightly increased (compared to the proposed estimates) for small establishments and increased for large establishments. The number of trainees increased significantly for both, so the per-establishment cost has gone up. However, we now estimate that far fewer establishments need training specifically for this rule because most establishments subject to the rule only receive FTL foods, which we have assumed to be a simple task on its own, so the total hours have gone down. As a result, we have revised the estimated one-time burden associated with training personnel as shown in table 3. In addition, we have added to the

estimated annual recordkeeping burden an estimate of recurring, or annual, training costs, as shown in table 5.

(Comment 571) Some comments maintain that the time and cost estimates for annual recordkeeping are far too low. One comment asserts that they will need to hire people to create and maintain a database system for electronic recordkeeping, even if it can be an Excel spreadsheet that is made available to FDA upon request, because it is not clear what is needed for the spreadsheet. One comment asserts the proposed growing area coordinates requirement for growers will cause a paperwork hardship. One comment maintains that scanning a barcode vs. scanning and typing even three pieces of information such as brand, pack date, and lot code will take more than the estimated 0.004 hour. The comment further maintains that as a company receiving loads that have one-case quantities of some products and straight truckloads of other products, having to type in the identifying factors for hundreds of products each week will quickly become more costly than the software. One comment asserts that the ''high'' numbers noted in table 31 in the PRIA for recurring recordkeeping costs were too low. The comment maintains that assuming 0.01 hours for each record (the high number in the table was 0.006 hours) is a truer estimate, simply adjusting the time needed to establish and maintain records and the time needed to send records would increase the costs by 67 percent. The comment further asserts that 5 minutes to type each transaction is a more reasonable estimate than the proposed rule's ''high'' estimate of 3 minutes, and states that this change would increase costs by 67 percent.

(Response 571) We have updated our estimates of the number of covered entities and costs to reflect additional full exemptions for small entities and certain food, as well as the exemption of smaller entities from the requirement to provide an electronic, sortable spreadsheet in certain circumstances upon the Agency's request. Additionally, the final rule aims to simplify recordkeeping by aligning requisite elements more closely with data elements already captured and communicated in standard business practices. Therefore, we have updated our estimates of burden per traceability lot, accounting both for changes to the proposed rule and expert elicitation (Ref. 34). Additionally, section II.F.5 the FRIA distinguishes ''capturing'' from ''submitting'' information and accounts for them as distinct activities.

Regarding the proposed growing area coordinates requirement for growers of FTL foods, we note this is no longer a requirement of the rule. Instead, persons that grow or raise an FTL food (other than eggs) that are subject to the rule will need to keep, as part of their traceability plan, a farm map showing the area in which the FTL food was grown or raised. We have received farm maps with field names and coordinates during outbreak investigations, and because of the widespread availability and use of no-cost mapping and direction websites and web applications with GPS coordinate-plotting functionality, we expect most affected entities either already keep the required map or will be able to produce it in minutes.

Regarding the comments specific to the estimates for scanning and typing information and the high estimates for annual recordkeeping, because our cost estimates include significant capital investment by manufacturers and wholesalers, our estimated average recordkeeping times therefore assume that many of these entities will significantly reduce manual data entry in recordkeeping. Since retailers need only keep the records provided to them by suppliers and do not generally need to use the information for further compliance activities, we do not expect retailers in general to perform data entry, manual or otherwise.

(Comment 572) One comment maintains that when a raw product is transformed, it may become multiple products, therefore multiplying the number of required records. One comment maintains that counting a shipment as one traceability lot is inaccurate, asserting instead that most shipments contain multiple lots because of breakdowns into different sizes (*e.g.,* 4-, 6-, 8-ounce sizes). The comment maintains that these multiple lots would necessitate multiple data entries for the same shipment, thus increasing costs.

(Response 572) Based on expert elicitation (Ref. 34) in response to FDA outreach regarding this rulemaking, we have revised our estimate of the attendant recordkeeping burden upward to better reflect the scope of coverage. These revisions are discussed in detail in Section II.F.5.h of the FRIA.

(Comment 573) A number of comments maintain that FDA has underestimated the time and cost attendant to proposed revisions to the FTL under proposed § 1.1465(a); however, the comments did not include an alternative basis upon which we could form a burden estimate.

(Response 573) It is challenging to estimate the burden associated with possible future revisions to the FTL, such as learning about the changes or submitting comments, because we do not know whether those revisions would reduce or increase the number of foods on the FTL or what the public response to the revisions would be. We remind respondents that we invite public comment at regular intervals on our information collection activities, including burden associated with recordkeeping requirements already required under part 1, subpart J. As we implement the subpart S requirements, we will continue to monitor and invite feedback regarding burden associated with revisions to the FTL.

Burden Tables

Upon consideration of these comments, we estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ONE-TIME RECORDKEEPING BURDEN

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Reading and understanding the new recordkeeping requirements	323,872	1	323,872	[1] 16.8	5,441,050
§ 1.1315; traceability plan (one-time set-up)	212,368	1	212,368	6.2	1,316,682
Training personnel	34,737	10.5	364,739	4.2	1,531,904
Total					8,289,635

[1] There is likely to be more than one reader at each large firm. The estimated average sum over all readers of the time spent reading and understanding the rule at each firm is 16.8 hours.

The Estimated One-Time Recordkeeping Burden table reflects several changes to the proposed information collection. The estimated number of respondents for reading and understanding the recordkeeping requirements decreased because of additional exemptions and revisions to exemptions added in the final rule and our use of more recent data sources on the number of covered entities. We also increased the average burden to read and understand the rule from 3.3 hours to 16.8 hours because the length of the rule increased. The number of respondents for the one-time set up costs for the traceability plan (''traceability program records'' under the proposed rule) was updated based on updated overall coverage estimates for the number of firms, plus new data on the share of entities that will establish a traceability plan from the ERG expert elicitation study (Ref. 34). This is now a per-firm rather than per-establishment (facility) burden, and because we have moved from traceability program records to a traceability plan, the number of records per respondent has decreased to one. Finally, we have updated the number of respondents for training personnel based on updated coverage estimates plus newer data from the ERG expert elicitation study. Now training is per-establishment (facility) rather than per-firm. We have also updated the number of records per respondent for training personnel based on the ERG expert elicitation study.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
1.1370; Requests for modified requirements and exemptions	5	1	5	10	50
1.1415 through 1.1425; Requests for waivers	15	1	15	10	150
1.1465(a); Comments on proposed revisions to the Food Traceability List	1	1	1	1	1
Total			22		201

As discussed above, we have made no changes to the estimated annual reporting burden associated with the final rule.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Training personnel (recurring)	26,053	10.5	273,557	2.7	738,604
§ 1.1330(b); seed lot records (sprout growers).	95	882	83,790	0.04 (2.4 minutes)	3,352
§ 1.1325; harvester	6,058	578	3,501,524	0.03 (1.8 minutes)	105,046
§ 1.1325; cooler	3,511	572	2,008,292	0.03 (1.8 minutes)	60,249
§ 1.1330(a) and (c); initial packer	4,218	861	3,631,698	0.02 (1.2 minutes)	72,634
§ 1.1335; first land-based receiver	367	1,471	539,857	0.02 (1.1 minutes)	10,797
§ 1.1340; shipper	31,434	5,032	158,175,888	0.006 (22 seconds)	949,055
§ 1.1345; receiver	470,580	5,968	2,808,421,440	0.003 (11 seconds)	8,425,264
§ 1.1350; transformer	8,574	1,101	9,439,974	0.02 (1.2 minutes)	188,799
§ 1.1455(c)(3)(ii); electronic sortable spreadsheet upon request.	75	1	75	16.0	1,200
Total					10,555,000

The revised estimated annual recordkeeping burden in table 5 reflects several changes we made to the proposed information collection. First, the list of provisions changed consistent with revisions we made to the CTEs and related annual activities such as training personnel. The number of recordkeepers generally decreased because of additional exemptions and revisions to exemptions we added in the final rule and our use of more recent data sources on the number of covered entities. We have also estimated the burden for training personnel as a recurring burden rather than a one-time burden and altered the number of records per recordkeeper for the various provisions based on information from the ERG expert elicitation study (Ref. 34). Finally, we have updated the average burden per recordkeeping based on information from the ERG expert elicitation study. Apart from changes to the proposed rule, we also newly estimated the annual burden of formatting traceability information as an electronic sortable spreadsheet upon request by FDA.

Because we have deleted the requirements (in proposed § 1.1350(b)(2)) that farms disclose information (if applicable) about the origination, harvesting, cooling, and packing of food shipped by the farm, we have removed the disclosure burden previously included. Under § 1.1325(a)(2) and (b)(2) of the final rule, harvesters and coolers of FTL foods must disclose certain information about those activities to the initial packers of such food. However, as we stated in the preamble to the proposed rule with respect to the disclosure burden for shippers of FTL foods (85 FR 59984 at 60027), we are including the estimate of burden we attribute to the disclosure requirements for harvesters and coolers

as part of our recordkeeping burden estimate for these provisions because we believe this disclosure burden will be minimal, since these respondents must maintain harvesting and cooling information in accordance with those provisions.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. * Institute of Food Technologists, ''Pilot Projects for Improving Product Tracing Along the Food Supply System—Final Report,'' August 2012.
2. FDA, ''Report to Congress on Enhancing Tracking and Tracing of Food and Recordkeeping. Submitted Pursuant to Section 204 of the FDA Food Safety Modernization Act, Public Law 111–353,'' November 16, 2016 (*https://www.fda.gov/media/102784/download*).
3. * FDA, ''Food Traceability List for Requirements for Additional Traceability Records for Certain Foods Proposed Rule 2020,'' August 12, 2020 (*https://www.fda.gov/media/142283/download*).
4. * FDA Memorandum, ''Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223),'' August 2020 (*https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies*).
5. * FDA Memorandum, ''Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing (2019 Version),'' September 2, 2020 (*https://www.fda.gov/media/142282/download*).
6. * Dewey-Mattia, D., et al. ''Surveillance for Foodborne Disease Outbreaks—United States, 2009–2015.'' *Morbidity and Mortality Weekly Report. Surveillance Summaries (Washington, DC: 2002),* vol. 67,10 1–11. 27 July 2018, doi:10.15585/mmwr.ss6710a1.
7. Irvin, K., S. Viazis, A. Fields, et al., ''An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of Escherichia coli O157:H7 Infections Linked to Romaine Lettuce,'' *Journal of Food Protection,* 84:1340–1356, 2021.
8. * FDA Memorandum, ''Food Traceability List for Requirements for Additional Traceability Records for Certain Foods Proposed Rule—Clarified Language,'' January 12, 2021 (*https://www.fda.gov/media/145050/download*).
9. * FDA, ''FDA's Response to External Peer Review—Model Review on FDA's 'Draft Report for Peer Review: Risk-Ranking Model for Product Tracing as Required by Section 204 of FSMA' (September 2015),'' August 2020 (*https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews* and *https://www.fda.gov/media/142280/download*).
10. * FDA Memorandum, ''Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223),'' September 2022.
11. * FDA Memorandum, ''FDA Foodborne Illness Outbreak Data Used to Inform the 'Requirements for Additional Traceability Records for Certain Foods' Proposed Rule,'' August 2020.
12. * FDA, ''Investigation Report: Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of *Salmonella* Typhimurium During the Summer of 2021,'' January 2022 (*https://www.fda.gov/media/155402/download*).
13. * FDA, ''FDA's Response to External Peer Review—Data Review on FDA's 'Draft Report for Peer Review: Risk-Ranking Model for Product Tracing as Required by Section 204 of FSMA' (September 2015),'' August 2020 (*https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews* and *https://www.fda.gov/media/142281/download*).
14. * Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO), ''Microbiological Risk Assessment: Guidance for Food,'' Microbiological Risk Assessment Series 36, 2021 (*https://www.fao.org/policy-support/tools-and-publications/resources-details/en/c/1412247/*).
15. * FDA Memorandum, ''Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing,'' October 2022.
16. * FDA, ''Final Regulatory Impact Analysis,'' Docket No. FDA–2014–N–0053, November 2022.
17. * FDA, ''Risk-Ranking Model for Food Tracing: Web-based tool for Criteria and Results,'' 2022. (*https://cfsanapps external.fda.gov/scripts/FDARisk RankingModelforFoodTracingfinalrule/*).
18. * FDA, ''New Era of Smarter Food Safety Blueprint,'' July 2020 (*https://www.fda.gov/media/139868/download*).
19. * FDA Memorandum, ''Food Traceability List for Requirements for Additional Traceability Records for Certain Foods Final Rule 2022,'' October 2022.
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22. * FDA and Health Canada, ''Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Report.,'' July 2015 (*https://www.fda.gov/food/cfsan-risk-safety-assessments/joint-fda-health-canada-quantitative-assessment-risk-listeriosis-soft-ripened-cheese-consumption*).
23. * FDA, ''Fish and Fishery Products Hazards and Controls Guidance (June

2022 Edition),'' June 2022 (*https://www.fda.gov/media/80637/download*).
24. * FDA Memorandum, ''Categorical Exclusion—Requirements for Additional Traceability Records for Certain Foods,'' Docket No. FDA–2014–N–0053,'' October 2022.
25. * FDA Memorandum, ''Inclusion of Retail Establishments of All Sizes Under FSMA Section 204,'' August 13, 2020.
26. * FDA, ''Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition),'' August 2018 (*https://www.fda.gov/media/85043/download*).
27. * FDA, ''Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities,'' August 2016 (*https://www.fda.gov/media/99911/download*).
28. * FDA Memorandum, ''Seed Intended for Agricultural Purposes Sold for Sprouting,'' October 2022.
29. * FDA, ''Guidance for Industry: The Seafood List,'' July 2012 (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list*).
30. * FDA, ''Low- or No-Cost Tech-Enabled Traceability Challenge,'' October 19, 2021. (*https://precision.fda.gov/challenges/13*).
31. * Codex Alimentarius Commission, ''Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System'' (CAC/GL 60–2006) (*https://www.fao.org/fao-who-codexalimentarius/sh-proxy/tr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B60-2006%252FCXG_060e.pdf*).
32. * FDA, ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements'' (*https://www.fda.gov/media/131229/download*).
33. * FDA and National Oceanic and Atmospheric Administration, ''Memorandum of Understanding Between the Food and Drug Administration, United States Department of Health and Human Services and the National Oceanic and Atmospheric Administration, United States Department of Commerce,'' 2009 (*https://www.fda.gov/about-fda/domestic-mous/mou-225-09-0008*).
34. * Eastern Research Group, ''Traceability Costs and Costs Savings From Avoiding Overly Broad Recalls,'' 2022.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

■ 2. Add subpart S, consisting of §§ 1.1300 through 1.1465, to read as follows:

Subpart S—Additional Traceability Records for Certain Foods

Sec.

General Provisions

1.1300 Who is subject to this subpart?
1.1305 What foods and persons are exempt from this subpart?
1.1310 What definitions apply to this subpart?

Traceability Plan

1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?
1.1320 When must I assign traceability lot codes to foods on the Food Traceability List? Records of Critical Tracking Events
1.1325 What records must I keep and provide when I harvest or cool a raw agricultural commodity on the Food Traceability List?
1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?
1.1335 What records must I keep when I am the first land-based receiver of a food on the Food Traceability List that was obtained from a fishing vessel?
1.1340 What records must I keep and provide when I ship a food on the Food Traceability List?
1.1345 What records must I keep when I receive a food on the Food Traceability List?
1.1350 What records must I keep when I transform a food on the Food Traceability List?

Procedures for Modified Requirements and Exemptions

1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?
1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?
1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?
1.1375 What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?
1.1380 What process applies to a petition requesting modified requirements or an exemption?
1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?
1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?
1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?
1.1400 What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?

Waivers

1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?
1.1410 When will FDA consider whether to waive a requirement of this subpart?
1.1415 How may I request a waiver for an individual entity?
1.1420 What process applies to a request for a waiver for an individual entity?
1.1425 What must be included in a petition requesting a waiver for a type of entity?
1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?
1.1435 What process applies to a petition requesting a waiver for a type of entity?
1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?
1.1445 Under what circumstances may FDA modify or revoke a waiver?
1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

Records Maintenance and Availability

1.1455 How must records required by this subpart be maintained and made available?

Consequences of Failure To Comply

1.1460 What consequences could result from failing to comply with the requirements of this subpart?

Updating the Food Traceability List

1.1465 How will FDA update the Food Traceability List?

Subpart S—Additional Traceability Records for Certain Foods

General Provisions

§ 1.1300 Who is subject to this subpart?

Except as otherwise specified in this subpart, the requirements in this subpart apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are

required in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act (Food Traceability List). FDA will publish the Food Traceability List on its website, *www.fda.gov.,* in accordance with section 204(d)(2)(B) of the FDA Food Safety Modernization Act.

§ 1.1305 What foods and persons are exempt from this subpart?

(a) *Exemptions for certain small producers.* (1) *Certain produce farms.* (i) This subpart does not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter,

(ii) This subpart does not apply to produce farms when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(2) *Certain shell egg producers.* This subpart does not apply to shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm.

(3) *Certain other producers of raw agricultural commodities.* This subpart does not apply to producers of raw agricultural commodities other than produce or shell eggs (*e.g.,* aquaculture operations) when the average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of the raw agricultural commodities they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(b) *Exemption for farms when food is sold or donated directly to consumers.* This subpart does not apply to a farm with respect to food produced on the farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.

(c) *Inapplicability to certain food produced and packaged on a farm.* This subpart does not apply to food produced and packaged on a farm, provided that:

(1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(2) The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. FDA will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm.

(d) *Exemptions and partial exemptions for foods that receive certain types of processing.* This subpart does not apply to the following foods that receive certain types of processing:

(1) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in § 112.2(b) of this chapter are met for the produce;

(2) Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in § 118.3 of this chapter) in accordance with § 118.1(a)(2) of this chapter;

(3) Food that you subject to a kill step, provided that you maintain records containing:

(i) The information specified in § 1.1345 for your receipt of the food to which you apply the kill step (unless you have entered into a written agreement concerning your application of a kill step to the food in accordance with paragraph (d)(6) of this section); and

(ii) A record of your application of the kill step;

(4) Food that you change such that the food is no longer on the Food Traceability List, provided that you maintain records containing the information specified in § 1.1345 for your receipt of the food you change;

(5) Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the Food Traceability List;

(6) Food that will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List, provided that:

(i) There is a written agreement between the shipper of the food and the receiver stating that the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or

(ii) There is a written agreement between the shipper of the food and the receiver stating that an entity in the supply chain subsequent to the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List and that the receiver will only ship the food to another entity that agrees, in writing, it will:

(A) Apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or

(B) Enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the Food Traceability List.

(iii) A written agreement entered into in accordance with paragraph (d)(6)(i) or (ii) of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and

(iv) A written agreement entered into in accordance with paragraph (d)(6)(i) or (ii) must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years.

(e) *Exemption for produce that is rarely consumed raw.* This subpart does not apply to produce that is listed as rarely consumed raw in § 112.2(a)(1) of this chapter.

(f) *Exemption for raw bivalve molluscan shellfish.* This subpart does not apply to raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program, subject to the requirements of part 123, subpart C, and § 1240.60 of this chapter, or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish.

(g) *Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the U.S. Department of Agriculture (USDA).* This subpart does not apply to persons who manufacture, process, pack, or hold food on the Food Traceability List during or after the time when the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(h) *Partial exemption for commingled raw agricultural commodities.* (1) Except as specified in paragraph (h)(3) of this section, this subpart does not apply to commingled raw agricultural commodities (which, as defined in

§ 1.1310, do not include types of fruits and vegetables to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply).

(2) Except as specified in paragraph (h)(3) of this section, this subpart does not apply to a raw agricultural commodity that will become a commingled raw agricultural commodity, provided that:

(i) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that the receiver will include the commodity as part of a commingled raw agricultural commodity; or

(ii) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that an entity in the supply chain subsequent to the receiver will include the commodity as part of a commingled raw agricultural commodity and that the receiver will only ship the raw agricultural commodity to another entity that agrees, in writing, it will either:

(A) Include the raw agricultural commodity as part of a commingled raw agricultural commodity; or

(B) Enter into a similar written agreement with a subsequent receiver stating that the raw agricultural commodity will become part of a commingled raw agricultural commodity;

(iii) A written agreement entered into in accordance with paragraph (h)(2)(i) or (ii) of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and

(iv) A written agreement entered into in accordance with paragraph (h)(2)(i) or (ii) must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years;

(3) With respect to a commingled raw agricultural commodity that qualifies for either of the exemptions set forth in paragraphs (h)(1) and (2) of this section, if a person who manufactures, processes, packs, or holds such commodity is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable raw agricultural commodity, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

(i) *Exemption for small retail food establishments and small restaurants.* This subpart does not apply to retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(j) *Partial exemption for retail food establishments and restaurants purchasing directly from a farm.* (1) Except as specified in paragraph (j)(2) of this section, this subpart does not apply to a retail food establishment or restaurant with respect to a food that is produced on a farm (including food produced and packaged on the farm) and both sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm.

(2) When a retail food establishment or restaurant purchases a food directly from a farm in accordance with paragraph (j)(1) of this section, the retail food establishment or restaurant must maintain a record documenting the name and address of the farm that was the source of the food. The retail food establishment or restaurant must maintain such a record for 180 days.

(k) *Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant.* (1) Except as specified in paragraph (k)(2) of this section, this subpart does not apply to either entity when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice (*e.g.,* not pursuant to a contractual agreement to purchase food from the seller).

(2) When a retail food establishment or restaurant purchases a food on the Food Traceability List from another retail food establishment or restaurant in accordance with paragraph (k)(1) of this section, the retail food establishment or restaurant that makes the purchase must maintain a record (*e.g.,* a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase.

(l) *Partial exemption for farm to school and farm to institution programs.* (1) Except as specified in paragraph (l)(2) of this section, this subpart does not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution.

(2) When a school or institution conducting a farm to school or farm to institution program obtains a food from a farm in accordance with paragraph (l)(1) of this section, the school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food. The school food authority or relevant food procurement entity must maintain such record for 180 days.

(m) *Partial exemption for owners, operators, or agents in charge of fishing vessels.* (1) Except as specified in paragraph (m)(2) of this section, with respect to a food that is obtained from a fishing vessel, this subpart does not apply to the owner, operator, or agent in charge of the fishing vessel, and this subpart also does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.

(2) With respect to any person who receives the partial exemption set forth in paragraph (m)(1) of this section, if such person is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

(n) *Exemption for transporters.* This subpart does not apply to transporters of food.

(o) *Exemption for nonprofit food establishments.* This subpart does not apply to nonprofit food establishments.

(p) *Exemption for persons who manufacture, process, pack, or hold food for personal consumption.* This subpart does not apply to persons who manufacture, process, pack, or hold food for personal consumption.

(q) *Exemption for certain persons who hold food on behalf of individual consumers.* This subpart does not apply to persons who hold food on behalf of specific individual consumers, provided that these persons:

(1) Are not parties to the transaction involving the food they hold; and

(2) Are not in the business of distributing food.

(r) *Exemption for food for research or evaluation.* This subpart does not apply to food for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public; and

(2) Is accompanied by the statement ''Food for research or evaluation use.''

§ 1.1310 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, the following definitions apply to words and phrases as they are used in this subpart:

Commingled raw agricultural commodity means any commodity that is combined or mixed after harvesting but before processing, except that the term ''commingled raw agricultural commodity'' does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply. For the purpose of this definition, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Also, for the purpose of this definition, the term ''processing'' means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

Cooling means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Critical tracking event means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

Farm means farm as defined in § 1.328. For producers of shell eggs, ''farm'' means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3 of this chapter.

First land-based receiver means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)).

Food Traceability List means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act. The term ''Food Traceability List'' includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (*e.g.,* fresh) in which it appears on the list.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.,* foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Initial packing means packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.

Key data element means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.

Kill step means lethality processing that significantly minimizes pathogens in a food.

Location description means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the

Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes an individual, partnership, corporation, and association.

Point of contact means an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.

Produce means produce as defined in § 112.3 of this chapter.

Product description means a description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.

Raw agricultural commodity means ''raw agricultural commodity'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving means an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (*e.g.,* by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.

Reference document number means the identification number assigned to a specific reference document.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ''consumers'' does not include businesses. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. A ''retail food establishment'' also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, ''farm-operated business'' means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Shipping means an event in a food's supply chain in which a food is arranged for transport (*e.g.,* by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an

intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Traceability lot means a batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability lot code source means the place where a food was assigned a traceability lot code.

Traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

Transformation means an event in a food's supply chain that involves manufacturing/processing a food or changing a food (*e.g.,* by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event (*e.g.,* harvesting, cooling).

Transporter means a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air.

You means a person subject to this subpart under § 1.1300.

Traceability Plan

§ 1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

(a) If you are subject to the requirements in this subpart, you must establish and maintain a traceability plan containing the following information:

(1) A description of the procedures you use to maintain the records you are required to keep under this subpart, including the format and location of these records.

(2) A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;

(3) A description of how you assign traceability lot codes to foods on the Food Traceability List in accordance with § 1.1320, if applicable;

(4) A statement identifying a point of contact for questions regarding your traceability plan and records; and

(5) If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.

(i) Except as specified in paragraph (a)(5)(ii) of this section, the farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.

(ii) For aquaculture farms, the farm map must show the location and name of each container (*e.g.,* pond, pool, tank, cage) in which you raise seafood on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each container.

(b) You must update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you are in compliance with the requirements of this subpart. You must retain your previous traceability plan for 2 years after you update the plan.

§ 1.1320 When must I assign traceability lot codes to foods on the Food Traceability List?

(a) You must assign a traceability lot code when you do any of the following: Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel; perform the first land-based receiving of a food obtained from a fishing vessel; or transform a food.

(b) Except as otherwise specified in this subpart, you must not establish a new traceability lot code when you conduct other activities (*e.g.,* shipping) for a food on the Food Traceability List.

Records of Critical Tracking Events

§ 1.1325 What records must I keep and provide when I harvest or cool a raw agricultural commodity on the Food Traceability List?

(a) *Harvesting.* (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must maintain records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(ii) The commodity and, if applicable, variety of the food;

(iii) The quantity and unit of measure of the food (*e.g.,* 75 bins, 200 pounds);

(iv) The location description for the farm where the food was harvested;

(v) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;

(vi) For aquacultured food, the name of the container (*e.g.,* pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;

(vii) The date of harvesting; and

(viii) The reference document type and reference document number.

(2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must provide (in electronic, paper, or other written form) your business name, phone number, and the information in paragraphs (a)(1)(i) through (vii) of this section to the initial packer of the raw agricultural commodity you harvest, either directly or through the supply chain.

(b) *Cooling before initial packing.* (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must maintain records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(ii) The commodity and, if applicable, variety of the food;

(iii) The quantity and unit of measure of the food (*e.g.,* 75 bins, 200 pounds);

(iv) The location description for where you cooled the food;

(v) The date of cooling;

(vi) The location description for the farm where the food was harvested; and

(vii) The reference document type and reference document number.

(2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must provide (in electronic, paper, or other written form) the information in paragraphs (b)(1)(i) through (vi) of this section to the initial packer of the raw agricultural commodity you cool, either directly or through the supply chain.

§ 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

(a) Except as specified in paragraph (c) of this section, for each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;

(2) The date you received the food;

(3) The quantity and unit of measure of the food received (*e.g.,* 75 bins, 200 pounds);

(4) The location description for the farm where the food was harvested;

(5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;

(6) For aquacultured food, the name of the container (*e.g.,* pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;

(7) The business name and phone number for the harvester of the food;

(8) The date of harvesting;

(9) The location description for where the food was cooled (if applicable);

(10) The date of cooling (if applicable);

(11) The traceability lot code you assigned;

(12) The product description of the packed food;

(13) The quantity and unit of measure of the packed food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(14) The location description for where you initially packed the food (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;

(15) The date of initial packing; and

(16) The reference document type and reference document number.

(b) For each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, you must also maintain records containing the following information and linking this information to the traceability lot:

(1) The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available;

(2) The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing;

(3) The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse;

(4) The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter;

(5) A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment;

(6) The date of receipt of the seeds by the sprouter; and

(7) The reference document type and reference document number.

(c) For each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack that you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;

(2) The date you received the food;

(3) The quantity and unit of measure of the food received (*e.g.,* 75 bins, 200 pounds);

(4) The location description for the person from whom you received the food;

(5) The traceability lot code you assigned;

(6) The product description of the packed food;

(7) The quantity and unit of measure of the packed food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(8) The location description for where you initially packed the food (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;

(9) The date of initial packing; and

(10) The reference document type and reference document number.

§ 1.1335 What records must I keep when I am the first land-based receiver of a food on the Food Traceability List that was obtained from a fishing vessel?

For each traceability lot of a food obtained from a fishing vessel for which you are the first land-based receiver, you must maintain records containing the following information and linking this information to the traceability lot:

(a) The traceability lot code you assigned;

(b) The species and/or acceptable market name for unpackaged food, or the product description for packaged food;

(c) The quantity and unit of measure of the food (*e.g.,* 300 kg);

(d) The harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught;

(e) The location description for the first land-based receiver (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;

(f) The date the food was landed; and

(g) The reference document type and reference document number.

§ 1.1340 What records must I keep and provide when I ship a food on the Food Traceability List?

(a) For each traceability lot of a food on the Food Traceability List you ship, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;

(2) The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(5) The location description for the location from which you shipped the food;

(6) The date you shipped the food;

(7) The location description for the traceability lot code source, or the traceability lot code source reference; and

(8) The reference document type and reference document number.

(b) You must provide (in electronic, paper, or other written form) the information in paragraphs (a)(1) through (7) of this section to the immediate subsequent recipient (other than a transporter) of each traceability lot that you ship.

(c) This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).

§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?

(a) Except as specified in paragraphs (b) and (c) of this section, for each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;

(2) The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate previous source (other than a transporter) for the food;

(5) The location description for where the food was received;

(6) The date you received the food;

(7) The location description for the traceability lot code source, or the traceability lot code source reference; and

(8) The reference document type and reference document number.

(b) For each traceability lot of a food on the Food Traceability List you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this paragraph does not apply if you are a retail food establishment or restaurant);

(2) The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate previous source (other than a transporter) for the food;

(5) The location description for where the food was received (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;

(6) The date you received the food; and

(7) The reference document type and reference document number.

(c) This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

§ 1.1350 What records must I keep when I transform a food on the Food Traceability List?

(a) Except as specified in paragraphs (b) and (c) of this section, for each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:

(1) For the food on the Food Traceability List used in transformation (if applicable), the following information:

(i) The traceability lot code for the food;

(ii) The product description for the food to which the traceability lot code applies; and

(iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.

(2) For the food produced through transformation, the following information:

(i) The new traceability lot code for the food;

(ii) The location description for where you transformed the food (*i.e.,* the traceability lot code source), and (if applicable) the traceability lot code source reference;

(iii) The date transformation was completed;

(iv) The product description for the food;

(v) The quantity and unit of measure of the food (*e.g.,* 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and

(vi) The reference document type and reference document number for the transformation event.

(b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b).

(c) Paragraphs (a) and (b) of this section do not apply to retail food establishments and restaurants with respect to foods they do not ship (*e.g.,* foods they sell or send directly to consumers).

Procedures for Modified Requirements and Exemptions

§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?

(a) *General.* Except as specified in paragraph (b) of this section, FDA will modify the requirements of this subpart applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this subpart, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

(b) *Registered facilities.* If a person to whom modified requirements or an exemption applies under paragraph (a) of this section (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under paragraph (a) of this section) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (and in accordance with the requirements of subpart H of this part) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

§ 1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?

FDA will consider modifying the requirements of this subpart applicable to a food or type of entity, or exempting a food or type of entity from the requirements of this subpart, on our own initiative or in response to a citizen petition submitted under § 10.30 of this chapter by any interested party.

§ 1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting modified requirements or an exemption from the requirements of this subpart must:

(a) Specify the food or type of entity to which the modified requirements or exemption would apply;

(b) If the petition requests modified requirements, specify the proposed modifications to the requirements of this subpart; and

(c) Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health.

§ 1.1375 What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1380 What process applies to a petition requesting modified requirements or an exemption?

(a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting modified requirements or an exemption. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.

(b) Under § 10.30(h)(3) of this chapter, FDA will publish a notice in the **Federal Register** requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the **Federal Register** setting forth any modified requirements or exemptions and the reasons for them.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

§ 1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?

(a) If FDA, on our own initiative, determines that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notice in the **Federal Register** setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notice will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a notice in the **Federal Register** stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

§ 1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?

Any modified requirements that FDA adopts or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the **Federal Register**, unless otherwise stated in the notice.

§ 1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?

FDA may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health.

§ 1.1400 What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?

(a) If FDA tentatively determines that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:

(1) We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition; and

(2) We will publish a notice in the **Federal Register** of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

(b) After considering any comments timely submitted, we will publish a notice in the **Federal Register** of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. If we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Waivers

§ 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?

FDA will waive one or more of the requirements of this subpart when we determine that:

(a) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;

(b) The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(c) The waiver will not otherwise be contrary to the public interest.

§ 1.1410 When will FDA consider whether to waive a requirement of this subpart?

FDA will consider whether to waive a requirement of this subpart on our own initiative or in response to the following:

(a) A written request for a waiver for an individual entity; or

(b) A citizen petition requesting a waiver for a type of entity submitted under § 10.30 of this chapter by any person subject to the requirements of this subpart.

§ 1.1415 How may I request a waiver for an individual entity?

You may request a waiver of one or more requirements of this subpart for an individual entity by submitting a written request to the Food and Drug Administration as described at *www.fda.gov.* The request for a waiver must include the following:

(a) The name, address, and point of contact of the individual entity to which the waiver would apply;

(b) The requirements of this subpart to which the waiver would apply;

(c) Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements;

(d) Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively

identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(e) Information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1420 What process applies to a request for a waiver for an individual entity?

(a) After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.

(b) Any waiver for an individual entity that FDA grants will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

§ 1.1425 What must be included in a petition requesting a waiver for a type of entity?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting a waiver for a type of entity must:

(a) Specify the type of entity to which the waiver would apply and the requirements of this subpart to which the waiver would apply;

(b) Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements;

(c) Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(d) Present information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1435 What process applies to a petition requesting a waiver for a type of entity?

(a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting a waiver. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.

(b) Under § 10.30(h)(3) of this chapter, FDA will publish a notice in the **Federal Register** requesting information and views on a submitted petition requesting a waiver for a type of entity, including information and views from persons who could be affected by the waiver if we granted the petition.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the **Federal Register** setting forth any requirements we have waived and the reasons for the waiver.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

§ 1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?

(a) If FDA, on our own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notice in the **Federal Register** setting forth the proposed waiver and the reasons for such waiver. The notice will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a notice in the **Federal Register** stating whether we are granting the waiver (in whole or in part) and the reasons for our decision.

(c) Any waiver for a type of entity that FDA grants will become effective on the date that notice of the waiver is published in the **Federal Register**, unless otherwise stated in the notice.

§ 1.1445 Under what circumstances may FDA modify or revoke a waiver?

FDA may modify or revoke a waiver if we determine that:

(a) Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies;

(b) The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; or

(c) The waiver is otherwise contrary to the public interest.

§ 1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

(a) *Waiver for an individual entity.* (1) If FDA tentatively determines that we should modify or revoke a waiver for an individual entity, we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked.

(2) Upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. If we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

(b) *Waiver for a type of entity.* (1) If FDA tentatively determines that we should modify or revoke a waiver for a type of entity, we will provide the following notifications:

(i) We will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition.

(ii) We will publish a notice in the **Federal Register** of our tentative determination that the waiver should be

modified or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

(2) After considering any comments timely submitted, we will publish a notice in the **Federal Register** of our decision whether to modify or revoke the waiver and the reasons for the decision. If we do modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Records Maintenance and Availability

§ 1.1455 How must records required by this subpart be maintained and made available?

(a) *General requirements for records.* (1) You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under this subpart.

(2) All records must be legible and stored to prevent deterioration or loss.

(b) *Establishment and maintenance of records by another entity.* You may have another entity establish and maintain records required under this subpart on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.

(c) *Record availability.* (1) You must make all records required under this subpart available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required under this subpart.

(2) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act, you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) of a request made in-person or remotely (*e.g.,* by phone) by an authorized FDA representative, the information you are required to maintain under this subpart, for the foods and date ranges or traceability lot codes specified in the request.

(i) If FDA's request for the information specified in paragraph (c)(3) of this section is made by phone, we will also provide the request to you in writing upon your request; however, you must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request.

(ii) Except as specified in paragraph (c)(3)(iii) and (iv) of this section, when the information requested by FDA under paragraph (c)(3) of this section is information you are required to maintain under §§ 1.1325 through 1.1350, you must provide such information in an electronic sortable spreadsheet, along with any other information needed to understand the information in the spreadsheet.

(iii) You may provide the information requested by FDA under paragraph (c)(3) of this section in a form other than an electronic sortable spreadsheet if you are:

(A) A farm whose average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment;

(B) A retail food establishment or restaurant with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment; or

(C) A person (other than a farm, retail food establishment, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.,* held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(iv) FDA will withdraw a request for an electronic sortable spreadsheet under paragraph (c)(3)(ii) of this section, as appropriate, to accommodate a religious belief of a person asked to provide such a spreadsheet.

(4) Upon FDA request, you must provide within a reasonable time an English translation of records required under this subpart maintained in a language other than English.

(d) *Record retention.* Except as specified otherwise in this subpart, you must maintain records containing the information required by this subpart for 2 years from the date you created or obtained the records.

(e) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter, if not otherwise exempt.

(f) *Use of existing records.* You do not need to duplicate existing records you have (*e.g.,* records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(g) *Use of multiple sets of records.* You do not have to keep all of the information required by this subpart in a single set of records. However, your traceability plan must indicate the format and location of the records you are required to keep under this subpart, in accordance with § 1.1315(a)(1).

(h) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

Consequences of Failure To Comply

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

(a) *Prohibited act.* The violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act, including the violation of any requirement of this

subpart, is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.

(b) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of that section), including the requirements of this subpart, have not been complied with regarding such article.

Updating the Food Traceability List

§ 1.1465 How will FDA update the Food Traceability List?

(a) When FDA tentatively concludes, in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act, that it is appropriate to revise the Food Traceability List, we will publish a notice in the **Federal Register** stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes.

(b) After considering any information and views submitted on the proposed changes to the Food Traceability List, FDA will publish a notice in the **Federal Register** stating whether we are making any changes to the list and the reasons for the decision. If FDA revises the list, we will also publish the revised list on our website.

(c) When FDA updates the Food Traceability List in accordance with this section, any deletions from the list will become effective immediately. Any additions to the list will become effective 2 years after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice.

Dated: November 3, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–24417 Filed 11–15–22; 11:15 am]

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Part III

Department of Agriculture

Food and Nutrition Service

7 CFR Part 246

Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

[FNS–2022–0007]

RIN 0584–AE82

Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages

AGENCY: Food and Nutrition Service (FNS), Department of Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: This rulemaking proposes to revise regulations governing the WIC food packages to align them with the current Dietary Guidelines for Americans and reflect recommendations made by the National Academies of Sciences, Engineering and Medicine (NASEM) in its 2017 report, ''Review of WIC Food Packages: Improving Balance and Choice,'' while promoting nutrition security and equity and taking into account program administration considerations. The proposed changes are intended to provide WIC participants with a wider variety of foods that align with the latest nutritional science; provide WIC State agencies with greater flexibility to prescribe and tailor food packages that accommodate participants' special dietary needs and personal and cultural food preferences; provide more equitable access to supplemental foods; and better promote and support individual breastfeeding goals of participants to help establish successful long-term breastfeeding.

DATES: Written comments must be received on or before February 21, 2023 to be assured of consideration. Online comments submitted through the Federal eRulemaking Portal on this proposed rule must be received on or before February 21, 2023.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comments on this proposed rule. USDA seeks comment on all aspects of this proposal. Comments may be submitted in writing by one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Regular U.S. Mail:* WIC Administration, Benefits, and Certification Branch, Policy Division, Food and Nutrition Service, P.O. Box 2885, Fairfax, Virginia 22031–0885.
- *Overnight, Courier, or Hand Delivery:* Allison Post, WIC Administration, Benefits, and Certification Branch, Policy Division, Food and Nutrition Service, 1320 Braddock Place, 3rd Floor, Alexandria, Virginia 22314.

All written comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the written comments publicly available online at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Post, Chief, Administration, Benefits, and Certification Branch, Policy Division, Food and Nutrition Service, USDA, 1320 Braddock Place, 3rd Floor, Alexandria, Virginia 22314, (703) 305–2746 OR *Allison.Post@usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This rulemaking proposes to revise regulations governing the WIC [1] food packages to align them with the Dietary Guidelines for Americans (DGA), 2020–2025 [2] and reflect the National Academies of Sciences, Engineering and Medicine's (NASEM) recommendations,[3] while promoting nutrition security and equity, and program administration considerations in implementing the proposed changes. The proposed changes are discussed in detail in part III. This part provides a brief background on the WIC food packages and the prior review of and changes to the WIC food packages.

A. WIC Food Packages

WIC provides supplemental foods to address the nutritional needs of low-income pregnant, breastfeeding, and non-breastfeeding postpartum individuals, infants, and children up to 5 years of age at nutritional risk. Supplemental foods and nutrition education are the primary means by which WIC affects the dietary quality and behavior of participants. WIC also is intended to serve as an adjunct to health care during critical times of growth and development to prevent health problems and to improve the health status of Program participants.

The specific amounts and categories of foods provided by the WIC food packages are intended to be supplemental to an individual's diet and provide specific nutrients determined by nutritional research to be lacking in the diets of WIC's target population. Every WIC participant receives supplemental foods on a monthly basis from one of seven science-based food packages, according to their participant category and nutritional needs.

By design, the quantities and types of foods included in the WIC food packages are intended to (1) contribute to an overall dietary pattern consistent with the DGA, and (2) deliver priority nutrients to participants to meet their supplemental nutrition needs.

The seven food packages currently available in the following participant categories are:

(1) *Food Package I:* Infants birth through 5 months (Fully Breastfed, Partially Breastfed, and Fully Formula Fed)
(2) *Food Package II:* Infants ages 6 through 11 months (Fully Breastfed, Partially Breastfed, and Fully Formula Fed)
(3) *Food Package III:* Medically Fragile Women, Infants, and Children
(4) *Food Package IV:* Children ages 1 through 4 years
(5) *Food Package V:* Pregnant and Partially Breastfeeding Women up to 1 year postpartum
(6) *Food Package VI:* Postpartum Women (minimally or non-breastfeeding) up to 6 months postpartum
(7) *Food Package VII:* Fully Breastfeeding Women up to 1 year postpartum

Depending on the food package, the authorized food categories include: infant formula, cereal, and foods; exempt infant formulas; WIC-eligible nutritionals; [4] milk; cheese; breakfast cereal; juice; fruits and vegetables; whole wheat/whole grain bread; eggs; legumes and peanut butter; and canned

[1] The authorizing legislation for WIC uses the word ''women'' in the Program title and thus it is used in the title for this proposed rule. However, gender neutral language is used when possible throughout this proposed rule.

[2] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020–2025. 9th Edition. December 2020. Available at: Home | Dietary Guidelines for Americans. Referred to in this proposed rule as ''2020–2025 DGA'' or ''DGA.''

[3] National Academies of Sciences, Engineering, and Medicine. ''Review of WIC Food Packages: Improving Balance and Choice: Final Report,'' 2017. Available at internet site: *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

[4] Certain enteral products that are specifically formulated and commercially manufactured (as opposed to a naturally occurring foodstuff used in its natural state) to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate.

fish. Food categories and quantities,[5] as well as minimum nutritional requirements, are established at the Federal level and outlined in WIC Program regulations at 7 CFR 246.10.

As part of the WIC certification process, a comprehensive nutrition assessment[6] is conducted for each individual WIC participant. Through this process, medical conditions and/or special dietary needs as well as cultural and personal preferences are identified. Food packages can be tailored to accommodate the nutritional needs, personal and cultural preferences, and housing/living conditions of individual participants (*e.g.,* a medical condition such as a food allergy, or if a participant cannot use or refuses a food item). This individual nutrition tailoring involves modifying the food types or forms issued to the participant to best meet their individual supplemental needs and dictates what foods a participant can purchase with their benefits, consistent with State agency policies. For example, nutrition tailoring could entail issuing a participant lactose-free milk as an alternative to regular cow's milk (*e.g.,* due to an intolerance or preference). In addition to tailoring the food package to meet the individual's nutritional needs, personal and cultural preferences and housing/living conditions, WIC staff instructs participants on how to redeem their WIC food benefits at retail vendors to include information about substitution options that are available within each food package. It is through nutrition tailoring and the issuance of Food Package III that WIC conforms with Section 504 of the Rehabilitation Act by providing participants with special dietary needs with the supplemental foods that meet their medical needs.

The WIC Program is administered by 89 WIC State agencies, including the 50 States, 33 Indian Tribal Organizations, the District of Columbia, and five U.S. Territories (the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands). WIC State agencies identify the brands and package sizes that will be made available to their participants in accordance with Federal WIC regulations and consider factors such as product availability, participant acceptance, variety of choices, and price. WIC State agencies may establish criteria in addition to the Federal minimum requirements (*e.g.,* allow only low-sodium canned vegetables), authorize substitution options specified in regulations (*e.g.,* yogurt as a substitute for milk), and implement administrative adjustments to manage food costs. State agencies include a list of acceptable foods in their State Plans submitted annually for FNS approval.

Participants may redeem their benefits for the foods included in their food packages at retail vendors authorized by the State agency, and, in some instances, through home delivery or direct distribution systems operated by the State agency; there are roughly 40,000 WIC-authorized vendors nationwide.

B. Prior Review and Update of the WIC Food Packages

In 2003, FNS contracted with the Institute of Medicine (IOM, now known as the National Academies of Sciences, Engineering and Medicine or NASEM) to independently review the WIC food packages. This 22-month study was the first comprehensive review of the food packages since 1980. FNS tasked IOM with reviewing the nutritional needs of the WIC population and recommending changes to the WIC food packages. In 2006, IOM released its report, ''WIC Food Packages: Time for a Change,'' which cited fundamental changes that have occurred in the major health and nutrition risks faced by WIC's target population, including overweight and obesity; diets lacking in whole grains, fruits, and vegetables; and short duration of breastfeeding.[7] The report provided the scientific basis for the proposed rule that FNS published in August 2006.[8] This proposed rule garnered broad support from public commenters, the majority of whom were Program participants.

Using the comments received, FNS published an interim rule in December 2007 that implemented revised food packages.[9] Due to the extent and comprehensive nature of the revisions, FNS provided an extended public comment period on the interim rule to obtain comments on the impacts of implementing the new food packages. A final rule was published in March 2014.[10] The revisions in that rule aligned the food packages more closely with updated nutrition science, aimed to promote and support the establishment of successful long-term breastfeeding, provided participants with a wider variety of foods, and provided WIC State agencies with greater flexibility in prescribing food packages to accommodate participants' cultural food preferences. Key changes implemented as a result of the interim and final rules include:

- Introduction of the cash-value voucher (CVV)[11] for the purchase of fruits and vegetables.
- Addition of whole grains (*e.g.,* bread, tortillas, brown rice, etc.).
- Addition of soy-based beverage and tofu as milk alternatives.
- Reductions in some foods (*e.g.,* milk, egg, and juice) to better align with the supplemental nature of the Program.
- Allowance for participants in Food Package III to receive all authorized WIC foods.

II. Framework for Developing the Proposed Changes to the WIC Food Packages

This part summarizes the framework used to develop the proposed changes to the WIC food packages, including the 2017 NASEM report, the 2020–2025 DGA, promotion of nutrition security and equity, and program administration considerations, and outlines the goals of the proposed changes.

A. The 2017 NASEM Report

In 2014, FNS contracted with NASEM to conduct a second review of the WIC food packages, in accordance with the Healthy, Hunger-Free Kids Act of 2010 (Pub. L. 111–296, HHFKA), which required USDA to conduct a scientific review of the WIC food packages at least every ten years. FNS tasked NASEM with issuing both a set of cost-neutral recommendations and offering additional recommendations not constrained by cost-neutrality to identify and prioritize additional changes should a higher level of funding be appropriated. NASEM's process included a comprehensive review and analysis of available scientific evidence, including relevant published literature, National Health and Nutrition Examination Survey (NHANES 2005–2012) data, WIC benefit redemption

[5] At the individual level, food packages are tailored to meet a participant's needs, such as eliminating or substituting foods (*e.g.,* dry beans for peanut butter) due to a special dietary need (*e.g.,* allergy, medical condition), cultural or personal preferences, or in situations where a participant cannot use or refuses the item.

[6] A comprehensive nutrition assessment includes a review of anthropometric measurements; blood iron levels; medical conditions; dietary practices and needs; and predisposing conditions (*e.g.,* homelessness and migrancy).

[7] WIC Food Packages: Time for a Change | USDA–FNS.

[8] **Federal Register**: Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages (71 FR 44784).

[9] Interim Rule: Revisions in the WIC Food Packages | USDA–FNS (72 FR 68966).

[10] Final Rule: Revisions in the WIC Food Packages | USDA–FNS (79 FR 12274).

[11] (§ 246.2) Cash-value voucher means a fixed dollar amount check, voucher, electronic benefit transfer (EBT) card or other document which is used by a participant to obtain authorized fruits and vegetables. Cash-value voucher is also known as cash-value benefit (CVB) in an EBT environment.

data, the 2015–2020 DGA, and, for children under age 2 years, recommendations of the American Academy of Pediatrics (AAP), the Academy of Nutrition and Dietetics, and the World Health Organization, among other authoritative organizations. In 2017, NASEM published its recommendations in the report, ''Review of WIC Food Packages: Improving Balance and Choice: Final Report,'' [12] which informed many of the revisions in this proposed rule.

Using a systematic process, NASEM developed recommendations to satisfy the following seven criteria:

(1) The packages provide a balanced supplement to the diets of women and children.

(2) The packages contribute to reduced prevalence of inadequate and excessive nutrient intake.

(3) The packages contribute to a dietary pattern that is consistent with the 2015–2020 DGA for individuals 2 years of age and older.

(4) The packages contribute to a diet that is consistent with established recommendations for infants and children less than 2 years of age, including encouragement of and support for breastfeeding.

(5) The foods in the packages are available in forms and amounts suitable for low-income persons who may have limited transportation options, storage, and cooking facilities.

(6) The foods in the packages are readily acceptable, commonly consumed, widely available, take into account cultural eating patterns and food preferences, and provide incentives for families to participate in the WIC Program.

(7) The foods in the packages do not create an undue burden on State agencies or vendors.

NASEM's review emphasized the ''supplemental'' nature of the food packages—that they are meant to provide a balanced supplement to participants' diets. Accordingly, NASEM designed food packages that provide moderate proportions of individuals' nutrients requirements and recommended food group amounts and that prioritize nutrients that are under-consumed and associated with health outcomes relevant to the WIC-eligible population. Finding that the current food packages provide varying proportions of required nutrients (between 5 and 400 percent of the Dietary Reference Intake (DRI)) and recommended food groups (between 0 and 177 percent of recommended intake amounts),[13] NASEM recommended reducing foods that provide more-than-supplemental amounts and increasing foods needed to improve intake of priority nutrients and food groups.

B. The Dietary Guidelines for Americans (DGA) 2020–2025

On December 29, 2020, the USDA and the U.S. Department of Health and Human Services published the 2020–2025 DGA, which provide recommendations for healthy dietary patterns by life stage and, for the first time since the 1985 edition, specific recommendations for infants and children up to 2 years of age. Because NASEM's review and recommendations were based on the 2015–2020 DGA, to ensure continued alignment with the current DGA, FNS conducted a thorough review of the new guidelines and incorporated relevant updates into the proposed changes to the WIC food packages.

C. Nutrition Security and Equity, and Program Administration Considerations

The Department developed proposed changes to the WIC food packages to align with NASEM and DGA recommendations, while promoting nutrition security and equity, and taking into account program administration considerations. The proposed changes would expand substitution options for participants with dietary restrictions to align with Section 504 of the Rehabilitation Act. The Department has prioritized improving nutrition security and equity, where individuals have consistent access to and availability of foods and beverages that promote well-being and prevent disease, particularly among our nation's most socially disadvantaged populations.[14]

USDA's nutrition programs are the most far-reaching tools available to support nutrition security. The proposed changes to the food packages were considered within the framework of enhancing WIC participants' equitable access to nutritious foods and better meeting their special dietary needs due to medical conditions (*e.g.,* allergies, intolerances) or limited cooking or storage facilities, cultural traditions, and personal preferences (*e.g.,* vegetarian diets).

Guided by the nutritional science presented in NASEM's report, the 2020–2025 DGA, and in recognition of the importance of nutrition security, FNS is proposing revisions to the food packages that prioritize WIC participants' supplemental nutrition needs over maintaining cost neutrality. The proposed changes (described below in part III, ''Proposed Revisions to the WIC Food Packages'') are intended to achieve a better balance of nutrients and align with the supplemental nature of the Program.

In addition, in developing the proposed changes, the Department considered the potential impact on program administration. Accordingly, the proposed changes reflect efforts to promote ease of implementation for State agencies, local agencies, vendors, and participants. These program administration considerations are discussed in Part III below.

D. Goals of the Proposed Changes to WIC Food Packages

The proposed changes are designed to achieve the following:

- Provide additional flexibility, variety, and choice to build on current reasonable modifications for individuals with special dietary needs due to medical conditions, as well as accommodations for people with limited cooking and/or storage facilities or cultural and personal preferences (including, but not limited to, vegan and vegetarian diets), while ensuring the delivery of priority nutrients to WIC participants.
- Consider marketplace availability of supplemental foods.
- Increase the actual and perceived value of the WIC food packages to eligible populations.
- Improve equitable access to nutritious foods.
- Promote and support breastfeeding of all durations and intensities (*i.e.,* partially or fully).
- Provide foods in amounts that are more consistent with the supplemental nature of the Program.
- Provide a better balance of required nutrients and align with the 2020–2025 DGA, which emphasize nutrient-dense foods and beverages.
- Align with DGA guidance to consume a balanced diet that meets, but does not exceed, recommended food group and subgroup amounts and nutrients appropriate for an individual's life stage.
- Build on the 2014 changes to the WIC food packages and the positive impact those changes had on participant

[12] National Academies of Sciences, Engineering, and Medicine 2017. *Review of WIC Food Packages: Improving Balance and Choice: Final Report.* Washington, DC: The National Academies Press. Available at internet site: *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

[13] Zero refers to the lack of seafood in the majority of current WIC food packages.

[14] Mozaffarian D, Fleischhacker S, Andrés J. Prioritizing Nutrition Security in the US. JAMA. 2021;325(16):1605–1606. doi: *https://doi.org/10.1001/jama.2021.1915*).

diet quality and reduced prevalence of obesity among children.[15 16 17]

These goals provided the basis for the proposed changes to the food packages presented in part III below.

III. Proposed Revisions to the WIC Food Packages

The proposed revisions to the WIC food packages align with the 2017 NASEM report and the 2020–2025 DGA, promote nutrition security and equity, and account for program administration considerations. This part first summarizes the proposed changes to the food packages in the table below and then describes the proposed changes in detail, including the underlying rationale, in the sections that follow.

Section	Summary of proposed change
A. Fruits and Vegetables	1. Increase CVV maximum monthly allowances for child, pregnant, breastfeeding, and postpartum participants. 2. Require State agencies to authorize at least one other form of fruits and vegetables in addition to fresh. 3. Require vendors to stock at least three varieties of vegetables. 4. Expand what can be purchased with the CVV.
B. Juice	1. Reduce or remove maximum monthly allowance for juice. 2. Allow CVV as a substitute for juice.
C. Milk and Milk Substitutions	1. Reduce maximum monthly allowances of milk. 2. Require authorization of lactose-free milk. 3. Permit only unflavored milk and reduce total sugars allowed in yogurt and soy-based beverages. 4. Add a calcium specification for tofu and a vitamin D specification for yogurt. 5. Increase yogurt substitution amounts for milk. 6. Add soy-based yogurts and soy-based cheeses as substitution options for milk. 7. Update Food and Drug Administration (FDA) standard of identity citations for yogurt. 8. Allow reduced-fat yogurts for 1-year-old children without restrictions. 9. Remove cheese as a food category from the fully breastfeeding food package.
D. Infant Foods	1. Reduce infant cereal, infant fruits and vegetables, and infant meat. 2. Increase CVV substitution amounts for infant fruits and vegetables, allow forms other than fresh, and lower the minimum age for infants to receive a CVV. 3. Prohibit added fats in infant foods.
E. Add Infant Formula Flexibilities and Create a Separate Food Package for Partially (Mostly) Breastfeeding Participants.	1. Increase formula amounts in the first month for partially (mostly) breastfed infants. 2. Allow all prescribed infant formula quantities to be considered ''up to'' amounts. 3. Create a separate and enhanced food package for partially (mostly) breastfeeding participants.
F. Breakfast Cereals	1. Change whole grain criteria for breakfast cereals. 2. Require all breakfast cereals meet whole grain criteria.
G. Whole Wheat Bread, Whole Grain Bread, and other Whole Grain Options.	1. Revise (reduce for children and increase for pregnant, postpartum, and breastfeeding participants) maximum monthly allowances for whole wheat and whole grain bread and other whole grain options. 2. Change criteria for whole grain breads. 3. Expand whole grain options.
H. Canned Fish	1. Add canned fish to food packages for children (2 through 4 years) and specify WIC-eligible varieties for children. 2. Add canned fish in food packages for pregnant, partially (mostly) breastfeeding, and postpartum participants not currently receiving canned fish, revise amounts for fully breastfeeding participants, and revise WIC-eligible varieties.
I. Legumes and Eggs	1. Require State agencies to authorize both dried and canned legumes. 2. Require authorization of legumes and peanut butter as substitutes for eggs and allow State agencies to choose to authorize tofu to substitute for eggs.
J. Maximum Monthly Allowances	1. Allow State agencies to authorize a greater variety of package sizes to increase variety and choice, while still providing participants with package sizes that ensure they can receive the full benefit amount (i.e., at least one package size, or a combination of sizes, must add up to the full maximum monthly allowance).

A. Fruits and Vegetables

As recommended by NASEM, the proposed rule would increase the CVV amount for child, pregnant, postpartum, and breastfeeding participants; require the authorization of an additional form of fruits and vegetables beyond fresh, dependent on participant category; require vendors to stock at least three varieties of vegetables; and expand what can be purchased with the CVV.

1. Increase CVV Maximum Monthly Allowances for Child, Pregnant, Breastfeeding and Postpartum Participants (§ 246.10(e)(10) and (11), Tables 2 and 3)

This rulemaking proposes to increase the monthly CVV amounts to provide $24 for child participants, $43 for

[15] Pan L, Blanck HM, Park S, Galuska DA, Freedman DS, Potter A, Petersen R. State-Specific Prevalence of Obesity Among Children Aged 2–4 Years Enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children—United States, 2010–2016. MMWR Morb Mortal Wkly Rep. 2019 Nov 22;68(46):1057–1061. doi: 10.15585/mmwr.mm6846a3. PMID: 31751324; PMCID: PMC6871901.

[16] Daepp MIG, Gortmaker SL, Wang YC, Long MW, Kenney EL. WIC Food Package Changes: Trends in Childhood Obesity Prevalence. Pediatrics. 2019 May;143(5):e20182841. doi: 10.1542/peds.2018–2841. Epub 2019 Apr 1. PMID: 30936251; PMCID: PMC6565338.

[17] Chiasson MA, Findley SE, Sekhobo JP, Scheinmann R, Edmunds LS, Faly AS, McLeod NJ. Changing WIC changes what children eat. Obesity (Silver Spring). 2013 Jul;21(7):1423–9. doi: 10.1002/oby.20295. Epub 2013 May 22. PMID: 23703806.

pregnant and postpartum participants, and $47 for partially (mostly) and fully breastfeeding participants (with annual adjustments for inflation), depending on category (current regulatory amounts are $9 for children and $11 per month for pregnant, postpartum, and breastfeeding participants).[18] The proposed increases reflect the amounts recommended by NASEM (determined to provide approximately half of the recommended daily amounts of fruits and vegetables for adults and children), outside of cost neutrality, and adjusted upward for inflation, and the amounts in the Department's Fiscal Year 2022 budget. The proposed increases also reflect 2020–2025 DGA recommendations for the applicable life stages of WIC adult participants (postpartum, pregnant, and lactating) based on the average caloric needs of these various groups (2,000 kcal, 2,200 kcal, and 2,400 kcal, respectively). In alignment with NASEM's emphasis on providing supplemental amounts of foods and nutrients and with the DGA recommendation for greater fruit and vegetable consumption to achieve a healthy dietary pattern, the proposed revised amounts would afford participants greater choice and variety to select fruits and vegetables that accommodate their cultural and other food preferences. The following are the proposed CVV maximum monthly allowances for the purchase of fruits and vegetables by participant category (monthly CVV amounts would be adjusted annually for inflation):

Children 1 through 4 years: $24
Pregnant: $43
Postpartum: $43
Partially (mostly) breastfeeding: $47
Fully breastfeeding: $47

2. Require One Other Form of Fruits and Vegetables in Addition to Fresh (§ 246.10(e)(3)(v), (e)(4)(ii), (ii), (ii), and (ii), and (9) Through (11))

As recommended by NASEM, the proposed rule would require State agencies to authorize fresh and at least one other form (frozen, canned, and/or dried) of both fruits and vegetables for the child, pregnant, postpartum, and breastfeeding food packages and require fresh and at least one other form (frozen or canned) for the CVV substitution for infants (ages 6 through 11 months) food packages. Dried fruits and vegetables are not authorized for infants since they pose a choking hazard.[19]

Certain processed fruits and vegetables offer similar nutrition benefits to fresh forms, are less perishable, and can be suitable for those who have allergic reactions to certain raw fruits and vegetables. Additionally, limiting fruits and vegetables to fresh only may compromise seasonally and geographically available options for participants. Thus, this change would further provide participants with greater flexibility to accommodate various storage or cooking conditions as well as special dietary needs (*e.g.,* allergy/intolerance to fruits and vegetables) and cultural and personal food preferences. Requiring an additional form of fruits and vegetables also promotes equity by ensuring participants have access to a variety of options, including those that are available seasonally and in certain geographic regions.

Currently, WIC State agencies are not required, but may choose, to authorize other forms of fruits and vegetables in addition to fresh for child, pregnant, postpartum, and breastfeeding participants. In 2021, 81 State agencies authorized a form other than fresh. Therefore, the Department anticipates that the proposed change would have minimal impact on most State agencies, while ensuring greater participant choice in those States currently not authorizing other forms of fruits and vegetables. Additionally, with the proposed increase in the CVV, having the option to buy other forms that are not as perishable as fresh may encourage fuller redemption and consumption of the benefit, as well as less food waste.[20]

Current regulations allow State agencies the option to provide a CVV for only fresh fruits and vegetables as a substitute for jarred infant fruits and vegetables. Consistent with the proposed change to the child, pregnant, postpartum, and breastfeeding food packages, this proposed rule would allow State agencies the option to provide a CVV for fresh and at least one other form of fruits and vegetables (frozen and/or canned; dried would not be authorized for infants) as a substitute for jarred infant fruits and vegetables (see section D below, ''Infant Foods''). However, given potential concerns about sodium amounts in frozen and/or canned forms of vegetables exceeding infants' needs, the Department requests public comment to better understand the impact of, and potential barriers to, the proposed change to allow fresh and other forms (frozen and/or canned) of fruits and vegetables as an option in the infant food package.

The Department also requests public comment on the impact and feasibility of requiring State agencies to authorize all forms of fruits and vegetables (fresh, frozen, canned, and dried) for CVV redemption for pregnant, postpartum, breastfeeding, and child participants, specifically the potential burden on State agencies and vendors. The Department also seeks comment on the potential for confusion among households with infant participants whose benefits are aggregated with children and women participants who may receive dried forms.

3. Require Vendors To Stock at Least Three Varieties of Vegetables (§ 246.12(g)(3)(i))

As recommended by NASEM, the proposed rule would require vendors to stock at least three varieties of vegetables. Currently, vendors are required to stock two varieties of vegetables. NASEM recommended the requirement for stocking a greater variety of vegetables as opposed to fruits because its review of WIC redemption data showed that on average a much higher proportion of the CVV is redeemed for fruits (67 percent) compared to vegetables (33 percent). NASEM also cited the low intake of vegetables (particularly in contrast to fruits) in all WIC participant categories and recommended increased stocking requirements for vegetables. In a systematic review of fruit and vegetable purchases and consumption among WIC participants (after the 2009 WIC food packages changes) the evidence generally points toward increased variety in stores as a result of increased minimum stocking requirements and increased consumption of fruits and vegetables.[21] Thus, the proposed change is intended to increase the purchase and consumption of vegetables among WIC participants, particularly given the proposed increase to the value of the CVV, by requiring vendors to offer more variety for participants to select from. In addition, the proposed change is intended to promote equity by ensuring all participants, regardless of where they

[18] This change would sustain a temporary, legislation-based increase in the CVV that has been in place since October 1, 2021 and will remain through the end of fiscal year (FY) 2022 as a result of two continuing resolutions (Pub. L. 117–43 and Pub. L. 117–70) and the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2022 (Pub. L. 117–103).

[19] United States Department of Agriculture. Infant Nutrition and Feeding: A Guide for Use in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). 2019. Available at internet site: Infant Nutrition and Feeding Guide | WIC Works Resource System (*usda.gov*).

[20] *https://www.usda.gov/foodwaste/.*

[21] Fruit and Vegetable Purchases and Consumption among WIC Participants after the 2009 WIC Food Package Revision: A Systematic Review—PMC (*nih.gov*).

redeem benefits, have access to a variety of vegetables.

The proposed change to the Federal minimum stocking requirement for vegetables may present a challenge for some vendors. Therefore, the Department requests public comment regarding the proposed increased vegetable stocking requirement on vendors, particularly remote and/or small vendors, to better understand the potential effects of this change.

4. Expand What Can Be Purchased With the CVV (§ 246.10(e)(12), Table 4)

The Department proposes to allow fresh herbs, codify that State agencies cannot exclude white potatoes from purchase with the CVV, and allow larger sizes of packaged fresh fruits and vegetables.

a. Allow Fresh Herbs (§ 246.10(e)(12), Table 4)

The Department proposes to allow the purchase of fresh, cut herbs with the CVV to increase participant choice in conjunction with the proposed increase to the CVV value, accommodate cultural eating patterns, and align with the DGA, which categorize herbs (*e.g.,* cilantro and basil) as ''Dark-Green Vegetables.'' Additionally, herbs can help enhance the flavor of foods as a strategy to reduce added sugars, saturated fat, and/or sodium, as well as to potentially increase consumption of other vegetables. Spices and dried herbs would remain ineligible for purchase with the CVV.

b. Codify That White Potatoes Are WIC-Eligible (§ 246.10(e)(12), Table 4)

The WIC food packages final rule, published in March 2014, excluded the purchase of white potatoes with the CVV. This was an IOM recommendation based on data indicating that starchy vegetable consumption met or exceeded the recommended amounts. Subsequently, the Consolidated and Further Continuing Appropriations Act, 2015 (the Act, Pub. L. 113–235), enacted on December 16, 2014, precluded the exclusion or restriction of the eligibility of any variety of fresh, whole, or cut vegetables (except vegetables with added sugars, fats, or oils) in the WIC Program. In response to the Act, FNS issued WIC Policy Memorandum #2015–3: Eligibility of White Potatoes for Purchase with the Cash-Value Voucher,[22] allowing the purchase of white potatoes with the CVV. Thus, the Department proposes to codify in regulations the requirements of the Act by removing white potatoes as an excluded vegetable. This would not be a change to current Program requirements.

c. Allow Larger Sizes of Packaged Fresh Fruits and Vegetables (§ 246.10(e)(12), Table 4)

The Department is proposing to permit larger sizes of packaged fresh fruit and vegetables that are currently disallowed under the term ''party trays'' to provide additional variety and choice for participants. Such food items may also increase consumption of fruits and vegetables as they are already prepared and ready to eat. Eligible products must meet current requirements in that they may not contain added sugars, fats, or oils (which may appear in the form of dips, sauces, or glazes). Nutrition education provided to participants may address consideration of package size selections for individual consumption to minimize food spoilage.

Regulations (§ 246.10(b)(1)(i)) only allow State agencies to restrict container size of processed fruits and vegetables. Therefore, the proposed change in this section would result in all packages of fresh fruits and vegetables being WIC-eligible, regardless of package size. As such, the Department is requesting public comments specifically on any potential challenges to implementing the allowance of larger sizes of packaged fresh fruits and vegetables for State agencies, particularly related to managing approved product lists.

B. Juice

As recommended by NASEM and to align with the DGA, the Department proposes to reduce juice in the child, pregnant and breastfeeding food packages, eliminate juice for postpartum participants, and allow the substitution of a $3 CVV for the full juice amount.

1. Reduce or Remove Maximum Monthly Allowance for Juice (§ 246.10(e)(10) and (11), Tables 2 and 3)

The proposed reduction of juice in the child, pregnant and breastfeeding food packages would better provide supplemental quantities of juice and align with the latest dietary guidance. The DGA emphasize the consumption of whole forms of fruits and vegetables over juice. While the DGA includes 100% juice as part of the fruit and vegetable food groups, it emphasizes whole fruit and a variety of vegetables from all subgroups, and places limits on fruit juice amounts that should contribute toward an overall dietary pattern. Juice is not a separate food subgroup (like dark-green vegetables) in the dietary patterns that Americans should consume each day. Additionally, the DGA recognizes juice as lower in dietary fiber than whole fruits or vegetables. The DGA identify dietary fiber as a dietary component of public health concern for the U.S. population due to underconsumption, and these low intakes are associated with health concerns.

With this proposed change, the child, pregnant and breastfeeding food packages would contain 64 fluid ounces of juice per month and juice would be eliminated for postpartum participants, who have lower caloric needs relative to those who are pregnant and lactating. The current food packages provide between 96 and 144 fluid ounces (depending on participant category), or 40 to 107 percent of DGA-recommended limits for fruit juice. The reduced quantities would provide approximately 27 to 53 percent of DGA-recommended limits for children and most participants.[23]

The following are the proposed maximum monthly allowances for juice:

- Child, pregnant and breastfeeding participants: 64 fluid ounces.
- Postpartum participants: 0 fluid ounces.

2. Allow CVV as a Substitute for Juice (§ 246.10(e)(10) and (11), Tables 2 and 3)

As recommended by NASEM, this proposed rule would allow participants to substitute a $3 CVV for the full juice amount (64 fluid ounces). This change would provide additional flexibility to accommodate special dietary needs, cultural and personal preferences and align with a healthy dietary pattern as recommended by the DGA that includes mostly whole fruits and vegetables in nutrient dense forms. In conjunction with the proposal to significantly increase the CVV for pregnant, postpartum, breastfeeding, and child participants, these changes would encourage the consumption of whole fruits and vegetables versus juice. The monthly value of the CVV substitution amount for juice will be adjusted annually for inflation consistent with the inflation adjustments made to pregnant, postpartum, breastfeeding, and child participant CVV values.

C. Milk and Milk Substitutions

As recommended by NASEM to improve the nutritional quality of the

[22] Eligibility of White Potatoes for Purchase with the Cash-Value Voucher | USDA–FNS.

[23] For children ages 12 to 23 months, the reduced juice quantity provides 53% of the upper DGA limit based on 4 oz/day for 700–1000 kcal. For children 2 to 4 years, the reduced juice quantity provides 36%–53% of the upper DGA limit based on 4–6 oz/day for 1000–1600 kcals. For all pregnant and breastfeeding food packages, the reduced juice quantity provides 27% of the upper DGA limit based on 8 oz/day for 2000–2400 kcals.

WIC food packages, align with the DGA, and provide a better balance of foods, the Department proposes a variety of changes to milk and milk substitutions in the WIC food packages:

- Reduce the amount of milk provided in all child, pregnant, postpartum, and breastfeeding participant food packages.
- Require authorization of lactose-free milk.
- Permit only unflavored milk and reduce the total sugars allowed in yogurt and soy-based beverages.
- Add calcium specifications for tofu and vitamin D specifications for yogurt.
- Increase yogurt substitution amounts.
- Add substitution options for milk.
- Update the FDA standards of identity citations for yogurt.
- Allow reduced-fat yogurts for 1-year-old children without restrictions.
- Remove cheese from the fully breastfeeding food package.

1. Reduce Maximum Monthly Allowances of Milk (§ 246.10(e)(10) and (11), Tables 2 and 3)

In the current food packages, milk provides 85 to 128 percent of the amount of dairy recommended in the DGA Healthy U.S.-Style Dietary Pattern. The supplemental quantities of milk under this proposed rule would provide approximately 71 to 96 percent of the amount recommended by the DGA Healthy U.S.-Style Dietary Pattern for the dairy food group.[24] The proposed quantities reflect NASEM recommendations, are more consistent with the supplemental nature of the Program, and are consistent with nutrition education messages to consume a balanced diet that meets, but does not exceed, recommended amounts of foods and nutrients to prevent overweight/obesity and/or displace other healthy and important food groups and nutrients. Compared to current maximum monthly allowances for milk, children (depending on age) would receive 2 to 4 quarts less per month. Pregnant and partially (mostly) breastfeeding participants would receive 6 quarts less per month, fully breastfeeding participants would receive 8 quarts less per month, and the amount for postpartum participants would remain unchanged.

The following are the proposed maximum monthly allowances (MMA) for milk:

Participant category	Proposed MMA for milk (quarts)
Children 1 year (12 through 23 months)	12
Children 2 through 4 years	14
Pregnant	16
Partially (Mostly) & Fully Breastfeeding	16
Postpartum	16

Due to the different quantities of milk prescribed for children 12 through 23 months of age compared to children 2 through 4 years of age, the Department is proposing to create Food Package IV–A (children 12 through 23 months) and Food Package IV–B (children 2 through 4 years). This differentiation would also align with the differences in fat content in the standard milk issued for these two age groups and the proposed change to add canned fish to the food package for children 2 through 4 years of age (see Section H ''Canned Fish'', below).

2. Require Authorization of Lactose-Free Milk (§ 246.10(e)(3)(10) Through (12), Tables 2 Through 4)

Currently it is a State agency option to authorize lactose-free milk. Data from a WIC study and FNS Regional Office[25] input indicate that almost all WIC State agencies authorize lactose-free milk, suggesting that a regulatory change requiring State agencies to authorize lactose-free milk would not result in additional administrative efforts. Additionally, this proposed change improves consistency regarding lactose-free milk across FNS nutrition assistance programs. Therefore, to further promote nutrition security and equity the Department proposes to require State agencies to authorize both fluid and lactose-free milk, with the intent of ensuring additional options for participants with special dietary needs and preferences across all State agencies.

3. Permit Only Unflavored Milk and Reduce Total Sugars Allowed in Yogurt and Soy-Based Beverages (§ 246.10(e)(12), Table 4)

As recommended by NASEM, this rule proposes to revise the total sugars requirements for milk, yogurt and soy-based beverages offered in WIC to align with the DGA, which emphasize nutrient dense foods and beverages—among other aspects, nutrient-dense foods and beverages include little or no added sugars. As noted in the DGA, nutrient dense foods and beverages are particularly important for toddlers since their relatively high nutrient needs leave virtually no room for added sugars in their diet. The DGA also recommend that beverages with no added sugars be the primary choice for children to assist in the establishment of healthy food choices early in life. The proposed changes are also consistent with the reduction in total sugars in the Child and Adult Care Food Program (CACFP). As a result, the Department proposes the following revisions that would limit total sugars:

- Unflavored milk only.
- Plain or flavored yogurt with ≤30 grams of total sugars per 8 ounces.
- Soy-based beverage with ≤12 grams of total sugars per 8 ounces.

For yogurt, the total sugars limit would be reduced from ≤40 grams per 8 ounces to ≤30 grams per 8 ounces. Since there are no total sugars limits for soy-based beverages, this proposed rule would require that a soy-based beverage not exceed 12 grams of total sugars per 8 fluid ounces. The Department requests public comment on the proposed limit on total sugars for yogurt and soy-based beverage, with specific interest in the use of an *added sugars* limit instead of a *total sugars* limit such as the suggested added sugars limits for yogurt provided in Table 6.5 (page 303) of the NASEM report[26] or an alternative. While NASEM provided an added sugars limit for yogurt in its 2017 report, the final recommendation was for a total sugars limit given that FDA's regulation to include added sugars on food labels was not yet implemented. Thus, NASEM could not review and compare the suggested added sugars limits against marketplace availability, a core tenet of their charge in this report. USDA recognizes there is value in aligning with the DGA recommendation to reduce added sugars while maintaining consistency with other Federal Child Nutrition Programs. With FDA's labeling requirement for added sugars now in place, USDA seeks additional information on the marketplace availability, administrative burden, and nutritional impacts of implementing an added sugar requirement.

To further accommodate special dietary needs and cultural and personal

[24] For children ages 12 to 23 months, the reduced milk quantity provides 80–96% of the DGA based on 1 and ⅔ cup-2 cup eq/day for 700–1000 kcal. For children 2 to 4 years, the reduced milk quantity provides 75–93% of the DGA based on 2–2.5 cup eq/day for 1000–1600 kcals. For all women food packages, the reduced milk quantity provides 71% of the DGA based on 3 cup eq/day for 2000–2400 kcals.

[25] U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support. WIC Food Packages Policy Options Study II, by B. Thorn, N. Huret, D. Bellows, E. Ayo, R. Myers, and E.Wilcox-Cook. Project Officer: Grant Lovellette. Alexandria, VA: October 2015. Available at: *https://www.fns.usda.gov/wic/wic-food-package-policy-options-ii.*

[26] *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

preferences, the Department requests public comment on the availability of other plant-based beverages (*e.g.,* oat, almond) that would meet the nutrient specifications for WIC-eligible soy beverages, as described in current WIC regulations (§ 246.10(e)(12), Table 4) (*i.e.,* be nutritionally equivalent to milk). The 2020–2025 DGA currently includes fortified soy beverages, which are fortified with calcium, vitamin A and vitamin D, as part of the dairy group because they are similar to milk based on nutrient content and use in meals. Other products sold as ''milks'' but made from plants (*e.g.,* almond, rice, coconut, oat, and hemp ''milks'') may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages. Due to the rapid growth of the plant-based beverage industry and the potential over time for plant-based milk alternatives to meet the nutrient specifications of the Program, the Department requests public comment on the feasibility (*e.g.,* cost, State-wide product availability) of allowing other plant-based milk alternatives that meet Federal WIC nutrient specifications for soy beverage.

4. Add a Calcium Specification for Tofu and a Vitamin D Specification for Yogurt (§ 246.10(e)(12), Table 4)

In accordance with NASEM recommendations, the proposed rule would add nutrient specifications for calcium for tofu and vitamin D for yogurt. Currently, tofu, a milk substitution option, is required to be calcium-set prepared with calcium salts with no minimum amount of calcium. Similarly, yogurt currently has no specifications for vitamin D. These nutrients are critical for healthy development, and the DGA identify vitamin D and calcium as nutrients of public health concern as well as highlight the importance of vitamin D for calcium absorption. The DGA also note that vitamin D recommendations are harder to achieve through natural sources from diet alone and would require consuming foods and beverages fortified with this nutrient. Therefore, the Department proposes changes to ensure that WIC milk substitutes provide an amount of calcium and vitamin D that is closer to milk. The proposed rule would add nutrient specifications for calcium for tofu and vitamin D for yogurt as follows:

- Tofu with a minimum of 200 milligrams of calcium per 100 grams.
- Plain or flavored yogurt with 100 IU (2.5 micrograms) of vitamin D per 8 ounces.

The calcium specification for tofu would ensure that those who do not consume milk or yogurt due to special dietary needs (*e.g.,* allergy, medical condition) or cultural or personal preferences could still obtain calcium through the tofu option. The Department requests public comment on the proposed vitamin D amount for yogurt and on the availability of yogurts and tofu meeting the proposed specifications.

5. Increase Yogurt Substitution Amounts for Milk (§ 246.10(e)(10) and (11), Tables 2 and 3)

As recommended by NASEM, the proposed rule would increase the amount of yogurt that can be substituted for milk. This change would maintain the ratio of 1 quart of yogurt for 1 quart of milk that is currently allowed but would increase the maximum substitution of yogurt for milk from 1 to 2 quarts. By providing additional flexibility and variety this change would better accommodate participant special dietary needs and cultural and personal preferences. The following proposed monthly maximum substitution amounts for child, pregnant, postpartum, and breastfeeding participants would allow:

- 2 quarts of yogurt for 2 quarts of milk.

To further increase participant variety and choice, as well as in consideration of the proposed additional nutrient specifications for yogurt and tofu, the Department proposes to remove the limitation that no more than a total of 4 quarts of milk (for participants in Food Packages IV–VI) or 6 quarts of milk (for participants in Food Package VII) may be substituted for a combination of cheese, yogurt, or tofu. Lifting this restriction would allow participants to substitute all three (cheese, yogurt, and tofu) in combination at their current substitution rates and current (1 pound of cheese; 1 pound of tofu) and proposed (2 quarts of yogurt) maximum substitution amounts.

Although NASEM recommended a maximum range (30 to 32 ounces) for yogurt, the Department is not proposing this change. This recommendation was intended to allow more flexibility in products' package sizes that equal or add up to the proposed range. The Department recognizes the value of increasing package size flexibility for participants; therefore, the Department is proposing to allow State agencies the option to authorize additional package sizes that may not equal or add up to the full maximum monthly amount (see section J ''Maximum Monthly Allowances'') for all WIC allowable foods (excluding formula), thus allowing for greater overall flexibility and choice for participants that would apply to yogurt and other products. State agencies would continue to be required to authorize package sizes that add up to or provide the full amount. For example, State agencies would still be required to authorize packages sizes of yogurt that equal or add up to the maximum monthly allowance of 32 ounces (one quart) but may also authorize package sizes of yogurt that do not equal or add up to 32 ounces (*e.g.,* 5.3-ounce containers). Therefore, the proposed flexibility related to maximum monthly allowances negates the need to implement a maximum range specific to yogurt.

NASEM also recommended that the partial substitution option of cheese for milk be revised to only allow 1 pound of cheese plus 1 quart of yogurt for 4 quarts of milk. This was intended to help alleviate the ''dangling quart'' that arises when cheese is substituted for milk given the current option of one pound of cheese for 3 quarts of milk. However, State agencies currently have the option to make available other authorized milk alternatives to fulfill the milk maximum allowance, such as a quart of yogurt or a 12-ounce can of evaporated milk. State agencies also currently have the option to prescribe half gallon containers of milk every other month for participants in lieu of the ''dangling quart.'' Only allowing cheese plus yogurt as a partial substitution for milk would limit this option to those State agencies that authorize yogurt and require issuing a food that participants may not want. Such a change would also require State agencies that currently do not authorize yogurt to do so for participants to be able to substitute cheese. Thus, the Department is not proposing to change the current cheese substitution option.

6. Add Soy-Based Yogurts and Soy-Based Cheeses as Substitution Options for Milk (§ 246.10(e)(10) Through (12), Tables 2 Through 4)

As recommended by NASEM, this proposed rule would add soy-based yogurts and cheeses, with nutrient specifications for calcium and protein, as milk substitution options. This would provide additional flexibility, variety, and choice to the food packages to accommodate special dietary needs and cultural and personal participant preferences. Currently, only cow's milk-

based varieties of yogurts and cheeses are allowed.

For participants who do not consume the current dairy-based WIC-eligible milk substitution options (yogurt and cheese) due to allergies, lactose intolerance, or a vegan diet, non-milk-based substitution options must still deliver important nutrients. As stated above (see section 3. ''Add Nutrient Specifications for Tofu and Yogurt''), the DGA identify vitamin D and calcium as nutrients of public health concern. Therefore, in addition to the NASEM-recommended nutrient specifications for calcium and protein, the Department proposes to add a nutrient specification for vitamin D for soy-based yogurt, consistent with the proposed requirement in this rulemaking to add a vitamin D requirement for cow's milk-based yogurt. The proposed soy-based yogurt and cheese milk substitution options for child, pregnant, postpartum, and breastfeeding participant food packages would therefore include the following minimum nutrient specifications:

- Soy-based yogurts that contain ≤30 grams of total sugars and at least 250 milligrams of calcium, 6.5 grams of protein, and 100 International Units (2.5 micrograms) of vitamin D per 8-ounce serving.
- Soy-based cheeses that contain at least 250 milligram of calcium and 6.5 gram of protein per 1.5-ounce serving.

The Department requests public comment on this provision, particularly related to the marketplace availability of soy-based yogurts and cheeses meeting these proposed nutrient specifications. The Department is also requesting public comment on the possibility of a State agency option to allow, and the marketplace availability of, other plant-based yogurts that meet the proposed specifications for cow's milk-based yogurt.

As described above, the Department also requests public comment on the limit of total sugars in soy-based yogurts proposed provision with specific interest in the use of an *added sugars* limit instead of a *total sugars* limit such as the suggested added sugars limits for yogurt provided in Table 6.5 (page 303) of the NASEM report [27] or an alternative.

7. Update FDA Standard of Identity Citations for Yogurt (§ 246.10(e)(12), Table 4)

The Department proposes to update the standard of identity citations for low-fat and nonfat yogurt to conform with newly published regulations from FDA. The FDA issued a final rule [28] to amend and modernize the standard of identity for yogurt that revokes the previous standards of identity for low-fat yogurt (21 CFR 131.203) and nonfat yogurt (21 CFR 131.206) and amends the standard of identity for yogurt (21 CFR 131.200).[29] The FDA rule was effective July 12, 2021, with a compliance date of January 1, 2024.

8. Allow Reduced-Fat Yogurts for 1-Year-Old Children Without Restrictions (§ 246.10(e)(10) and (11), Tables 2 and 3)

To better align with the DGA, the Department proposes to allow yogurts other than whole fat yogurt to be issued to children 12 through 23 months of age based on an individual nutrition assessment. This proposed change would eliminate the current State Agency option to require (if necessary) a consultation with the child's health care provider to issue low-fat (0.5%–2%) or nonfat yogurt to children 12 through 23 months of age. Whole fat and low-fat yogurt, which is referred to as 'reduced-fat yogurt' in the DGA, would be the standard yogurt for issuance to children 12–23 months of age. The DGA dietary pattern for children 12 through 23 months of age includes low-fat plain yogurts in the dairy food group for this age category, to support consumption of a combination of foods to meet nutrient needs within limited calories. This change would expand yogurt variety and participant choice for children in this age group as well as reduce administrative burden.

9. Remove Cheese From the Fully Breastfeeding Food Package (§ 246.10(e)(7)(ii) and (e)(10) and (11), Tables 2 and 3)

As recommended by NASEM, this proposed rule would remove cheese as a separate food category for fully breastfeeding participants (Food Package VII). This change aligns with the DGA recommendation for reducing saturated fat consumption and would provide better balance of nutrients—the current fully breastfeeding food package provides 159 percent of the daily recommended amount of calcium from the milk and cheese categories. Currently, cheese is only a separate food category in Food Package VII. However, cheese is a milk substitution option in other food packages (except for infant food packages), meaning that cheese can be substituted for a portion of the maximum monthly allowance of milk. The Department is not proposing to remove cheese as a milk substitute option or adjust the substitution ratio. Therefore, even with the removal of the standalone cheese category, fully breastfeeding participants would still be able to receive two pounds of cheese as a partial substitute for milk.

D. Infant Foods

As recommended by NASEM and consistent with the DGA, the proposed changes would reduce the amounts of (1) infant cereal for all infants and (2) infant fruits and vegetables and infant meat for fully breastfed infants; lower the minimum age for the option to substitute the CVV for infant fruits and vegetables and increase substitution amounts; and exclude added fats as an allowable ingredient in infant foods.

These proposed revisions would not change the types of infant foods offered and would maintain alignment with DGA recommendations to introduce foods from all food groups starting at about 6 months of age and to include foods rich in iron and zinc, particularly for infants fed human milk. The proposed reductions in infant foods would provide appropriate supplemental quantities and align with the AAP's complementary feeding recommendations.

1. Reduce Infant Cereal, Infant Fruits and Vegetables, and Infant Meat (§ 246.10(e)(9), Table 1)

For all infants ages 6 through 11 months, this proposed rule would reduce the amounts of infant cereal. For fully breastfed infants, this proposed rule would reduce the amounts of infant fruits and vegetables and infant meat. In response to NASEM's review, which found that the current food package provides 150 percent of the maximum amounts of infant cereal recommended by the AAP, the proposed rule would reduce quantities of infant cereal. The reduced infant cereal quantity for partially (mostly) breastfed and fully formula fed infants would provide approximately 50 percent of the AAP-recommended amount. The reduced infant cereal quantity for fully breastfed infants would provide 100 percent of the AAP-recommended amount because iron and zinc are critical nutrients for fully breastfed infants.

According to NASEM, the current food package provides fully breastfed infants with more than a one cup-equivalent amount of fruits and

[27] *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

[28] **Federal Register**: Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Low-fat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt (86 FR 31117, June 11, 2021).

[29] *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-131/subpart-B/section%20-131.200.*

vegetables per day, an amount difficult for 6 through 11-month-old infants to consume and with no apparent nutritional rationale (the DGA and AAP do not have specific recommendations for infant fruit and vegetable consumption for this age group). Further, fully breastfed infants do not have a greater need for fruits and vegetables compared to other infants. Therefore, the amount of infant fruits and vegetables for fully breastfed infants would be reduced (from 256 ounces per month) to the amount currently provided to partially (mostly) breastfed and fully formula fed infants (128 ounces per month, or a one-half-cup equivalent per day). There is no proposed change to the amount of infant fruits and vegetables for partially (mostly) breastfed or fully formula fed infants.

Infant meat, still limited to the fully breastfed infant food package, would be reduced from 77.5 to 40 ounces per month and provide approximately 65 percent of the AAP-recommended maximum amount. This reduction addresses NASEM's recommendation based on the finding that the current food package provides 130 percent of the amount of infant meat recommended by the AAP.

In summary, this proposed rule would provide the following maximum monthly amounts of infant cereal, infant fruits and vegetables, and infant meat:

- Fully breastfed infants:
  - 16 ounces infant cereal
  - 128 ounces infant fruits and vegetables
  - 40 ounces infant meat
- Partially (mostly) breastfed and fully formula fed infants:
  - 8 ounces infant cereal
  - 128 ounces infant fruits and vegetables (no change)
  - No infant meat (no change)

Due to the low redemption of infant meat and importance of this food as an iron source for fully breastfed infants, the Department requests public comment on ways to support increased redemption and consumption of this food category, and of iron-rich foods in general, for fully breastfed infants.

NASEM recommended allowing the option to substitute 10 ounces of canned fish for the same amount of infant meat, given widespread commercial availability and high iron content of fish. However, the Department is not proposing this change for a variety of reasons. Most importantly, since NASEM released its 2017 report, updated guidance (*i.e.,* the 2020–2025 DGA and the FDA and Environmental Protection Agency's (EPA) 2021 joint advice about eating fish [30]) provided updated information about methylmercury exposure for younger children. Although fish can be among the complementary foods offered to an older infant, the DGA do not provide an infant dietary pattern with recommended amounts and types of fish, nor does the FDA or EPA provide guidance about fish consumption for infants as they do for other age groups. Currently, there is no scientific guidance for the Department to determine which varieties of fish are safe or how much to recommend for infants to limit methylmercury exposure.

Another factor the Department considered is the sodium content of canned fish. Per ounce, canned fish is typically higher in sodium than infant meat. To stay within the DGA recommendations for sodium for infants, WIC-eligible canned fish for infants would need to have a sodium amount that is close to that for infant meat (approximately 30 to 40 milligrams of sodium per 2.5 ounces). Such products do not appear to be widely available in the marketplace. In addition, package sizes currently available for canned fish pose a challenge for ensuring food safety and minimizing waste given that low acid canned foods, such as fish, should be consumed within 3 to 4 days after opening.[31] A WIC-eligible container size would need to be small enough to provide a supplemental amount for weekly consumption. To date, the Department is not aware of widespread availability of package sizes of canned fish that would provide an appropriate portion for infants over the period of a week, without significant waste. Therefore, after a careful review of updated guidance and considerations of marketplace availability, the Department does not propose to add canned fish as a substitute for infant meat.

2. Increase CVV Substitution Amounts for Infant Fruits and Vegetables, Allow Forms Other Than Fresh, and Lower the Minimum Age for Infants To Receive a CVV (§ 246.10(e)(9), Table 1)

As recommended by NASEM, this proposed rule would increase the CVV substitution amount for infants; allow the CVV for infants to be used to purchase at least one other form (canned or frozen) of fruits and vegetables in addition to fresh, which can offer similar nutrition benefits to fresh forms (see Section A–2. ''Require One Other Form of Fruits and Vegetables in Addition to Fresh'' for more information); and lower the age (from 9 to 6 months) at which the CVV can be substituted for infant fruits and vegetables. These proposed changes would increase participant choice as well as accommodate participant cultural and personal preferences. In addition, by permitting the purchase of more fruits and vegetables through the CVV, a parent or caretaker has the opportunity to introduce a wider variety and texture of fruits and vegetables (compared to the jarred variety) to the infant according to the infant's developmental readiness. As noted in the DGA, exposure to different types of food is important early in life to better develop a child's interest and willingness to eat and enjoy a variety of foods.

The proposed changes to CVV substitution amounts would allow half (64 ounces) or all (128 ounces) of jarred infant fruits and vegetables to be substituted with a $10 or $20 CVV, respectively, for all food packages for infants ages 6 through 11 months. Current regulations allow substituting only half of the jarred infant fruits and vegetables with a $4 CVV for fully formula-fed and partially (mostly) breastfed infants or a $9 CVV for fully breastfed infants. The proposed CVV substitution amount for jarred infant fruits and vegetables is based on a composite cost of $0.16 per ounce, which gives a conversion rate of about $10.00 or 64 ounces of jarred infant fruits and vegetables. This composite cost aligns with the conversion rate used by NASEM and was further substantiated by the Department using more recent national retail data. The monthly value of the CVV substitution amounts for infant fruits and vegetables will be adjusted annually for inflation consistent with the inflation adjustments made to CVV values in other food packages.

In summary, this proposed rule would provide the following CVV substitution amounts and maximum monthly allowances of jarred infant fruits and vegetables for infants ages 6 through 11 months:

- $10 CVV and 64 ounces of jarred infant fruits and vegetables, or
- $20 CVV and no jarred infant fruits and vegetables.

3. Prohibit Added Fats in Infant Foods (§ 246.10(e)(12), Table 4)

The DGA support that infants 6 through 11 months of age should be on the path to a healthy dietary pattern that is recommended for those aged 12 through 23 months. A healthy dietary

[30] Advice about Eating Fish | FDA.

[31] FoodKeeper App | *FoodSafety.gov.*

pattern includes nutrient-dense foods prepared with minimal added sugars, refined starches, or sodium as well as foods that are lean or in low-fat forms (with the exception of dairy for the 1-year-old). The recommendation to limit saturated fat to less than 10 percent of calories does not apply to children under age 2 years; however, healthy dietary patterns for 12 through 23 months have no remaining calories available for consuming additional added sugars, saturated fat, or more than the recommended amount of foods. As such, the Department proposes to exclude ''added fats'' from the ingredients authorized for infant foods. This proposed rule does not intend to imply that total fat should be restricted in this age group, rather excluding ''added fats'' from the ingredients authorized for infant foods aligns with a healthy eating pattern and anticipates the transition that will occur as children continue their eating trajectory to a healthy diet.

E. Add Infant Formula Flexibilities and Create a Separate Food Package for Partially (Mostly) Breastfeeding Participants

As recommended by NASEM, this proposed rule would add flexibilities to infant formula amounts and create a separate food package to support individual breastfeeding goals of participants and may lead to the establishment of successful long-term breastfeeding. The proposed changes would:

- Increase formula amounts in the first month for partially (mostly) breastfed infants.
- Allow all prescribed infant formula quantities to be considered ''up to'' amounts.
- Create a separate and enhanced food package for partially (mostly) breastfeeding participants.

1. Increase Formula Amounts in the First Month for Partially (Mostly) Breastfed Infants (§ 246.10(e)(1)(ii) and (e)(9), Table 1)

As recommended by NASEM, the proposed rule would increase maximum monthly infant formula amounts in the first month for partially (mostly) breasted infants from 104 fluid ounces to up to 364 fluid ounces. Consistent with current requirements, the amount of formula provided would be tailored based on an individual nutrition and breastfeeding assessment and would not exceed the maximum 364 fluid ounces per month. Tailored issuance of formula in the first month, and nutrition and breastfeeding education and support from WIC staff, not only maximizes the potential for women to achieve exclusive breastfeeding goals, but also to achieve successful partial breastfeeding when exclusive breastfeeding is not possible or desired. [Note: The revised amount of 364 fluid ounces reflects the full nutrition benefit that corresponds to the maximum month allowance of 388 fluid ounce reconstituted liquid concentrate, 384 fluid ounces ready-to-feed, or 435 fluid ounces reconstituted powder formula for partially breastfed infants aged one through three months. Therefore, this proposed provision eliminates the need for the birth to one month feeding category.]

This proposed change is intended to encourage participants in the early postpartum period who are not certain they can succeed at breastfeeding to try to breastfeed. This change would increase flexibility and support for any amount of breastfeeding during the first month by providing partially (mostly) breastfeeding participants an amount of formula to support their desired level of breastfeeding. As NASEM noted, this change is intended to prevent the premature categorization of an infant as ''fully formula fed'' and a mother as ''postpartum'' and allow the mother to receive the partially (mostly) breastfeeding food package to better support her nutritional needs and her breastfeeding goals, with the ultimate goal of extending the duration of breastfeeding.

2. Allow All Prescribed Infant Formula Quantities To Be Considered ''Up To'' Amounts (§ 246.10(e)(9), Table 1)

As recommended by NASEM and consistent with FNS policy and guidance, formula quantities in all infant food packages would be ''up to'' amounts. Currently in regulations there are maximum monthly allowances and minimum, or ''full nutrition benefit,'' [32] (FNB) amounts. The proposed change to ''up to'' amounts would emphasize the importance of assessing, by WIC staff, the actual need for formula of the breastfeeding mother-infant dyad. Infant formula amounts for breastfed infants, even those in the fully formula-fed category, should be individually tailored. This change would allow the amount to be less than the FNB. The intent of this proposed change is to reduce interference with the successful establishment of the mother's desired breastfeeding behavior while issuing formula amounts for infants that meet their nutritional needs.

Although not proposing revisions to the iron standard for infant formula the Department seeks comment about the current iron requirement. Iron is important at all stages of a child's development. Young children who don't get enough iron are at higher risk for developmental problems. Iron fortified infant formula can help reduce iron deficiency in formula fed and partially breastfed babies. The NASEM review found that the current iron requirement for infant formula supports the needs of infants ages 0 to less than 12 months, without exceeding the Upper Limit for this age group, and also found that there was inadequate evidence available during the time of the study to support changing the concentration of iron required in WIC-eligible formula.

Reducing iron deficiency in children remains a public health priority and is a Healthy People 2030 objective. In addition, the NASEM review observed that inconclusive evidence suggests that iron intake in infants is associated with long-term cognitive, motor, and social-emotional outcomes and that updated data are needed to understand the optimal level of infant formula iron, particularly in cases where the baseline iron status of infants is poor compared to cases where iron status is adequate. The Department requests public comment on the current iron standard of 1.5 milligrams of iron per 100 kcal at standard dilution, with specific interest in the effect of reducing the standard while providing sufficient supplementation to prevent iron deficiency in infants.

3. Create a Separate and Enhanced Food Package for Partially (Mostly) Breastfeeding Participants (§ 246.10(e)(5), (7), (10), and (11), Tables 2 and 3)

Currently, pregnant (singleton pregnancy) and partially (mostly) breastfeeding participants receive the same food package (Food Package V), with no differentiation in monthly maximum allowances for the foods provided. As recommended by NASEM, this proposed rule would create separate food packages, with food package V–A for pregnant participants and food package V–B for partially (mostly) breastfeeding participants and pregnant participants with two or more fetuses (moving the latter category from Food Package VII to Food Package V–B). The food package changes for partially (mostly) breastfeeding participants would provide greater CVV and canned fish amounts compared to the pregnant participant food package. For more

[32] Full nutrition benefit is defined in § 246.2: The minimum amount of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of § 246.10(e)(9) for each food package category and infant feeding variation (*e.g.,* Food Package IA fully formula fed, IA–FF).

information about the changes to the CVV amounts and canned fish, please see sections A: ''Fruits and Vegetables'' and H: ''Canned Fish.''

These enhancements to the partially (mostly) breastfeeding food package are intended to promote breastfeeding among participants who are not exclusively breastfeeding their infants and align with the higher calorie needs of breastfeeding individuals.

F. Breakfast Cereals

As recommended by NASEM, the proposed revisions would change the criteria for whole grain breakfast cereals and require that all breakfast cereals meet the criteria for whole grain. These changes are designed to increase the amount of whole grains in the food packages that provide whole grains and improve consistency with FNS Child Nutrition Programs (CACFP, the National School Lunch Program, and the National School Breakfast Program).

1. Change Whole Grain Criteria for Breakfast Cereals (§ 246.10(e)(12), Table 4)

In response to NASEM's recommendation to align the whole grain criteria with the FNS Child Nutrition Programs' whole grain criteria, the Department proposes to require that WIC-eligible whole grain breakfast cereals contain a whole grain as the first ingredient. Currently, WIC-eligible whole grain breakfast cereals must have whole grain as the primary ingredient by weight and meet the FDA labeling requirements for making a health claim as a ''whole grain food with moderate fat content'' but does not have to have whole grain as the first ingredient. This change in criteria streamlines the process of determining whether a breakfast cereal is a whole grain cereal and may allow a broader variety of whole grain products for participants to choose from, compared to the existing criteria.

2. Require All Breakfast Cereals Meet Whole Grain Criteria (§ 246.10(e)(10) Through (12), Tables 2 Through 4)

The 2020–2025 DGA notes that 98 percent of Americans fall below recommendations for whole grain intake and 74 percent exceed limits for refined grains. The DGA also note that 80 percent of refined grains are generally eaten as separate food items, such as cereals, breads, tortillas, pasta, rice, or pancakes, and that fiber is a nutrient of public health concern since low intakes are associated with health concerns. Additionally, NASEM's report indicates that 100 percent of pregnant, breastfeeding, and postpartum WIC participants and over 93.3 percent of child participants do not meet recommended whole grain intakes.

To address inadequate consumption of whole grains and excess consumption of refined grains among WIC participants, NASEM recommended that all WIC-eligible breakfast cereals meet the criteria for whole grain cereal. This is also consistent with the DGA recommendation to shift intake from refined to whole-grain versions of foods to increase whole grain intake and would increase nutrition security and equity by increasing participant access to whole grains. Therefore, the Department proposes to require that all WIC-authorized breakfast cereals be whole grain, in accordance with the criteria described in section one (above). Currently, only one-half of the total number of breakfast cereals on the State agency's authorized food list must be a whole grain cereal.

The requirement that all breakfast cereals meet the criteria for whole grain cereal was first recommended by the IOM in its 2006 report and was included in the Department's 2006 proposed rule. However, the requirement was not included in the 2007 interim rule due to concerns that the proposed whole grain nutritional requirement for breakfast cereal would eliminate corn and rice-based cereals, which can be alternatives for people with allergies or intolerances. It would have also significantly limited the variety and choice of WIC-eligible breakfast cereals due to the lack of availability of whole grain cereals in the marketplace at the time. As a result, the 2007 interim rule revised the nutrient criteria to require at least one-half of all breakfast cereals on the State's authorized food list meet the whole grain requirement.

In its most recent review, NASEM reviewed product information provided by two large national breakfast cereal manufacturers and found that a sufficient number of breakfast cereals (including gluten-free varieties for those with celiac disease, allergies or intolerances) would meet the proposed whole grain criteria. NASEM also found a significant expansion in the availability of whole grain products in the marketplace since 2006, thus mitigating previous concerns.

Sufficient marketplace availability is an important consideration before implementing this change since breakfast cereals are a key source of important nutrients (*e.g.,* iron). Therefore, the Department specifically requests public comment on this change to better understand the impact of this provision. While USDA is not proposing a change to the specifications for sugar in breakfast cereals, the Department recognizes the 2020–2025 DGA recommendation to limit consumption of foods higher in *added sugars,* and requests public comment with regard to the use of an *added sugars* limit instead of a *total sugars* limit for breakfast cereal. The Department specifically seeks comment on an *added sugars* limit for breakfast cereal that would maintain palatability of the products, described by NASEM as significant contributors to micronutrient intakes in the U.S. population and a source of whole grains, while achieving the dietary recommendation to limit added sugars consumption and ensuring marketplace availability.

G. Whole Wheat Bread, Whole Grain Bread, and Other Whole Grain Options

As recommended by NASEM and supported by the DGA, the proposed revisions would reduce the amount of bread provided to children, increase the amount of bread provided to pregnant, postpartum, and breastfeeding participants, change the criteria for WIC-eligible whole grain breads, and expand whole grain options.

1. Revise Maximum Monthly Allowances for Whole Wheat and Whole Grain Bread and Other Whole Grain Options (§ 246.10(e)(10) and (11), Tables 2 and 3)

As recommended by NASEM, with modification, the proposed changes would provide whole wheat bread, whole grain bread, and whole grain options in supplemental amounts that better align with the DGA, particularly for pregnant, postpartum, and breastfeeding participants. The proposed revision would reduce (from 32 to 24 ounces) the quantity of bread or whole grain options for children. The reduced amount for children represents the upper end of NASEM's recommended range of 16 to 24 ounces and would provide 27 to 53 percent of the whole grains subgroup amount recommended in the DGA Healthy U.S.-Style Dietary Pattern.[33] The proposed revision would increase (from 16 to 48 ounces) the amount for pregnant, postpartum, and breastfeeding participants. This proposed increased

[33] For children ages 12 to 23 months, the reduced whole wheat bread/whole grain bread quantity provides 40–53% of the DGA based on 1.5–2 oz eq/day for 700–1,000 kcal. For children 2 to 4 years, the reduced whole wheat bread/whole grain bread quantity provides 27–53% of the DGA based on 1.5–3 oz. eq/day for 1,000–1,600 kcals. For postpartum, pregnant, and breastfeeding participants, the increased whole wheat bread/whole grain bread quantity provides 40%–53% of the DGA based on 3–4 oz eq/day for 2,000–2,400 kcals.

amount exceeds NASEM's recommended amount (24 ounces). The Department's proposed amount would provide 40 to 53 percent of the DGA recommended whole grains subgroup amount, while the amount recommended by NASEM would provide 13 to 27 percent. The increased amount would provide and encourage consumption of whole grains, consistent with the DGA, in quantities closer to NASEM's definition of a supplemental amount and align with common package sizes found in the marketplace.

The proposed changes would provide the following monthly maximum amounts of whole wheat bread, whole grain bread, and whole grain options:

- Children 1 through 4 years: 24 ounces
- Pregnant, Postpartum, and Breastfeeding: 48 ounces

NASEM also recommended a range for whole grains; however, the Department is not proposing this change. To achieve NASEM's intent to provide greater flexibility, the Department instead proposes changes to requirements related to the maximum monthly amounts (see Section J: ''Maximum Monthly Amounts''). The Department will maintain the requirement for State agencies to provide participants with the full amount by ensuring one or more State-authorized package sizes equal or add up to the full amount, while providing the flexibility to also authorize packages sizes that may not add up to full amount, if the participant chooses to take less. This proposed change could potentially ease the burden on small vendors who have expressed difficulty stocking the currently required package sizes.

The Department is not in support of NASEM's recommendation to limit bread options to 100 percent whole wheat as this would remove other whole grain breads from being WIC-eligible, thus limiting variety and choice for participants. Currently, State agencies can authorize whole wheat and/or whole grain bread such as whole grain rye, pumpernickel, oat, and honey wheat.

2. Change Criteria for Whole Grain Breads (§ 246.10(e)(12), Table 4)

Using NASEM's principle of aligning with CACFP guidance on breakfast cereal whole grain criteria, the Department is similarly proposing to change the whole grain criteria for WIC-eligible whole grain bread, consistent with CACFP. Currently, WIC regulations require whole grain bread meet all of the following: conform to FDA standards of identity as applicable, have a whole grain as the primary ingredient by weight, and meet the FDA labeling requirements for making a health claim as a ''whole grain food with moderate fat content.'' The proposed change would maintain the requirement for the FDA standards of identity, as applicable, and replace the primary ingredient and FDA labeling criteria with the requirement that whole grain bread contain at least 50 percent whole grains with the remaining grains being either enriched or whole grains. Because the whole grain content of food products is not always easily identifiable on a product label, the Department would provide additional guidance on evaluation of grain products as needed.

The Department requests public comment on the impact of adopting the revised criteria for whole grain breads.

3. Expand Whole Grain Options (§ 246.10(e)(10) Through (12), Tables 2 Through 4)

The Department proposes to expand whole grain options beyond those specifically recommended by NASEM, which would provide participants with additional variety, and choice to accommodate special dietary needs (*e.g.,* food allergies) and cultural and personal preferences while promoting increased consumption of whole grains overall. The proposed expansion of whole grain options is responsive to participant requests for more choices for bread substitutions, while still providing important priority nutrients, and is intended to increase whole grain consumption by offering a greater variety of grains.

The DGA recommend making at least half of all grains consumed whole grains and notes that whole grains are currently under-consumed by the U.S. population. Further, as noted above, NASEM's report indicates that refined grain intake of WIC participants is excessive. The current whole grain options for WIC participants are brown rice, bulgur, oats, whole-grain barley, and whole wheat macaroni products without added sugars, fats, oils, or salt (*i.e.,* sodium), and soft corn or whole wheat tortillas. The proposed additional whole grain options would add: quinoa; wild rice; millet; triticale; amaranth; kamut; sorghum; wheat berries; tortillas made with folic acid-fortified corn masa flour (once available in the marketplace); corn meal (including blue); teff; buckwheat; and whole wheat pita, English muffins, bagels, and naan. These additional options are nutritionally appropriate items that WIC State and local agency staff and participants expressed interest in adding to the food packages via NASEM's public comment process. The additional proposed whole grain options align with products allowed in other FNS Programs.

H. Canned Fish

In alignment with the DGA and NASEM recommendations, the proposed rule would add canned fish, which refers to processed products in cans, pouches, or other shelf-stable containers (see § 246.10(e)(12)), to several food packages, including the child food packages (for children ages 2 through 4 years) and food packages for pregnant, postpartum and partially (mostly) breastfeeding participants (currently fish is only provided to fully breastfeeding participants) and reduce the amount of canned fish currently provided to fully breastfeeding participants. These changes would expand the categories of participants receiving canned fish, creating more equitable access to this under-consumed food.

NASEM recommended adding canned fish to the additional food packages on a three-month rotation, alternating with peanut butter and legumes, to achieve a cost-neutral change. In this proposed rule, the Department instead proposes to maintain the monthly provision of peanut butter and legumes and add canned fish on a monthly basis to pregnant, postpartum, and partially (mostly) breastfeeding and child food packages (for children 2 through 4 years). In evaluating the three-month rotation recommendation, the Department determined that this could be confusing to participants and administratively challenging to implement. There are currently no WIC foods provided on a three-month rotation. In addition, the cost neutrality constraints that NASEM applied in making its recommendations are outweighed by the Department's goals of promoting nutrition security and equitable access to foods.

1. Add Canned Fish to Food Packages for Children (2 Through 4 Years) and Specify WIC-Eligible Varieties for Children (§ 246.10(e)(4)(ii), and (10) Through (12), Tables 2 Through 4)

As recommended by NASEM, with modifications, and in alignment with the DGA, this proposed rule would add 5 ounces of canned fish per month to the food packages for children ages 2 through 4 years. The only types of canned fish allowed for children would be salmon, sardines, and Atlantic mackerel. It is important to note that with the implementation of this proposed change, WIC nutrition

education would need to encourage parents/caretakers to select boneless canned fish or remove bones prior to consumption to prevent choking; choose lower sodium varieties; use the fish within 3 to 4 days of opening the can to ensure food safety; and serve fish varieties and amounts that limit the potential for methylmercury exposure. In addition, the Department would encourage WIC State agencies to authorize smaller package sizes whenever possible (*i.e.,* 2.5 ounces).

The proposed monthly maximum amount of canned fish for children (2 through 4 years of age) would be as follows:

- Children 2 through 4 years: 5 ounces canned fish

Based on the FDA and Environmental Protection Agency (EPA) 2014 joint advice on eating fish for breastfeeding and pregnant individuals, individuals who might become pregnant, and children, NASEM also recommended canned fish for 1-year-old children and allowing fish to be substituted for infant meat. However, based on updated Federal guidance, the Department is not proposing these changes. Specifically, in 2021 [34] [35] the FDA and EPA updated their joint advice about eating fish, which incorporates 2020–2025 DGA recommendations; identifies fish types and serving sizes safe for consumption based on estimated methylmercury exposure; and newly includes advice for children age 1 year (previous advice included recommendations for children 2 to 11 years), including a subset list of ''Best Choices'' that contain lower methylmercury to support children age 1 year in consuming the quantities recommended in the Healthy U.S.-Style Dietary Pattern without exceeding limits for estimated methylmercury exposure. The advice also indicates that many commonly consumed fish types (including light canned tuna, a WIC-eligible variety) should be limited to the amounts in the FDA–EPA Fish Advice (footnote) due to their methylmercury content. To the Department's knowledge, other WIC-eligible fish varieties that are part of the ''Best Choices'' subset (*i.e.,* salmon, sardines, and Atlantic mackerel) are not widely available in the marketplace in sizes appropriate for infants or 1-year old children to meet the FDA–EPA guidance and DGA recommendations or to provide supplemental amounts. Therefore, it is not feasible to safely include fish in WIC food packages for infants or 1-year-old children.

The Department specifically requests public comment on the availability of 3-ounce or smaller package sizes (*e.g.,* 1 oz. pouch) of salmon, Atlantic mackerel, and sardines [36] in boneless varieties for the potential of adding fish to the 1-year-old food package. The Department also requests public comment on the marketplace availability of canned light tuna in package sizes safe for consumption by young children (*i.e.,* 2 oz.).

2. Add Canned Fish in Food Packages for Pregnant, Postpartum, and Partially (Mostly) Breastfeeding Participants, Revise Amounts for Fully Breastfeeding Participants, and Revise WIC-Eligible Varieties (§ 246.10(e)(5)(ii), (e)(6)(ii), and (e)(10) Through (12), Tables 2 Through 4)

As recommended by NASEM, with modifications, this proposed rule would add canned fish to the pregnant, partially (mostly) breastfeeding, and postpartum participant food packages on a monthly basis. Currently, canned fish is included only in the fully breastfeeding food package and the proposed changes would decrease the monthly amount from 30 to 20 ounces. Proposed monthly fish amounts for these food packages align with NASEM's supplemental approach and DGA dietary patterns. In addition, the proposed monthly amounts of fish are consistent with NASEM's overall approach to enhancing the food package for partially (mostly) breastfeeding participants to promote breastfeeding.

The proposed monthly maximum amounts of canned fish for pregnant, postpartum, partially (mostly) and fully breastfeeding participants would be as follows:

- Pregnant and postpartum: 10 ounces canned fish
- Partially (mostly) breastfeeding: 15 ounces canned fish
- Fully breastfeeding: 20 ounces canned fish

Additionally, the FDA and EPA currently do not have methylmercury data on the commercial canned fish product ''jack mackerel'' and do not include this product in their joint advice about eating fish. Furthermore, the FDA guidance on defining jack mackerel species referenced in § 246.10(e)(12) is no longer available. Due to the lack of data on methylmercury levels in jack mackerel, the Department is proposing to eliminate jack mackerel as an allowable fish type for the WIC Program.

The Department will use any updated FDA–EPA guidance on fish, as appropriate, when developing a final rule as it relates to fish types and serving sizes safe for consumption based on estimated methylmercury exposure.

I. Legumes and Eggs

As recommended by NASEM, the proposed changes would require State agencies to authorize canned legumes in addition to dried legumes. The Department also proposes to require State agencies to authorize peanut butter and legumes, and to give State agencies the option to authorize tofu, as substitutes for eggs. Such authorization would be to provide greater variety and choice for participants who have an egg allergy, are vegan, or for other reasons (*e.g.,* cultural preferences) as determined by the State agency's policy. Currently there is no substitution option for eggs, except for participants experiencing homelessness. These proposed revisions expand upon NASEM's recommendation to permit the substitution of legumes for eggs if a participant has an egg allergy or is vegan.

While NASEM recommended reducing quantities of peanut butter and legumes to supplemental levels via a three-month rotation (previously described in section H ''Canned Fish''), the Department anticipates that such an approach would pose undue challenges for State agencies and participants. Further, the Department is unable to reduce monthly amounts of peanut butter and legumes since they are not generally available in smaller package sizes than those currently authorized. As such, the Department will maintain the current monthly amounts of peanut butter and legumes. The following changes related to legumes and eggs are proposed:

1. Require Both Dried and Canned Legumes (§ 246.10(e)(10) Through (12), Tables 2 Through 4)

As recommended by NASEM, this proposed change would require State agencies to authorize dried and canned legumes. Currently only dried legumes are required, and it is a State agency option to allow canned legumes. For participants in States that do not exercise this option, the change would reduce a potential barrier to preparing and consuming legumes for participants who may not have the time or ability to prepare dried beans. State agencies will

[34] *https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish.*

[35] Advice about Eating Fish | FDA.

[36] This list is not representative of all fish included in FDA's ''Best Choices'' category; the full list is available at: *https://www.fda.gov/food/metals-and-your-food/technical-information-development-fdaepa-advice-about-eating-fish-those-who-might-become-or-are.*

retain their current authority to authorize only low/lower sodium canned varieties.

The Department requests public comment on any potential barriers and/or unanticipated effects of requiring State agencies to offer both dried and canned legumes.

2. Require Authorization of Legumes and Peanut Butter as Substitutes for Eggs and Allow State Agencies to Choose To Authorize Tofu To Substitute for Eggs (§ 246.10(e)(10) Through (12), Tables 2 Through 4)

Based on NASEM's recommendations, with modification, the proposed changes would require that State agencies allow the substitution of eggs with legumes and peanut butter if a participant has an egg allergy, is vegan, or for other reasons (*e.g.,* cultural preferences) as determined by State agency policy and allow State agencies the option to authorize tofu as a substitute for eggs. Like eggs, legumes and peanut butter (to a lesser extent) are sources of choline, and both are sources of iron. Given iron's role in growth and development, the prevalence of inadequate intake among the WIC population, and the health consequences of inadequate intake, offering foods with iron is critical to WIC participants' health. In addition, peanut butter and legumes are required foods in the food packages, therefore the Department anticipates no additional administrative effort related to identifying and authorizing these foods as substitutes for eggs. For these reasons, the Department has determined that requiring peanut butter and legumes as substitutes for eggs is nutritionally appropriate, promotes equity, and will not increase administrative burden.

The Department also proposes to allow State agencies the option to authorize tofu as a substitute for eggs. Like eggs, tofu is a source of choline and iron. Currently, State agencies have the option to authorize tofu as a milk substitute and as of publication of this proposed rule, 54 of the 89 State agencies permit this option. Allowing the option to authorize it as an egg substitute creates more State agency flexibility and would give participants more options, particularly for those participants with special dietary needs that preclude the ability to receive peanut butter or legumes in lieu of eggs.

Since eggs are a source of heme iron (more readily absorbed by the body) and legumes, peanut butter, and tofu are sources of non-heme iron (less readily absorbed), appropriate food package tailoring and nutrition education would need to address other food sources of iron, especially for participants determined to have low iron levels.

This change would allow children and all other participant categories (except infants) to substitute the following for one dozen eggs if a participant has an egg allergy or is vegan, or for other reasons (*e.g.,* cultural preferences) as determined by the State agency's policy:

- 1 pound dry or 64 ounces canned legumes
- 18 ounces peanut butter
- 1 pound tofu (at State agency option)

The Department recognizes that it is currently a State agency option to authorize tofu as a substitute for milk, therefore, not all State agencies authorize this food item. The Department requests public comment on the impact of requiring State agencies to authorize tofu as an egg substitute for participants who have an egg allergy or are vegan, or for other reasons (*e.g.,* cultural preferences) as determined by the State agency's policy.

The Department also requests public comment on allowing other nut and seed butters as a legume or peanut butter substitution option to further accommodate participants with food allergies. To be consistent with the scientifically based standards described in this proposed rule, the Department is especially interested in public comment on the commercial availability of nut and seed butters that are nutritionally equivalent (or close) to peanut butter/legumes in terms of the priority nutrients (*e.g.,* protein, iron).

J. Maximum Monthly Allowances (§ 246.10(b)(1)(iii), (b)(2)(i), and (b)(2)(ii)(A); § 246.11(a)(1))

To further expand participant variety and choice, this proposed rule would allow State agencies more flexibility when authorizing product package sizes (with the exception of WIC formula) [37] for their approved product lists. WIC State agencies would continue to be required to make available the full maximum monthly allowance (MMA) amounts to participants (*i.e.,* at least one package size, or a combination of sizes, must add up to the full MMA provided in each of the food packages). However, this change would allow State agencies to authorize additional product package sizes that provide less than the full MMA. Participants could therefore choose to redeem less than the full amount their food package provided. This flexibility would allow States to offer more product package sizes, thus giving participants more variety and choice of foods available with their WIC food benefits. The Department encourages State agencies to provide participants with as much variety and choice as possible for as many food categories as possible, to the extent that is administratively and financially feasible given cost containment measures, to meet their participants' needs. The Department recognizes that, as part of their administrative option granted under § 246.10(b)(1)(i), modifying authorized package sizes is among the strategies State agencies use to control costs for the set funds they receive to administer their WIC programs; therefore, the Department is requesting public comment on requiring State agencies to authorize both package sizes that equal or add up to the maximum monthly allowance (to ensure participants have a pathway to receiving the full food benefits to which program participation entitles them) and packages sizes that do not (to ensure greater variety and choice).

Additionally, to accommodate instances when there are two or more participants from the same household (*e.g.,* a breastfeeding participant and a two-year old child), currently State agencies may aggregate food amounts but may not authorize container sizes that exceed the MMA for an individual participant. In current guidance, the Department notes that aggregation may be useful when benefits are issued via electronic benefits transfer (EBT). With the vast majority of State agencies now issuing benefits via EBT and the rest working toward EBT in the near term, the Department is proposing to allow State agencies to authorize package sizes that exceed the MMA for each individual food package to increase variety and choice for households with multiple participants. However, the household would still not be able to exceed the total of the combined MMA. Additionally, the Department would still require that foods on State agency authorized food lists meet the needs of each individual food package prescription. Therefore, some foods may not be aggregated for issuance to two or more participants from the same family but in a different participant category (*e.g.,* canned fish where certain types authorized for pregnant, postpartum, and breastfeeding participants are not authorized for child participants). Additionally, the requirement in § 246.10(b)(2)(ii)(D) that local agencies advise participants or their caretakers

[37] WIC formula includes infant formula, exempt infant formula and WIC-eligible nutritionals. WIC formula must be authorized in sizes that correspond with the maximum monthly allowances per § 246.10(e)(9) and (11).

that the supplemental foods are only for the participant's personal use remains in effect. This information is an important component of nutrition education for agencies that aggregate food benefits.

This proposed flexibility would not change the requirements in § 246.10(b)(2)(i) that State agencies identify the brands and packages sizes of foods that are acceptable for use in the Program in their State and must provide to local agencies, and include in the State Plan, a list of acceptable foods and their maximum monthly allowances. The Department requests comments from stakeholders about its intention to increase State agency flexibility when authorizing package sizes for WIC-eligible foods.

IV. Miscellaneous Related Revisions and Editorial Corrections

This part describes additional proposed amendments, which include updating the definition of *Individual with disabilities,* adding breast pumps as a Program benefit and corresponding participant violation provisions, clarifying the definition of WIC-eligible nutritionals, adding clarifying language to nutrition tailoring, updating the base year for the annual inflation adjustment to the CVV amounts, and making conforming revisions and editorial corrections.

A. Definition of Individual With Disabilities (§ 246.2)

The proposed rule would update the definition of *disability* by removing the words ''handicapped person'' and adding that the term disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more of the major life activities of such individual, a record of such an impairment, or being regarded as having such an impairment, as described in 28 CFR 35.108.

B. Breast Pumps as a Program Benefit (§§ 246.2, 246.7(j)(10) and 246.16(u)(2)(i)))

The proposed rule would include breast pumps as a Program benefit and add reference to the sale or offer to sell breast pumps to the definition of *participant violation* (§ 246.2). While previous FNS guidance excluded breast pumps from participant violations, upon further review, FNS has determined that breast pumps are a Program benefit when purchased with WIC funds and provided to participants. Therefore, consistent with other Program benefits, breast pumps are covered by the benefits in the regulatory definition of *participant violation.* A conforming regulatory provision (§ 246.7(j)(10)) would ensure that every Program applicant, parent or caretaker be informed that selling or offering to sell WIC benefits, including cash-value vouchers, food instruments, EBT cards, supplemental foods, or breast pumps in person, in print, or on-line is a participant violation.

While previous guidance excluded breast pumps from participant violations in part to provide some protection for infants from being sanctioned or disqualified from the Program, State agencies are provided other regulatory flexibility for this purpose (*e.g.,* an exception for infants for mandatory disqualification as described in § 246.12(u)(2)(ii)). Additionally, the dollar threshold at § 246.12(u)(2)(i) for disqualification is proposed to be increased from $100 to $1,000, which FNS feels is appropriate to indicate a pattern of Federal participant violations. This update means that whenever the State agency assesses a claim of $1,000 or more, assesses a claim for dual participation, or assesses a second or subsequent claim of any amount, the State agency must disqualify the participant for one year.

C. WIC-Eligible Nutritionals (§ 246.2)

The Department is proposing to clarify the definition of WIC-eligible nutritionals, enteral products specifically formulated to provide nutritional support for those with qualifying conditions (see § 246.2 for full definition), to convey the intent that homemade formulas and manufactured products in the marketplace that appear to be blenderized foods (*i.e.,* conventional foods liquified in a blender) do not meet WIC-eligible nutritionals requirements.

D. Nutrition Tailoring (§ 246.10(c))

The proposed rule would add clarifying language to nutrition tailoring (§ 246.10(c)) that exists in current policy, as indicated in § 246.10(e)(9) through (11). The current regulation for nutrition tailoring focuses on eliminating or reducing foods and was meant to specify the conditions under which the full food benefit (*i.e.,* the maximum monthly allowance) is not provided to a participant. However, nutrition tailoring also involves making substitutions to the types and forms of foods, as specified in § 246.10(e)(9) through (11), and is meant to accommodate an individual participant's food allergy or intolerance, cultural preferences, and medical or special dietary needs, as well as situations where the participant refuses or cannot use the item (*e.g.,* situations such as a lack of access to refrigeration). The proposed rule further clarifies that offering a participant substitutions in accordance with State agency policy and Federal regulations, is the first step before eliminating or reducing foods and must be based on their nutrition assessment.

E. Annual Inflation Adjustment for the Cash-Value Voucher (§ 246.16)(j))

The Department is proposing to update the base year (from 2008 to 2022) for the annual inflation adjustment to the CVV amounts primarily because the proposed rule establishes three different CVV amounts ($24, $43, and $47) compared to the two CVV amounts prescribed under current regulations ($9 and $11) making it impractical to base inflationary adjustments on the prior standard. Furthermore, the provision for the proposed CVV amounts was signed into law temporarily for fiscal year (FY) 2022 and adjusting the base year for the inflation adjustment to 2022 will allow the Department to more accurately adjust for inflation by setting the base year to be the first year that these new amounts were provided to WIC participants. In addition, this proposed rule specifies the Consumer Price Index used in the inflation adjustment calculation. The inflation-adjusted value of the voucher shall be equal to a base value increased by a factor based on the Consumer Price Index for All Urban Consumers (CPI–U) for fresh fruits and vegetables.

F. Conforming Revisions and Editorial Corrections (§ 246.10)

The proposed rule includes conforming revisions and corrections to typographical and grammatical errors as well as to improve conciseness and clarity. These changes will have no substantive effect on the public.

V. Implementation

The Department proposes that State agencies would have 18 months from publication of the final rule to implement the revisions to the food packages and all other provisions in the rule. During the 18-month phase-in period, State agencies would be required to issue food benefits based on either the revised food packages or current food packages but could not combine the two within any food package. For example, a State agency could not add canned fish to the current foods and quantities available in the child's food package. State agencies may, depending on their systems, phase-in the revised food packages on a participant category basis. To minimize

participant and vendor confusion, the Department proposes that once the State agency begins issuing each new food package, it must be done on a Statewide basis. The Department seeks comments from State agencies on the type and scope of administrative burden that may be associated with implementing the provisions in this proposed rule in this manner.

Procedural Matters

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule has been determined to be economically significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Regulatory Impact Analysis Summary

As required for all rules that have been designated as economically significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this proposed rule. The complete RIA follows this proposed rule as an appendix. The following summarizes the conclusions of the regulatory impact analysis:

Need for Action

Section 17 of the Child Nutrition Act mandates that the United States Department of Agriculture (USDA) conduct a comprehensive scientific review of the WIC food packages at least every ten years and revise the foods available, as needed, to reflect nutritional science, public health concerns, and cultural eating patterns (42 U.S.C. 1786(f)(11)(C)). This proposed rule would revise regulations governing the WIC food packages to align with the Dietary Guidelines for Americans 2020–2025 (DGA) [38] reflect recommendations made by the National Academies of Sciences, Engineering, and Medicine (NASEM),[39] while promoting nutrition security and equity and taking into account program administration considerations.

Benefits

The proposed changes to the WIC food packages are intended to provide WIC participants with a wider variety of foods that align with the latest nutritional science, provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participant personal and cultural food preferences and special dietary needs, and better promote and support the establishment of successful long-term breastfeeding.

The proposed increases in the value of the cash value voucher (CVV) for fruits and vegetables, increases in canned fish, and changes to whole grain requirements will better align the WIC food packages with the 2020–2025 DGA. The DGA identified average daily food group intakes of fruits, vegetables, seafood, and whole grains as falling below the recommended intake ranges for adults and children [40] Increased consumption of these foods is expected to increase intakes of key nutrients, including dietary fiber, potassium, vitamin D, vitamin A, vitamin C, folate, and polyunsaturated fatty acids. Dietary fiber, potassium, and vitamin D, considered nutrients of public health concern in the general U.S. population, are currently also under-consumed by WIC participants.[41] [42]

NASEM's analysis estimates that in order to meet half of the recommended intakes of fruits and vegetables, WIC participants would need to spend $25, $45, or $50 (adjusted for inflation to FY 2024), depending on participant category, to meet 50 percent of the recommended intakes for fruits and vegetables. This suggests that the current CVV levels of $9 for child participants and $11 for pregnant, postpartum, and breastfeeding participants only provide enough for around 19 percent and 12 percent of recommended fruit and vegetable intakes for child, pregnant, postpartum, and breastfeeding participants, respectively. By increasing the value of the CVV to the levels proposed by NASEM to meet 50 percent of the recommended fruit and vegetable intakes, the proposed rule is expected to significantly increase fruit and vegetable purchases and consumption among WIC participants.

While it is difficult to quantify the full extent of projected benefits associated with the revisions under this proposed rule, USDA's and NASEM's analyses find that the revisions better align the WIC food packages with the latest nutrition recommendations in the DGA and accordingly will support participants in achieving healthy dietary patterns. The 2020–2025 DGA highlight the importance of a healthy dietary pattern to help achieve a healthy body weight and reducing the risk of chronic disease. The DGA also emphasize the importance of exposing young children to nutrient-dense foods at an early age to support the establishment of healthy dietary patterns. By supporting healthy dietary patterns among pregnant women, the proposed changes to the WIC food packages will advance the Program's capacity to address nutrition-related causes of maternal and infant morbidity and mortality. The Department finds that this proposed rule presents an effective approach to supporting pregnant participants and families with infants and young children in achieving balanced, healthy diets and broadly promoting public health.

Costs

The Department estimates that the proposed rule to revise regulations governing the WIC food packages would result in a net increase in Federal WIC spending of $4.1 billion, in the form of Federal transfer payments for increased WIC food expenditures, over five years from FY 2024 through FY 2028. This increase in Federal WIC food expenditures is driven by the proposed increase in the CVV, which is estimated to increase WIC food expenditures by $4.9 billion over five years when compared to current CVV levels as outlined in 7 CFR 246.10. However, the CVV levels proposed in this rule were recently enacted on a temporary basis for FY 2022. As a result, when compared to the FY 2022 WIC food

[38] U.S. Department of Health and Human Services/U.S. Department of Agriculture, Dietary Guidelines for Americans, 2020–2025. Available at internet site: *Home | Dietary Guidelines for Americans.*

[39] National Academies of Sciences, Engineering, and Medicine. ''Review of WIC Food Packages: Improving Balance and Choice: Final Report,'' 2017. Available online at: *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

[40] Gleason, S., Hansen, D., & Wakar, B. (2021). Indicators of diet quality, nutrition, and health for Americans by program participation status, 2011–2016: WIC report. Prepared by Insight Policy Research, Contract No. GS–10F–0136X. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Michael Burke. *www.fns.usda.gov/research-and-analysis.*

[41] Ibid.

[42] Borger, C., Zimmerman, T., Vericker, T., et al. (2020). WIC Infant and Toddler Feeding Practices Study 2: Fourth Year Report. Prepared by Westat, Contract No. AG–3198–K–15–0033 and AG–3198–K–15–0050. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Courtney Paolicelli. Available online at: *www.fns.usda.gov/research-and-analysis.*

packages, the CVV increase proposed in this rule would not impact Federal WIC expenditures and would instead make permanent the CVV levels enacted in FY 2022. With the CVV impact zeroed out of the overall cost estimate for the proposed rule, the remaining provisions are expected to result in a net decrease in Federal WIC food spending of $821 million over five years when compared to the food packages as enacted in FY 2022. These estimates are summarized at the food category level in the attached RIA, where all changes proposed under a given food category (*e.g.,* changes to quantity issued, expanded substitution options, and flexibility in package sizes) are considered for their collective impacts on projected quantities redeemed and unit costs.

These costs conservatively assume full implementation of the rule in all State agencies at the start of FY 2024 (*i.e.,* the costs do not assume an incremental phase-in period). The estimates also assume annual increases in child participation at 2.08 percent between FY 2021 and 2023 and 4.82 percent between 2023 and 2026 before leveling off at the higher participation level in 2027 and 2028. Participation among pregnant, postpartum, breastfeeding individuals and infants is held constant at current levels through FY 2028. In 2018, the most recent data available, only 44.2 percent of eligible children participated in WIC.[43] The estimated increases in child participation used in this analysis reflect a projected narrowing of the large coverage gap among WIC-eligible children as a result of current efforts to improve child retention in the Program. While declining birth rates have contributed to a decrease in pregnant, postpartum, and breastfeeding individuals and infants participating in WIC each year since 2009, USDA projects participation among these groups to level off due to future outreach efforts to increase participation.

The increase in value of the CVV accounts for most of the increased Federal spending, adding around $4.9 billion in costs over five years. This estimate assumes that the redemption rate of the increased CVV will continue at 2020 redemption levels (71.6 percent) and accounts for annual inflation adjustments. The proposed change to add canned fish to most food packages is estimated to add around $171 million in additional spending over five years. The proposal to increase the amounts of jarred infant fruits and vegetables that can be substituted for CVV and the proposed expansion of the allowable age range to substitute CVV for jarred fruits and vegetables are estimated to increase redemptions for these items, adding $113 million in costs over five years, despite the proposed reduction in the quantity of jarred fruits and vegetables issued to fully breastfed infants. Requiring all State agencies to authorize both dry and canned legumes is estimated to increase costs by $18 million over five years as some participants shift from purchasing dry legumes to more costly canned legumes.

The remaining provisions will either result in net savings at the food category level or are not estimated to have a significant impact on costs. Although the expanded substitution options for milk and juice are expected to increase redemption rates for these food categories, the proposed reductions to the maximum monthly allowances issued are still expected to result in a net savings of $136 million for milk and $731 million for juice over five years. The estimated savings associated with the reduction in the allowances for juice offset part of the costs of the increase to the CVV—encouraging greater consumption of whole fruits and vegetables as emphasized in the DGA. While the proposed rule would increase the amount of infant formula allowed in the first month for partially breastfed infants, this change is intended to support continued breastfeeding and is estimated to result in a shift of 5 percent of infant mother dyads from fully formula feeding food packages to partially breastfeeding food packages, which would ultimately lead to a net savings of $31 million on infant formula over five years. The proposed changes to infant meats, infant cereals, whole wheat/whole grains, breakfast cereal, and cheese are also expected to result in cost savings as summarized in Table 2 of the attached RIA.

In addition to the above impact on Federal transfer payments, the Department also estimates that WIC State agencies and local agencies will incur an in administrative burden associated with implementing and explaining the proposed changes to participants. This additional administrative burden is expected to account for about $171 million in State agency and local agency labor costs over five years. These administrative costs are considered allowable expenses for State agencies under their annually awarded Nutrition Services and Administration (NSA) grants. In general, the Department expects that State agencies will be able to absorb the costs associated with implementing the provisions under this proposed rule with current NSA funds.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, it has been certified that this proposed rule would not have a significant impact on a substantial number of small entities.

This proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would not have an adverse impact of small entities in the Special Supplemental Nutrition Program for Women, Infants and Children; the impact is not significant as it allows for greater options and flexibilities within approved food lists for State and local agencies to offer participants. State agencies are already required on an annual basis to update their approved foods lists.

Factual Basis: The provisions of this proposed rule would apply to small local agencies operating the Special Supplemental Nutrition Program for Women, Infants and Children, and to State agency staff who must monitor local agencies in remote locations. These entities meet the definitions of ''small governmental jurisdiction'' and ''small entity'' in the Regulatory Flexibility Act. These entities would not be negatively impacted by the changes and options proposed in this rule.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this proposed rule as a 'major rule', as defined by 5 U.S.C. 804(2).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and Tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' that may

[43] Gray K., Meyers-Mathieu K., Johnson, P., and Giannarelli, L. (2021). National- and State-Level Estimates of WIC Eligibility and WIC Program Reach in 2018 With Updated Estimates for 2016 and 2017. Prepared by Insight Policy Research, Contract No AG–3198–D–16–0095. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Grant Lovellette. Available online at: *www.fns.usda.gov/research-analysis.*

result in expenditures by State, local or Tribal governments, in the aggregate, or the private sector, of $146 million or more (when adjusted for inflation; gross domestic product (GDP) deflator source: Table 1.1.9 at *https://www.bea.gov/iTable*) in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and Tribal governments or the private sector of $146 million or more in any one year. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

This Special Supplemental Nutrition Program for Women Infants and Children is listed in the Catalog of Federal Domestic Assistance under Number 10.557 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132.

The Department has considered the impact of this proposed rule on State and local governments and has determined this proposed rule does not have federalism implications. Therefore, under section 6(b) of the Executive order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This proposed rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed the proposed rule, in accordance with Department Regulation 4300–004, Civil Rights Impact Analysis, to identify and address any major civil rights impacts the proposed rule might have on minorities, women, and persons with disabilities. A comprehensive Civil Rights Impact Analysis (CRIA) was conducted on the proposed rule, including an analysis of participant data and provisions contained in the proposed rule. The CRIA outlines outreach, mitigation, and monitoring strategies to lessen any possible civil rights impacts. The CRIA concludes by stating FNS believes that the promulgation of this proposed rule would impact WIC State Agencies, WIC vendors, Indian Tribal Organizations (ITOs), WIC Local Agencies and Clinic Sites, Food Producers and Manufacturers, and WIC participants. Specifically, WIC participants would be impacted by the changes to the WIC food packages to align with the latest nutrition science, accommodate special dietary needs and personal and cultural food preferences, and promote breastfeeding. WIC vendors would be required to consistently stock three vegetable varieties. ITOs and State agencies would have to identify new foods and package sizes and update their WIC APLs consistent with the changes outlined in the proposed rule. WIC local agency and clinic staff would have to review and update procedures to ensure they prescribe the revised food package correctly and accurately communicate the changes to participants. Additionally, although the proposed rule's changes to the food packages were selected to align with available products, there may be a minimal need for food manufacturers to reformulate products or create new products or package sizes. However, FNS finds that the implementation of the outreach, mitigation, and monitoring strategies may lessen these impacts. If deemed necessary, FNS would propose further mitigation and outreach strategies to alleviate impacts that may result from the implementation of the final rule.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. On November 30, 2021, FNS provided opportunity for consultation on the issue and received substantive feedback from several Tribal leaders which were taken into consideration during the development of this proposed rule, including support for more traditional native foods, consideration of impacts on small or tribal stores, and swift publication of the proposed updates. FNS will explore additional opportunities for engagement as needed. Once the proposed rule is published in the **Federal Register**, FNS will encourage stakeholders representing Indian Tribal Organizations to provide input on whether the proposed rule poses any adverse tribal implications. If a Tribe requests additional consultation in the future, FNS will work with the Office of Tribal Relations to ensure meaningful consultation is provided. We are unaware of any current Tribal laws that could be in conflict with this proposed rule.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; 5 CFR part 1320) requires the Office of Management and Budget (OMB) to approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

In accordance with the Paperwork Reduction Act of 1995, this proposed rule contains existing information collections that are contained in OMB# 0584–0043 Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations—Reporting and Recordkeeping (expiration date December 31, 2023) which are subject to review and approval by the Office of Management and Budget; therefore, FNS is submitting for public comment the changes to the existing information collection requirements and burden that would result from adoption of the proposals in the rule.

Comments on information collection for this proposed rule must be received by January 20, 2023.

Comments may be sent to: Allison Post, Food and Nutrition Service, U.S. Department of Agriculture, 1320

Braddock Place, 3rd Floor, Alexandria, VA 22314. Comments may also be submitted via email to *Allison.Post@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *https://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this document will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations—Reporting and Record-keeping Burden.

OMB Number: 0584–0043.

Expiration Date: 12/31/2023.

Type of Request: Revision of a currently approved collection due to rulemaking.

Abstract: This rulemaking proposes to revise regulations governing the WIC food packages to align them with the current Dietary Guidelines for Americans [44] and reflect recommendations made by the National Academies of Sciences, Engineering and Medicine (NASEM) in its 2017 report, ''Review of WIC Food Packages: Improving Balance and Choice,'' [45] while promoting nutrition security and equity and taking into account program administration considerations. The proposed changes are intended to provide WIC participants with a wider variety of foods that align with the latest nutritional science; provide WIC State agencies with greater flexibility to prescribe food packages that accommodate participants' special dietary needs and personal and cultural food preferences; provide more equitable access to supplemental foods; and better promote and support individual breastfeeding goals of participants to help establish successful long-term breastfeeding. The average burden per respondent and the annual burden hours are summarized and explained below.

Respondents: Businesses or Other For-Profit Organizations, non-profit WIC local agencies, State, Local, or Tribal Government, and Individuals and Households. Respondent groups identified include State Agencies (including Indian Tribal Organizations and U.S. Territories), applicants for Program benefits, and retail vendors.

Estimated Number of Respondents: 6,885,560.

Estimated Number of Annual Responses Respondent: 4.98.

Estimated Total Annual Responses: 34,314,693.

Estimated Time Per Response: 0.16 hours.

Estimated Total Annual Burden on Respondents: 5,637,114.77 hours.

Current OMB Inventory: 3,469,735.53 hours related to the requirements for the identification of acceptable foods under § 246.10(b)(1), explanation of new food packages as part of the certification process under § 246.7(i), and vendor applications and agreements under § 246.12(h)(1)(i).

Revised Annual Burden Due to the Proposed Rule: 5,637,114.77 hours related to the requirements for the identification of acceptable foods under § 246.10(b)(1), training for State and local agencies on revised food lists under § 246.10(b)(2)(i), review of food packages and explanation of proposed changes to food packages as part of the certification process under § 246.7(i), and vendor applications and agreements under § 246.12(h)(1)(i).

Difference (Burden Revisions Requested): 2,167,379.24 additional hours.

Summary:

[44] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020–2025. 9th Edition. December 2020. Available at: Home | Dietary Guidelines for Americans.

[45] National Academies of Sciences, Engineering, and Medicine. ''Review of WIC Food Packages: Improving Balance and Choice: Final Report,'' 2017. Available at internet site: *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

ESTIMATED ANNUAL REPORTING & RECORDING BURDEN FOR 0584–0043 AS A RESULT OF THE PROPOSED RULEMAKING

Regulation citation	Description of activities	Estimated number of respondents	Annual responses per respondent	Total annual responses	Average burden hours per response	Estimated total annual burden hours	Hours currently approved under OMB #0584–0043	Estimated change in burden hours due to rulemaking	Estimated change in burden hours due to adjustments	Total estimated change in burden hours
					Reporting					
State and Local Agencies (including Indian Tribal Organizations and U.S. Territories)										
246.7(i) Women	Certification	1,265.60	1,807.37	2,287,409.60	.2167	495,681.66	545,711.00	+114,446.73	−164,476.07	−50,029.34
246.7(i) Children	Certification	1,265.60	2,923.56	3,700,056.15	.2167	801,802.17	882,728.00	+185,126.14	−266,051.98	−80,925.83
246.7(i) Infants	Certification	1,265.60	947.12	1,198,680.70	.2167	259,754.11	285,970.97	+59,973.99	−86,190.85	−26,216.86
246.7(i)	Explaining food package updates.	1,265.60	3,799.85	4,809,089.60	.0833	400,597.16	0.00	+400,597.16	0.00	+400,597.16
246.10(b)(1)	Identification of acceptable foods.	89.00	1.00	89.00	43.00	3,827.00	3,560.00	+267.00	0.00	+267.00
246.10(b)(2)(i)	Attend, develop and provide training to local agencies on revised food lists.	89.00	1.00	89.00	5.00	445.00	0.00	+445.00	0.00	+445.00
246.10(b)(2)(i)	Local agency training on revised food lists.	1,265.60	1.00	1,265.60	1.00	1,265.60	0.00	+1,265.60	0.00	+1,265.60
246.12(h)(1)(i)	Vendor applications & agreements*.	89	152.07	13,534.62	.75	10,150.97	10,188.09	−37.13	0	−37.13
					Reporting					
Applicants for Program Benefits										
246.7(i) Women	Certification	1,633,864.00	2.00	3,267,728.00	.2167	708,116.66	545,710.58	+162,406.08	0.00	+162,406.08
246.7(i) Children	Certification	3,523,863.00	1.50	5,285,794.50	.2167	1,145,431.67	882,727.68	+262,703.99	0.00	+262,703.99
246.7(i) Infants	Certification	1,712,401.00	1.00	1,712,401.00	.2167	371,077.30	285,970.97	+85,106.33	0.00	+85,106.33
246.7(i)	Explaining food package updates.	6,870,128.00	1.00	6,870,128.00	0.0833	572,281.66	0.00	+572,281.66	0.00	+572,281.66
					Reporting					
Retail Vendors (WIC-Authorized Food Stores) and Businesses (Non-Profit WIC Local Agencies)										
246.7(i) Women	Certification	542.40	1,807.37	980,318.40	0.2167	212,435.00	0.00	+49,048.60	+163,386.40	+212,435.00
246.7(i) Children	Certification	542.40	2,923.56	1,585,738.35	0.2167	343,629.50	0.00	+79,339.78	+264,289.73	+343,629.50
246.7(i) Infants	Certification	542.40	947.12	513,720.30	0.2167	111,323.19	0.00	+25,703.14	+85,620.05	+111,323.19
246.7(i)	Explaining food package updates.	542.40	3,799.85	2,061,038.40	0.0833	171,684.50	0.00	+171,684.50	0.00	+171,684.50
246.10(b)(2)(i)	Local agency training on revised food lists.	542.40	1.00	542.40	1.00	542.40	0.00	+542.40	0.00	+542.40
246.12(h)(1)(i)	Vendor applications & agreements.	13,534.62	1.00	13,534.62	1.00	13,534.62	13,584.12	−49.50	0.00	−49.50

Recordkeeping										
State Agencies (including Indian Tribal Organizations and U.S. Territories)										
246.12(h)(1)(i)	Vendor applications & agreements.	89.00	152.07	13,534.62	1.00	13,534.62	13,584.12	−49.50	0.00	−49.50
Total	.....	6,885,560	4.98	34,314,692.86	.16	5,637,114.77	3,469,735,.53	+2,170,801.96	−3,422.72	+2,167,379,24.87

*The baseline for the specific burden associated with this activity is not currently included in OMB Control #0584–0043 but can be referenced in the 60-day Notice published September 30, 2022 (87 FR 59392).

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR OMB #0584–0043 DUE TO PROPOSED RULEMAKING

	Burden currently approved *	Projected respondents/ responses/ burden due to proposed rule	Difference in respondents	Difference in responses	Difference in burden hours
Grand Total Respondents	6,913,189	6,913,039	−150		
Grand Total Responses	48,812,384	62,554,388		** 13,742,005	
Grand Total Annual Burden Hours	4,557,287	6,724,666			2,167,379

* The estimates shown above are the burden estimates for this proposed rule. The baseline estimates of 51,869.137 responses and 6,150,819 hours reported in the 60-Day Notice (87 FR 59392) include estimates for activities that are not associated with this proposed rule.
** Difference in total number due to rounding.

Based on the proposals outlined in this rule, the Department estimates that the overall burden for OMB# 0584–0043 will increase by 2,167,379 hours and 13,742,005 responses, while the respondents will decrease by 150. The decrease in the number of respondents is due to the decrease in number of vendor respondents as explained in the Reporting Burden for Vendors: Section 246.12(h)(1)(i).

Explanation

Reporting Burden (State and Local Agencies Including Indian Tribal Organizations and US Territories)

Section 246.7(i) requires that pertinent certification data (income and nutrition risk assessment information) be collected and recorded by the local agency on computer software provided by the State agency. In addition, participants must be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification and notification of expiration of each certification period. During the certification process participants are assigned a food package based on their nutrition risk assessment and categorical eligibility. Due to the program (food package) changes in the proposed rule it is estimated that it will take an additional three minutes per participant during the certification (the current estimate is 10 minutes per participant) for clinic staff to review procedures to ensure that they prescribe the food package correctly with the proposed changes. FNS estimates that the collection of certification data, the provision of appropriate notifications, and reviewing the food packages require 13 minutes (0.2167 hours) per participant. Additionally, communicating the proposed food package changes to current participants would require an estimated one-time five-minute (0.0833 hours) explanation per participant.

FNS estimates 495,681.66 annual burden hours for the certification of women (1,633,864 women × 2 certifications per year = 3,267,728 total annual responses ÷ 1,808 = 1,807.37 certifications per local agency × 1,265.60 local agencies = 2,287,409.60 total annual responses × 13 minutes (0.2167 hours) per response = 495,681.66 hours). Note: A program adjustment was made to account for the fact that 30 percent of WIC local agencies are non-profits and are reflected in the ''Business'' respondent category (see below). The number of government local agencies used in this calculation is 1,265.60 (1,808 × 0.70). Overall, the burden hours for the certification of women would decrease by 50,029.34, from 545,711.00 to 495,681.66 hours. The decrease is due to a program adjustment to account for non-profit local agencies, which is larger than the increase from a program change due to the proposed rule.

FNS estimates 801,802.17 annual burden hours for the certification of children (3,523,863 children × 1.5 certifications per year = 5,285,794.50 total annual responses ÷ 1,808 = 2,923.56 certifications per local agency × 1,265.60 local agencies = 3,700,056.15 total annual responses × 13 minutes (0.2167 hours) per response = 801,802.17 hours). This is a decrease of 80,925.83 hours for the certification of children, from 882,728.00 to 801,802.17 hours. This decrease is due to an adjustment to account for non-profit local agencies, which is larger than the increase from a program change due to the proposed rule.

FNS estimates 259,754.11 annual burden hours for the certification of infants (1,712,401 infants ÷ 1,808 = 947.12 certifications per local agency × 1,265.60 local agencies = 1,198,680.70 total annual responses × 13 minutes (0.2167 hours) per response = 259,754.11 hours). This is a decrease of 26,216.86 hours for the certification of infants, from 285,970.97 to 259,754.11 hours. This decrease is due to an adjustment to account for non-profit local agencies, which is larger than the increase from a program change due to the proposed rule.

FNS estimates 400,597.16 burden hours to explain the changes to the food package proposed in this rule once to all current WIC participants (6,870,128 participants ÷ 1,808 = 3,799.85 explanations per local agency × 1,265.60 local agencies = 4,809,089.60 total explanations × 5 minutes (0.0833 hours) per explanation = 400,597.16 hours. This one-time increase to the local agency reporting burden is due to a program change due to the proposed rule.

Section 246.10(b)(1) requires each State agency to identify foods that are acceptable for use in the program in their State, in accordance with program regulations. This includes establishing criteria for and identifying foods, substitutions, brands and packaging the State will authorize for use in the Program. The proposed rule includes additional requirements and options for WIC-authorized foods that will impact State agencies' identification of foods, substitutions, brands, and packaging acceptable for use in the Program to include:

- Requiring one other form of fruits and vegetables in addition to fresh.
- Allowing greater flexibility to authorize additional package sizes (*e.g.,* fresh fruits and vegetables, yogurt, bread).
- Allowing soy-based yogurts and soy-based cheeses as substitution options for milk.
- Requiring the authorization of lactose-free milk.[46]
- Allowing additional whole grain options as substitutes for bread.
- Requiring the authorization of canned legumes in addition to dry legumes.

The Department estimates that on average it will take each State agency 43 hours annually to comply with this regulatory provision (to include the proposed changes), which is an increase

[46] Although, currently an option (not a requirement) all States and most ITOs already authorize some kind of lactose-free milk.

of 3 hours (based on an estimated range of 2 to 4 hours) per State agency. This represents an average of a 5 to 10 percent increase in burden time. Therefore, the Department estimates 3,827 total annual burden hours for this provision (89 State agencies × 43 hours per State agency), which is an increase of 267 hours total, from 3,560 to 3,827 hours. This increase is due to a program change due to the proposed rule.

Section 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. Due to the proposed changes in the WIC food packages the food lists will be revised. State agencies will need to develop and deliver training for local agencies on the revised food lists. In addition, State agencies will attend an FNS-provided training about the food package changes. These training activities result in a one-time estimated burden of 5 hours for each State agency (1 hour to attend the FNS training, 3 hours to develop State agency-specific trainings for local agencies, and 1 hour to provide training to local agencies). FNS estimates an additional one-time State agency reporting burden of 445 hours for these training activities (89 × 5 = 445). This addition is due to a program change due to the proposed rule.

Section 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. Due to the proposed changes in the WIC food packages the food lists will be revised. Local agencies will need to attend a State agency training on the revised food lists, which FNS estimates will require one hour. FNS estimates an additional one-time burden of 1,265.60 hours for local agencies to attend the State agency training (1,265.60 × 1.00 = 1,265.60). This increase is due to a program change due to the proposed rule.

Section 246.12(h)(1)(i) requires the State agency to enter into a written agreement with retail vendors. State agencies must review completed application forms and sign a vendor agreement where the agreement period must not exceed three years.The Department estimates that one-third of all retail vendors will submit applications each year and that it requires the State agency 45 minutes (.75 hours) to review the application and sign each vendor agreement. The Department estimates that the proposed requirement for WIC-authorized retail vendors to stock three varieties of vegetables (currently vendors are required to stock two varieties) will result in 150 fewer vendors submitting applications and/or fewer vendors signing agreements, as the Department estimates particularly rural, remote, and/or small vendors with low WIC redemptions would be impacted by the small increase in the minimum stock requirement in the proposed rule (41,164 retail vendors − 150 = 41,014). As such, each State agency is estimated to review approximately 152 vendor applications and agreements annually (41,014 × 0.33/89 State agencies = 152.07). The Department estimates 10,150.97 burden hours for State agencies to review applications and sign the agreements (89 State agencies × 152.07 vendor applications and agreements per State agency = 13,534.62 vendor applications and agreements × 45 minutes (.75 hour) per application and agreement = 10,150.97 annual burden hours). With the expected decrease in the number of vendors filing applications and agreements, FNS estimates a decrease of 37.13 burden hours (10,188.09[47] − 10,150.97) for this provision. This decrease is due to a program change due to the proposed rule.

Reporting Burden (Applicants)

Section 246.7(i) requires that certification data including income and nutritional risk be collected from all participants and recorded by the local agency on computer software provided by the State agency. In addition, participants must be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification and notification of expiration of each certification period. The income eligibility is established by applicants providing written documentation to the local agency. Applicants or certain family members that receive Medicaid, Supplemental Nutrition Assistance Program (SNAP), Temporary Assistance for Needy Families Program (TANF), or State-administered programs with income criteria at or below 185 percent of the Federal poverty guidelines are not subject to the standard WIC income eligibility determination. Though some information is collected for the entire household, some documentation (such as nutrition risk) is required for each WIC applicant.

Nutritional risk is determined by a competent professional authority on the staff of the local agency through a nutritional assessment. This determination may be based on referral data submitted by a competent professional authority not on the staff of the local agency. At a minimum, height or length and weight measurements and a hematological test for anemia such as a hemoglobin or hematocrit shall be performed and/or documented in the applicant's file at the time of certification. In addition, medical/health history, dietary intake and environmental (*e.g.,* homelessness and migrancy) information is collected to determine all relevant nutrition risk(s). During the certification process participants are assigned a food package based on their nutrition risk assessment and categorical eligibility. Due to the program changes in the proposed rule it is estimated that the certification will take an additional three minutes (the current estimate is 10 minutes per participant) for clinic staff to communicate the food package changes to each participant. Additionally, communicating the proposed food package changes to current participants would require an estimated one-time five-minute (0.0833 hours) explanation per participant.

FNS estimates that providing certification data to the local agency requires 13 minutes (0.2167 hours) on average per participant.

Monthly WIC participation is 6,870,128 (1,633,864 women, 1,712,401 infants and 3,523,863 children).

Women are certified twice per year, thus FNS estimates 708,116.66 hours for this provision (1,633,864 participants × 2 times per year = 3,267,728 × 13 minutes (0.2167 hours) = 708,116.66 hours). This is an increase of 162,406.08 hours for the certification of women, from 545,710.58 to 708,116.66 hours. This increase is due to a program change due to the proposed rule.

Children may be certified once or twice per year. More than half of WIC State agencies certify children once per year. FNS estimates 1,145,431.67 hours for this provision (3,523,863 participants × 1.5 times per year = 5,285,794.5 × 13 minutes (0.2167 hours) = 1,145,431.67 hours). This is an increase of 262,703.99 hours for the certification of children, from 882,727.68 to 1,145,431.67 hours. This increase is due to a program change due to the proposed rule.

Infants are certified once per year, thus FNS estimates 371,077.30 hours for this provision (1,712,401 participants × 1 time per year = 1,712,401 × 13 minutes (0.2167 hours) = 371,077.30). This is an increase of 85,106.33 hours for the certification of infants, from 285,970.97 to 371,077.30 hours. This

[47] These hours reflect hours identified as in use without OMB approval which FNS is currently seeking approval for through a revision to OMB Control Number 0584–0043.

increase is due to a program change due to the proposed rule.

FNS estimates 572,281.66 burden hours to explain the changes to the food package proposed in this rule once to all WIC participants (6,870,128 participants × 1 explanation = 6,870,128 total explanations × 5 minutes (0.0833) hours per explanation = 572,281.66 total hours. This one-time increase is due to a program change due to the proposed rule.

Reporting Burden (Businesses: Non-Profit WIC Local Agencies and Vendors)

Section 246.7(i) requires that pertinent certification data (income and nutrition risk assessment information) be collected and recorded by the local agency on computer software provided by the State agency. In addition, participants must be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification and notification of expiration of each certification period. During the certification process participants are assigned a food package based on their nutrition risk assessment and categorical eligibility. Due to the program (food package) changes in the proposed rule it is estimated that it will take an additional three minutes per participant during the certification (the current estimate is 10 minutes per participant) for clinic staff to review procedures to ensure that they prescribe the food package correctly with the proposed changes. FNS estimates that the collection of certification data, the provision of appropriate notifications, and reviewing the food packages require 13 minutes (0.2167 hours) per participant. Additionally, communicating the proposed food package changes to current participants would require an estimated one-time five-minute explanation per participant.

FNS estimates 212,435.00 annual burden hours for the certification of women (1,633,864 women × 2 certifications per year = 3,267,728 total annual responses ÷ 1,808 = 1,807.37 certifications per local agency × 542.40 non-profit local agencies = 980,318.40 total annual responses × 13 minutes (0.2167 hours) per response = 212,435.00 hours). Note: Since 30% of WIC local agencies are non-profits, the number of local agencies used in this calculation for the ''Business'' respondent category is 542.40. Overall, the burden for the certification of women would increase by 212,435.00 hours. This increase is due to both an adjustment that separated non-profit businesses from government local agencies and a program change due to the proposed rule.

FNS estimates 343,629.50 annual burden hours for the certification of children (3,523,863 children × 1.5 certifications per year = 5,285,794.5 total annual responses ÷ 1,808 = 2,923.56 certifications per local agency × 542.40 non-profit local agencies = 1,585,738.35 total annual responses × 13 minutes (0.2167 hours) per response = 343,629.50 hours). This is an addition of 343,629.50 hours for the certification of children. This increase is due to both an adjustment that separated non-profit businesses from government local agencies and a program change due to the proposed rule.

FNS estimates 111,323.19 annual burden hours for the certification of infants (1,712,401 infants ÷ 1,808 = 947.12 certifications per local agency × 542.40 non-profit local agencies = 513,720.30 total annual responses × 13 minutes (0.2167 hours) per response = 111,323.19 hours). This is an addition of 111,323.19 hours for the certification of infants. This increase is due to both an adjustment that separated non-profit businesses from government local agencies and a program change due to the proposed rule.

FNS estimates 171,684.50 burden hours to explain the changes to the food package proposed in this rule once to all current WIC participants (6,870,128 participants ÷ 1,808 = 3,799.85 per local agency × 542.40 non-profit local agencies = 2,061,038.40 total explanations × 5 minutes (0.0833 hours) per explanation = 171,684.50 hours. This one-time increase to the non-profit WIC local agency reporting burden is due to a program change due to the proposed rule.

Section 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. Due to the proposed changes in the WIC food packages the food lists will be revised. Local agencies will need to attend a State agency training on the revised food lists, which FNS estimates will require one hour. FNS estimates an increase of 542.40 burden hours for non-profit WIC local agencies to attend the State agency training (542.40 × 1.00 = 524.40 hours). This one-time increase is due to a program change due to the proposed rule.

Section 246.12(h)(1)(i) requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. Retail vendor agreements can be for up to 3 years; therefore, the Department estimates that one-third of all retail vendors will submit applications each year. It is estimated that it requires one hour for the vendor to complete the application and sign the agreement. The Department further estimates that the proposed requirement for WIC-authorized retail vendors to stock three varieties of vegetables (currently vendors are required to stock two varieties) will result in 150 fewer vendors submitting applications and/or fewer vendors signing agreements, as the Department estimates particularly rural, remote, and/or small vendors with low WIC redemptions would be impacted by a small increase in minimum stock (41,164 retail vendors −150 = 41,014). This proposed change results in a decrease of 150 vendor respondents reducing the total number of respondents to 6,913,039 from the current total of 6,913,189. In addition, the Department estimates 13,534.62 burden hours for vendors to complete the applications and sign the agreements (41,014 retail vendors × 0.33 of all retail vendors submit applications per year = 13,534.62 × 1 per year = 13,534.62 × 1 hour per application = 13,534.62 annual burden hours). This results in a decrease of 49.50 hours since the previous submission, from 13,584.12 to 13,534.62 hours due to the decrease in the number of vendors. The decrease in the number of respondents and the burden hours is due to a program change due to the proposed rule.

Recordkeeping Burden (State Agencies)

Section 246.12(h)(1)(i) requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. Retail vendor agreements can be for up to 3 years; therefore, the Department estimates that one-third of all retail vendors will submit applications each year. It is estimated that each application takes State agency staff one hour to collect and record the documents in the State agency's recordkeeping system; most State agencies use an electronic Management Information System (MIS) for this purpose. The Department further estimates that the proposed requirement for WIC-authorized retail vendors to stock three varieties of vegetables (currently vendors are required to stock two varieties) will result in 150 fewer vendors submitting applications and/or fewer vendors signing agreements, as the Department estimates particularly rural, remote, and/or small vendors with low WIC redemptions would be

impacted by the small increase in the minimum stock requirement in the proposed rule (41,164 retail vendors—150 = 41,014). The Department estimates 13,534.62 annual burden hours for this provision for State agencies (41,014 vendor applications ÷ 89 = 460.83 applications per State agency × 0.33 of all retail vendors will submit applications each year = 152.07 applications per State agency × 89 State agencies = 13,534.62 × 1 burden hour = 13,534.62). This results in a decrease of 49.50 hours since the previous submission, from 13,584.12 to 13,534.62 hours due to the decrease in the number of vendors. This decrease is due to a program change due to the proposed rule.

This rule proposes to include breast pumps as a Program benefit and add reference to the sale or offer to sell breast pumps to the definition of *participant violation* (§ 246.2). In addition, the proposed change (increase) to the dollar threshold for participant violations (§ 246.16(u)(2)(i)) will result in a decrease in the number of participant claims. Taken together these two provisions will off-set each other and will not have an impact on the investigation and complaints filed and therefore will not impact the currently approved burden estimate for § 246.23(c)(1)—Disposition of Participant Claims.

The change in burden hours is a best estimate. The Department requests comments on the burden and all proposed changes. Comments received in response to the proposed rule and burden estimates will inform the final burden estimates.

E-Government Act Compliance

FNS is committed to complying with the E-Government Act of 2002 to promote the use of the internet and other information technologies to provide increased opportunities to provide for citizen access to government information and services, and for other purposes.

List of Subjects in 7 CFR Part 246

Administrative practice and procedure, Civil rights, Food assistance programs, Foods, Grants administration, Grant programs-health, Grant programs-social programs, Indians, Infants and children, Maternal and child health, Nutrition, Penalties, Public health, Reporting and recordkeeping requirements, Women.

Accordingly, Food and Nutrition Service proposes to amend 7 CFR part 246 as follows:

PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN

■ 1. The authority citation for part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

■ 2. Amend § 246.2 by adding the definition for ''Disability'' in alphabetical order, removing the definition for ''Individual with disabilities,'' and revising the definitions for ''Participant violation'' and ''WIC-eligible nutritionals for participants with qualifying conditions (hereafter referred to as 'WIC-eligible nutritionals')'' to read as follows:

§ 246.2 Definitions.

* * * * *

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more of the major life activities of such individual, a record of such an impairment, or being regarded as having such an impairment. See 28 CFR 35.108.

* * * * *

Participant violation means any deliberate action of a participant, parent, or caretaker of an infant or child participant, or proxy that violates Federal or State statutes, regulations, policies, or procedures governing the Program. Participant violations include, but are not limited to, deliberately making false or misleading statements or deliberately misrepresenting, concealing, or withholding facts, to obtain benefits; selling or offering to sell WIC benefits, cash-value vouchers, paper food instruments, EBT cards, supplemental foods, or breast pumps in person, in print, or online; exchanging or attempting to exchange WIC benefits, cash-value vouchers, paper food instruments, EBT cards, supplemental foods, or breast pumps for cash, credit, services, non-food items, or unauthorized food items, including supplemental foods in excess of those listed on the participant's food instrument; threatening to harm or physically harming clinic, farmer, farmers' market, or vendor staff; and dual participation.

* * * * *

WIC-eligible nutritionals for participants with qualifying conditions (hereafter referred to as ''WIC-eligible nutritionals'') means certain enteral products that are specifically formulated and commercially manufactured (as opposed to a naturally occurring foodstuff used in its natural state) to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible nutritionals must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme. WIC-eligible nutritionals include many, but not all, products that meet the definition of medical food in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).

■ 3. Amend § 246.7 by revising paragraph (j)(10) to read as follows:

§ 246.7 Certification of participants.

* * * * *

(j) * * *

(10) During WIC certification, every Program applicant, parent, or caretaker shall be informed that selling or offering to sell WIC benefits, cash-value vouchers, paper food instruments, EBT cards, supplemental foods, or breast pumps in person, in print, or on-line is a participant violation.

* * * * *

■ 4. Revise § 246.10 to read as follows:

§ 246.10 Supplemental foods.

(a) *General.* This section prescribes the requirements for providing supplemental foods to participants. The State agency must ensure that local agencies comply with this section.

(b) *State agency responsibilities.* (1) State agencies may:

(i) Establish criteria in addition to the minimum Federal requirements in table 4 to paragraph (e)(12) of this section for the supplemental foods in their States, except that the State agency may not selectively choose which eligible fruits and vegetables are available to participants. These State agency criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal. For eligible fruits and vegetables, State agencies may restrict packaging, *e.g.,* plastic containers, and package sizes such as single serving, of processed fruits and vegetables available for purchase with the cash-value voucher. In addition, State agencies may identify certain processed WIC-eligible fruits and vegetables on food lists where the potential exists for vendor or participant confusion in determining authorized WIC-eligible items.

(ii) Make food package adjustments to better accommodate participants who are homeless. At the State agency's option, these adjustments would include, but not be limited to, issuing authorized supplemental foods in

individual serving-size containers to accommodate lack of food storage or preparation facilities.

(iii) Authorize package sizes, in addition to those authorized to fulfill paragraph (b)(2)(i) of this section, that increase participant variety and choice, except WIC formula, which must be authorized in sizes that correspond with the maximum monthly allowances per paragraphs (e)(9) and (11) of this section.

(2) State agencies must:

(i) Identify the brands of foods and package sizes that are acceptable for use in the Program in their States in accordance with the requirements of this section; all State agencies must authorize at least one package size (or combination of package sizes) that equal or add up to the maximum monthly allowances of all authorized supplemental foods in each of the food packages. State agencies must also provide to local agencies, and include in the State Plan, a list of acceptable foods and their maximum monthly allowances as specified in tables 1 through 4 to paragraphs (e)(9) through (12) of this section; and

(ii) Ensure that local agencies:

(A) Make available to participants the maximum monthly allowances of authorized supplemental foods, except as noted in paragraph (c) of this section, inform participants about the maximum monthly allowances of authorized supplemental foods to which they are entitled as a Program participant and any food substitution options as specified in tables 1 through 3 to paragraphs (e)(9) through (11) of this section that the State agency authorizes, and abide by the authorized substitution rates for WIC food substitutions as specified in tables 1 through 3 to paragraphs (e)(9) through (11) of this section;

(B) Make available to participants more than one food from each WIC food category except for the categories of peanut butter and eggs, and any of the WIC-eligible fruits and vegetables (fresh or processed) in each authorized food package as listed in paragraph (e) of this section;

(C) Authorize only a competent professional authority to prescribe the categories of authorized supplemental foods in quantities that do not exceed the regulatory maximum and are appropriate for the participant, taking into consideration the participant's nutritional and breastfeeding needs; and

(D) Advise participants or their caretaker, when appropriate, that the supplemental foods issued are only for their personal use. However, the supplemental foods are not authorized for participant use while hospitalized on an in-patient basis. In addition, consistent with § 246.7(m)(1)(i)(B), supplemental foods are not authorized for use in the preparation of meals served in a communal food service. This restriction does not preclude the provision or use of supplemental foods for individual participants in a nonresidential setting (*e.g.,* child care facility, family day care home, school, or other educational program); a homeless facility that meets the requirements of § 246.7(m)(1); or, at the State agency's discretion, a residential institution (*e.g.,* home for pregnant teens, prison, or residential drug treatment center) that meets the requirements currently set forth in § 246.7(m)(1) and (2).

(c) *Nutrition tailoring.* Nutrition tailoring is the process of modifying an individual food package to better meet the supplemental nutritional needs of each participant. It entails making substitutions, reductions, and/or eliminations to food types and physical food forms in accordance with paragraphs (e)(9) through (11) of this section. The full maximum monthly allowances of all supplemental foods in all food packages must be made available to participants if medically or nutritionally warranted. Reductions in these amounts cannot be made for cost-savings, administrative convenience, caseload management, or to control vendor abuse. Reductions in these amounts or eliminations of foods cannot be made for categories, groups, or subgroups of WIC participants and may be done only after a nutrition assessment and offering substitution options available in the State in accordance with paragraphs (e)(9) through (11) of this section and State agency policy. The provision of less than the maximum monthly allowances of supplemental foods to an individual WIC participant in all food packages is appropriate only when:

(1) Medically or nutritionally warranted (*e.g.,* to eliminate a food due to a food allergy);

(2) A participant refuses or cannot use the maximum monthly allowances, or chooses to take less than the maximum monthly allowance; or

(3) The quantities necessary to supplement another program's contribution to fill a medical prescription would be less than the maximum monthly allowances.

(d) *Medical documentation*—(1) *Supplemental foods requiring medical documentation.* Medical documentation is required for the issuance of the following supplemental foods:

(i) Any non-contract brand infant formula;

(ii) Any infant formula prescribed to an infant, child, or adult who receives Food Package III;

(iii) Any exempt infant formula;

(iv) Any WIC-eligible nutritional;

(v) Any authorized supplemental food issued to participants who receive Food Package III;

(vi) Any contract brand infant formula that does not meet the requirements in table 4 to paragraph (e)(12) of this section.

(2) *Medical documentation for other supplemental foods.* (i) State agencies may authorize local agencies to issue a non-contract brand infant formula that meets the requirements in table 4 to paragraph (e)(12) of this section without medical documentation in order to meet religious eating patterns; and

(ii) The State agency has the discretion to require medical documentation for any contract brand infant formula other than the primary contract infant formula and may decide that some contract brand infant formula may not be issued under any circumstances.

(3) *Medical determination.* For purposes of this program, medical documentation means that a health care professional licensed to write medical prescriptions under State law has:

(i) Made a medical determination that the participant has a qualifying condition as described in paragraphs (e)(1) through (7) of this section that dictates the use of the supplemental foods, as described in paragraph (d)(1) of this section; and

(ii) Provided the written documentation that meets the technical requirements described in paragraphs (d)(4)(ii) and (iii) of this section.

(4) *Technical requirements*—(i) *Location.* All medical documentation must be kept on file (electronic or hard copy) at the local clinic. The medical documentation kept on file must include the initial telephone documentation, when received as described in paragraph (d)(4)(iii)(B) of this section.

(ii) *Content.* All medical documentation must include the following:

(A) The name of the authorized WIC formula (infant formula, exempt infant formula, WIC-eligible nutritional) prescribed, including amount needed per day;

(B) The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts;

(C) Length of time the prescribed WIC formula and/or supplemental food is required by the participant;

(D) The qualifying condition(s) for issuance of the authorized supplemental food(s) requiring medical documentation, as described in paragraphs (e)(1) through (7) of this section; and

(E) Signature, date and contact information (or name, date and contact information), if the initial medical documentation was received by telephone and the signed document is forthcoming, of the health care professional licensed by the State to write prescriptions in accordance with State laws.

(iii) *Written confirmation*—(A) *General.* Medical documentation must be written and may be provided as an original written document, an electronic document, by facsimile or by telephone to a competent professional authority until written confirmation is received.

(B) *Medical documentation provided by telephone.* Medical documentation may be provided by telephone to a competent professional authority who must promptly document the information. The collection of the required information by telephone for medical documentation purposes may only be used until written confirmation is received from a health care professional licensed to write medical prescriptions and used only when absolutely necessary on an individual participant basis. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time (*i.e.,* one- or two-weeks' time) after accepting the initial medical documentation by telephone.

(5) *Medical supervision requirements.* Due to the nature of the health conditions of participants who are issued supplemental foods that require medical documentation, close medical supervision is essential for each participant's dietary management. The responsibility remains with the participant's health care provider for this medical oversight and instruction. This responsibility cannot be assumed by personnel at the WIC State or local agency. However, it would be the responsibility of the WIC competent professional authority to ensure that only the amounts of supplemental foods prescribed by the participant's health care provider are issued in the participant's food package.

(e) *Food packages.* There are seven food packages available under the Program that may be provided to participants. The authorized supplemental foods must be prescribed from food packages according to the category and nutritional needs of the participants. Breastfeeding assessment and the mother's plans for breastfeeding serve as the basis for determining food package issuance for all breastfeeding women. The intent of the WIC Program is that all breastfeeding women be supported to exclusively breastfeed their infants and to choose the fully breastfeeding food package without infant formula. Breastfeeding mothers whose infants receive formula from WIC are to be supported to breastfeed to the maximum extent possible with minimal supplementation with infant formula. Formula amounts issued to a breastfed infant are to be tailored to meet but not exceed the infant's nutritional needs. The seven food packages are as follows:

(1) *Food Package I—Infants birth through 5 months*—(i) *Participant category served.* This food package is designed for issuance to infants from birth through age 5 months who do not have a condition qualifying them to receive Food Package III. The following infant feeding variations are defined for the purposes of assigning food quantities and types in Food Packages I: Fully breastfeeding (the infant doesn't receive formula from the WIC Program); partially (mostly) breastfeeding (the infant is breastfed but also receives infant formula from WIC up to the maximum allowance described for partially (mostly) breastfed infants in table 1 to paragraph (e)(9) of this section; and fully formula fed (the infant is not breastfed or is breastfed minimally (the infant receives infant formula from WIC in quantities that exceed those allowed for partially (mostly) breastfed infants).

(ii) *Infant feeding age categories—Birth through 5 months.* Three infant food packages are available from birth through 5 months—fully breastfeeding, partially (mostly) breastfeeding, or fully formula-fed.

(iii) *Infant formula requirements.* This food package provides iron-fortified infant formula that is not an exempt infant formula and that meets the requirements in table 4 to paragraph (e)(12) of this section. The issuance of any contract brand or noncontract brand infant formula that contains less than 10 milligrams of iron per liter (at least 1.5 milligrams iron per 100 kilocalories) at standard dilution is prohibited. Except as specified in paragraph (d) of this section, local agencies must issue as the first choice of issuance the primary contract infant formula, as defined in § 246.2, with all other infant formulas issued as an alternative to the primary contract infant formula. Noncontract brand infant formula and any contract brand infant formula that does not meet the requirements in table 4 to paragraph (e)(12) of this section may be issued in this food package only with medical documentation of the qualifying condition. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that indicates the need for the infant formula. For situations that do not require the use of an exempt infant formula, such determinations include, but are not limited to, documented formula intolerance, food allergy or inappropriate growth pattern. Medical documentation must meet the requirements described in paragraph (d) of this section.

(iv) *Physical forms.* Local agencies must issue all WIC formulas (infant formula, exempt infant formula and WIC-eligible nutritionals) in concentrated liquid or powder physical forms. Ready-to-feed WIC formulas may be authorized when the competent professional authority determines and documents that:

(A) The participant's household has an unsanitary or restricted water supply or poor refrigeration;

(B) The person caring for the participant may have difficulty in correctly diluting concentrated or powder forms; or

(C) The WIC infant formula is only available in ready-to-feed.

(v) *Authorized category of supplemental foods.* Infant formula is the only category of supplemental foods authorized in this food package. Exempt infant formulas and WIC-eligible nutritionals are authorized only in Food Package III. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for infants in Food Packages I are stated in table 1 to paragraph (e)(9) of this section.

(2) *Food Package II—Infants 6 through 11 months*—(i) *Participant category served.* This food package is designed for issuance to infants from 6 through 11 months of age who do not have a condition qualifying them to receive Food Package III.

(ii) *Infant food packages.* Three food packages for infants 6 through 11 months are available—fully breastfeeding, partially (mostly) breastfeeding, or fully formula fed.

(iii) *Infant formula requirements.* The requirements for issuance of infant formula in Food Package I, specified in paragraphs (e)(1)(iii) and (iv) of this section, also apply to the issuance of infant formula in Food Package II.

(iv) *Authorized categories of supplemental foods.* Infant formula,

infant cereal, and infant foods are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for infants in Food Packages II are stated in table 1 to paragraph (e)(9) of this section.

(3) *Food Package III—Participants with qualifying conditions*—(i) *Participant category served and qualifying conditions.* This food package is reserved for issuance to women, infants, and children who have a documented qualifying condition that requires the use of a WIC formula (infant formula, exempt infant formula, or WIC-eligible nutritional) because the use of conventional foods is precluded, restricted, or inadequate to address their special nutritional needs. Medical documentation must meet the requirements described in paragraph (d) of this section. Participants who are eligible to receive this food package must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under State law. The qualifying conditions include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant's nutrition status. This food package may not be issued solely for the purpose of enhancing nutrient intake or managing body weight.

(ii) *Non-authorized issuance of Food Package III.* This food package is not authorized for:

(A) Infants whose only condition is:

(*1*) A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula; or

(*2*) A non-specific formula or food intolerance.

(B) Women and children who have a food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages (*i.e.,* Food Packages IV–VII); or

(C) Any participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

(iii) *Restrictions on the issuance of WIC formulas in ready-to-feed (RTF) forms.* WIC State agencies must issue WIC formulas (infant formula, exempt infant formula and WIC-eligible nutritionals) in concentrated liquid or powder physical forms unless the requirements for issuing RTF are met as described in paragraph (e)(1)(iv) of this section. In addition to those requirements, there are two additional conditions which may be used to issue RTF in Food Package III:

(A) If a ready-to-feed form better accommodates the participant's condition; or

(B) If it improves the participant's compliance in consuming the prescribed WIC formula.

(iv) *Unauthorized WIC costs.* All apparatus or devices (*e.g.,* enteral feeding tubes, bags, and pumps) designed to administer WIC formulas are not allowable WIC costs.

(v) *Authorized categories of supplemental foods.* The supplemental foods authorized in this food package require medical documentation for issuance and include WIC formula (infant formula, exempt infant formula, and WIC-eligible nutritionals), infant cereal, infant foods, milk/lactose-free milk, cheese, eggs, canned fish, fresh and other State-authorized forms of fruits and vegetables, breakfast cereal, whole wheat/whole grain bread, juice, legumes and/or peanut butter. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for infants in Food Package III are stated in table 1 to paragraph (e)(9) of this section. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for children and women in Food Package III are stated in table 3 to paragraph (e)(11) of this section.

(vi) *Coordination with medical payors and other programs that provide or reimburse for formulas.* WIC State agencies must coordinate with other Federal, State, or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC-eligible nutritionals benefits to mutual participants. At a minimum, a WIC State agency must coordinate with the State Medicaid Program for the provision of exempt infant formulas and WIC-eligible nutritionals that are authorized or could be authorized under the State Medicaid Program for reimbursement and that are prescribed for WIC participants who are also Medicaid recipients. The WIC State agency is responsible for providing up to the maximum amount of exempt infant formulas and WIC-eligible nutritionals under Food Package III in situations where reimbursement is not provided by another entity.

(4) *Food Package IV–A and B—Children 1 through 4 years*—(i) *Participant category served.* This food package is designed for issuance to children 1 through 4 years of age who do not have a condition qualifying them to receive Food Package III and is divided into: IV–A for children 1 to less than 2 years of age (*i.e.,* 12 through 23 months), and IV–B for children 2 years through 4 years.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fresh and other State-authorized forms of fruits and vegetables, whole wheat/whole grain bread, eggs, and legumes or peanut butter, and canned fish are the categories of supplemental foods authorized for both Food Package IV–A and IV–B. Canned fish is authorized for Food Package IV–B only. The maximum monthly allowances, canned fish varieties, allowed options and substitution rates of supplemental foods for children in Food Package IV are stated in table 2 to paragraph (e)(10) of this section.

(5) *Food Package V–A and B—Pregnant and partially (mostly) breastfeeding women*—(i) *Participant categories served.* This food package is designed for issuance to three categories of women who do not have a condition qualifying them to receive Food Package III and is divided into: Food Package V–A for issuance to women with singleton pregnancies, and Food Package V–B for issuance to women pregnant with two or more fetuses and, for up to 1 year postpartum, partially (mostly) breastfeeding women participants, whose partially (mostly) breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum allowances described in table 1 to paragraph (e)(9) of this section. Women participants partially (mostly) breastfeeding more than one infant from the same pregnancy and pregnant women fully or partially breastfeeding singleton infants, are eligible to receive Food Package VII as described in paragraph (e)(7) of this section.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fresh and other State-authorized forms of fruits and vegetables, whole wheat/whole grain bread, eggs, legumes and peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for women in Food Packages V–A and

V–B are stated in table 2 to paragraph (e)(10) of this section.

(6) *Food Package VI—Postpartum women*—(i) *Participant categories served.* This food package is designed for issuance to women up to 6 months postpartum who are not breastfeeding their infants, and to breastfeeding women up to 6 months postpartum whose participating infant receives more than the maximum amount of formula allowed for partially (mostly) breastfed infants as described in table 1 to paragraph (e)(9) of this section, and who do not have a condition qualifying them to receive Food Package III.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, fresh and other State-authorized forms of fruits and vegetables, eggs, legumes or peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for women in Food Package VI are stated in table 2 to paragraph (e)(10) of this section.

(7) *Food Package VII—Fully breastfeeding*—(i) *Participant categories served.* This food package is designed for issuance to breastfeeding women up to 1 year postpartum whose infants do not receive infant formula from WIC (these breastfeeding women are assumed to be exclusively breastfeeding their infants), and who do not have a condition qualifying them to receive Food Package III. This food package is also designed for issuance to women participants partially (mostly) breastfeeding multiple infants from the same pregnancy, and pregnant women who are also partially (mostly) breastfeeding singleton infants, and who do not have a condition qualifying them to receive Food Package III. Women participants fully breastfeeding multiple infants from the same pregnancy receive 1.5 times the supplemental foods provided in Food Package VII.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fresh and other State-authorized forms of fruits and vegetables, whole wheat/whole grain bread, eggs, legumes, peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for women in Food Package VII are stated in table 2 to paragraph (e)(10) of this section.

(8) *Supplemental foods—Maximum monthly allowances, options and substitution rates, and minimum requirements.* Tables 1 through 3 to paragraphs (e)(9) through (11) of this section specify the maximum monthly allowances of foods in WIC food packages and identify WIC food options and substitution rates. Table 4 to paragraph (e)(12) of this section describes the minimum requirements and specifications of supplemental foods in the WIC food packages.

(9) *Full nutrition benefit and maximum monthly allowances supplemental foods for infants in Food Packages I, II, and III.* Full nutrition benefit and maximum monthly allowances, options and substitution rates of supplemental foods for infants in Food Packages I, II, and III are stated in table 1 to this paragraph (e)(9) as follows:

TABLE 1 TO PARAGRAPH (e)(9)—FOOD PACKAGES I, II, AND III: FULL NUTRITION BENEFIT (FNB) AND MAXIMUM MONTHLY ALLOWANCES (MMA) OF SUPPLEMENTAL FOODS FOR INFANTS BY FEEDING OPTION AND FOOD PACKAGE TIMEFRAME

Foods [1]	Fully formula fed (FF)		Partially (mostly) breastfed (BF/FF)		Fully breastfed (BF)	
	Food Packages I–FF & III–FF A: 0 through 3 months B: 4 through 5 months	Food Packages II–FF & III–FF 6 through 11 months	Food Packages IBF/FF & III BF/FF A:0 through 3 months B: 4 through 5 months	Food Packages II BF/FF & III BF/FF 6 through 11 months	Food Package I–BF 0 through 5 months	Food Package II–BF 6 through 11 months
WIC Formula [2 3 4 5 6 7 8]	A: FNB = Up to 806 fl oz MMA = 823 fl oz reconstituted liquid concentrate or 832 fl. oz. RTF or 870 fl oz reconstituted powder. B: FNB = Up to 884 fl oz MMA = 896 fl oz reconstituted liquid concentrate or 913 fl oz RTF or 960 fl oz reconstituted powder.	FNB = Up to 624 fl oz MMA = 630 fl oz reconstituted liquid concentrate or 643 fl. oz RTF or 696 fl oz reconstituted powder.	A: FNB = Up to 364 fl oz MMA = 388 fl oz reconstituted liquid concentrate or 384 fl oz RTF or 435 fl oz reconstituted powder. B: FNB = Up to 442 fl oz MMA = 460 fl oz reconstituted liquid concentrate or 474 fl oz RTF or 522 fl oz reconstituted powder.	FNB = Up to 312 fl oz MMA = 315 fl oz reconstituted liquid concentrate or 338 fl oz RTF or 384 fl oz reconstituted powder.	N/A	N/A.
Infant *Cereal [9 10 11]	N/A	8 oz	N/A	8 oz	N/A	16 oz.
Infant food fruits and vegetables [9 10 11 12 13].	N/A	128 oz	N/A	128 oz	N/A	128 oz.
Infant food meat [9 10]	N/A	N/A	N/A	N/A	N/A	40 oz.

Table 1 Footnotes (abbreviations in order of appearance in table): FF = fully formula fed; BF/FF = partially (mostly) breastfed; BF = fully breastfed; RTF = ready-to-feed; N/A = Not applicable.

[1] Table 4 to paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods. The competent professional authority (CPA) is authorized to determine nutritional risk and prescribe supplemental foods in Food Packages I, II and III (per medical documentation) as established by State agency policy. Food Package III is issued to participants with qualifying medical conditions. A WIC formula is issued to participants receiving Food Package III under the direction of a health care provider.

[2] Amounts represent the FNB defined as the minimum amount of reconstituted fluid ounces of liquid concentrate infant formula as specified for each infant food package category and feeding variation. The FNB is based on a 13-ounce can that formed the basis of substitution rates for other physical forms of infant formula (*i.e.,* powder and RTF infant formula).

[3] Following a WIC nutrition and breastfeeding assessment of the needs of the dyad, breastfed infants, even those in the fully formula fed category, should be issued the quantity of formula needed to support any level of breastfeeding, up to the FNB. This amount may be less than the FNB.

[4] WIC formula means infant formula, exempt infant formula, or WIC-eligible nutritionals. Infant formula may be issued for infants in Food Packages I, II and III. Medical documentation is required for issuance of WIC formula and other supplemental foods in Food Package III. Only infant formula may be issued for infants in Food Packages I and II.

[5] State agencies must issue whole containers that are all the same size of the same physical form.

[6] The MMA is specified in reconstituted fluid ounces for liquid concentrate, RTF liquid, and powder forms of infant formula and exempt infant formula. Reconstituted fluid ounce is the form prepared for consumption as directed on the container. Formula provided to infants in any form may not exceed the MMA.

[7] State agencies must provide at least the FNB authorized to non-breastfed infants up to the MMA for the physical form of the product specified for each food package category.

[8] State agencies may round up and disperse whole containers of infant formula over the food package timeframe to allow participants to receive the FNB. State agencies must use the methodology described in accordance with paragraph (h)(1) of this section.

[9] Per paragraph (b)(2)(ii)(A) of this section, State agencies must make the full MMA of all foods available to participants by providing at least one package size (or combination of sizes) that add up to the full MMA. However, per paragraph (b)(1)(iii) of this section, State agencies may authorize other package sizes (excluding WIC formula) to increase participant variety and choice.

[10] State agencies may round up and disperse whole containers of infant foods (infant cereal, fruits and vegetables, and meat) over the food package timeframe. State agencies must use the methodology described in accordance with paragraph (h)(2) of this section.

[11] In lieu of infant foods (cereal, fruit and vegetables), infants greater than 6 months of age in Food Package III may receive WIC formula (infant formula, exempt infant formula or WIC-eligible nutritionals) at the same MMA as infants ages 4 through 5 months of age of the same feeding option.

[12] At State agency option, infants 6 through 11 months in Food Packages II and III may receive a cash-value voucher (CVV) to purchase fruits and vegetables in lieu of the infant food fruits and vegetables. Fully breastfed infants, partially (mostly) breastfed infants and fully formula fed infants may substitute half (64 oz.) or all (128 oz.) of jarred infant fruits and vegetables with a $10 or $20 CVV, respectively. The monthly value of the CVV substitution amounts for infant fruits and vegetables will be adjusted annually for inflation consistent with the inflation adjustments made to women and children CVV values. State agencies must authorize fresh and one other form (frozen or canned). Dried fruits and vegetables are not authorized for infants.

[13] State agencies may not categorically issue cash-value vouchers (CVV) for infants 6 through 11 months. The CVV is to be provided to the participant only after an individual nutrition assessment, as established by State agency policy. State agencies must ensure that appropriate nutrition education is provided to the caregiver addressing developmental readiness, safe food preparation, storage techniques, and feeding practices to make certain participants are meeting their nutritional needs in a safe and effective manner.

(10) *Maximum monthly allowances of supplemental foods in Food Packages IV through VII.* The maximum monthly allowances, options, and substitution rates of supplemental foods for children and women in Food Package IV through VII are stated in table 2 to this paragraph (e)(10) as follows:

TABLE 2 TO PARAGRAPH (e)(10)—FOOD PACKAGES IV, V, VI AND VII: MAXIMUM MONTHLY ALLOWANCES (MMA) OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN

Foods [1]	Children	Women		
	Food Package IV: 1 through 4 years A: 12 through 23 months B: 2 through 4 years	Food Package V: A: Pregnant B: Partially (mostly) breastfeeding (up to 1 year postpartum) [2]	Food Package VI: Postpartum (up to 6months postpartum) [3]	Food Package VII: Fully Breastfeeding (up to 1year post-partum) [4 5]
Juice, single strength [6 7]	64 fl oz	64 fl oz	N/A	64 fl oz.
Milk, fluid [8 9 10 11 12 13 14 15]	A: 12 qt [8 9 11 12 14] B: 14 qt [8 10 11 12 13 14].	16 qt [8 10 11 12 13 15]	16 qt [8 10 11 12 13 15]	16 qt. [8 10 11 12 13 15]
Breakfast cereal [16]	36 oz	36 oz	36 oz	36 oz.
Eggs [17]	1 dozen	1 dozen	1 dozen	2 dozen.
Fresh fruits and vegetables [18 19]	$24.00 CVV	A: $43.00 CVV B: $47.00 CVV.	$43.00 CVV	$47.00 CVV.
Whole wheat or whole grain bread [20].	24 oz	48 oz	48 oz	48 oz.
Fish (canned) [21 22]	A: N/A B: 5 oz.	A: 10 oz B: 15 oz.	10 oz	20 oz.
Legumes *and/or* Peanut butter [23].	1 lb dry, or 64 oz canned Or 18 oz.	1 lb dry, or 64 oz canned And 18 oz.	1 lb dry, or 64 oz canned Or 18 oz.	1 lb dry, or 64 oz canned And 18 oz.

Table 2 Footnotes (abbreviations in order of appearance in table): N/A = the supplemental food is not authorized in the corresponding food package; CVV = cash-value voucher.

[1] Table 4 to paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods. Per paragraph (b)(2)(ii)(A) of this section, State agencies must make the full MMA of all foods available to participants by providing at least one package size (or combination of sizes) that add up to the full MMA. However, per paragraph (b)(1)(iii) of this section, State agencies may authorize other package sizes (excluding WIC formula) to increase participant variety and choice. The competent professional authority (CPA) is authorized to determine nutritional risk and prescribe supplemental foods, as established by State agency policy.

[2] Food Package V–A is issued to women participants with singleton pregnancies. Food Package V–B is issued to two categories of WIC participants: breastfeeding women whose partially (mostly) breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances, as appropriate for the age of the infant as described in table 1 to paragraph (e)(9) of this section, and women pregnant with two or more fetuses.

[3] Food Package VI is issued to two categories of WIC participants: Non-breastfeeding postpartum women and breastfeeding postpartum women whose infants receive more than the maximum infant formula allowances, as appropriate for the age of the infant as described in table 1 to paragraph (e)(9) of this section.

[4] Food Package VII is issued to three categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women partially (mostly) breastfeeding multiple infants from the same pregnancy; and pregnant women who are also fully or partially (mostly) breastfeeding singleton infants.

[5] Women fully breastfeeding multiple infants from the same pregnancy are prescribed 1.5 times the maximum monthly allowances.

[6] Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the MMA for single-strength juice.

[7] Children and pregnant, partially, and fully breastfeeding women may choose to substitute a $3 CVV for the full juice amount (64 fluid ounces). The monthly value of the CVV substitution amount for juice will be adjusted annually for inflation consistent with the inflation adjustments made to women and children CVV values. A partial CVV substitution for juice is not authorized.

[8] Regular and lactose-free milk must be authorized. ''Regular milk'' refers to milk that conforms to FDA standard of identity 21 CFR 131.110 and contains lactose exclusive of fat content (*e.g.,* low-fat milk).

[9] Whole milk is the standard milk for issuance to 1-year-old children (12 through 23 months). Whole fat or low-fat yogurts may be issued to 1-year-old children. At State agency option, fat-reduced milks or nonfat yogurt may be issued to 1-year-old children for whom overweight or obesity is a concern. The need for fat-reduced milks or nonfat yogurt for 1-year-old children must be based on an individual nutritional assessment.

[10] Low-fat (1%) or nonfat milks are the standard milk for issuance to children ≥24 months of age and women. Reduced-fat (2%) milk is authorized only for participants with certain conditions, including but not limited to, underweight and maternal weight loss during pregnancy. The need for reduced-fat (2%) milk for children receiving food package IV–B and women must be based on an individual nutritional assessment, as established by State agency policy.

[11] Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk (*i.e.,* 1:2 fluid ounce substitution ratio). Dry milk may be substituted at an equal reconstituted rate to fluid milk.

[12] For children and women, 1 pound of cheese may substitute for 3 quarts of milk; 1 quart of yogurt may substitute for 1 quart of milk, with a maximum of 2 quarts of yogurt that may be substituted for 2 quarts of milk. Women receiving Food Package VII also have the option of 2 pounds of cheese substituting for 6 quarts of milk. For children and women in Food Packages IV–VI, no more than 1 pound of cheese may be substituted. State agencies do not have the option to issue additional amounts of cheese or yogurt beyond these maximums even with medical documentation.

[13] For children ≥24 months of age (Food Package IV–B) and women, low-fat or nonfat yogurts are the only types of yogurts authorized. At State agency option, soy-based yogurt and/or soy-based cheese substitutes are authorized yogurt and cheese options for individuals who have a milk allergy, are lactose intolerant, or consume a vegan diet, as established by State agency policy.

[14] For children, issuance of tofu and soy-based beverage as substitutes for milk must be based on an individual nutritional assessment and consultation with the participant's health care provider, if necessary, as established by State agency policy. Such determination can be made for situations that include, but are not limited to, milk allergy, lactose intolerance, and vegan diets. Soy-based beverage may be substituted for milk for children on a quart for quart basis up to the total MMA of milk. Tofu may be substituted for milk for children at the rate of 1 pound of tofu per 1 quart of milk. Additional amounts of tofu may be substituted, up to the MMA for fluid milk for lactose intolerance or other reasons, as established by State agency policy.

[15] For women, soy-based beverage may be substituted for milk on a quart for quart basis up to the total MMA of milk. Tofu may be substituted for milk at the rate of 1 pound of tofu per 1 quart of milk; a maximum of 1 pound of tofu can be substituted. Additional amounts of tofu may be substituted, up to the MMA for milk, for lactose intolerance or other reasons, as established by State agency policy.

[16] All cereals authorized on a State agency's food list must meet whole grain criteria (refer to table 4 to paragraph (e)(12) of this section and its footnotes).

[17] A substitution of dry legumes (1 pound) or canned legumes (64 ounces) or peanut butter (18 ounces) for each 1 dozen eggs is permitted for individuals with an egg allergy or who consume a vegan diet or other reasons, as established by State agency policy. At State agency option, tofu (1 pound) may be substituted for each 1 dozen eggs for individuals with an egg allergy or who consume a vegan diet or other reasons, as established by State agency policy.

[18] State agencies must authorize fresh and one other form of processed (*i.e.,* canned (shelf-stable), frozen, and/or dried) fruits and vegetables. State agencies may choose to authorize additional or all processed forms of fruits and vegetables. The CVV may be redeemed for any eligible fruit and vegetable (refer to table 4 to paragraph (e)(12) of this section and its footnotes). Except as authorized in paragraph (b)(1)(i) of this section, State agencies may not selectively choose which fruits and vegetables are available to participants. For example, if a State agency chooses to offer dried fruits, it must authorize all WIC-eligible dried fruits.

[19] The monthly value of the fruit/vegetable CVV will be adjusted annually for inflation as described in § 246.16(j).

[20] Whole wheat and/or whole grain bread must be authorized. State agencies have the option to also authorize other whole grain options as described in table 4 to paragraph (e)(12) of this section and its footnotes.

[21] Issuance of smaller container sizes is encouraged to reduce the likelihood of exceeding weekly safe consumption level of methylmercury. The U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) provide joint advice regarding seafood consumption to limit methylmercury exposure for children. Depending on body weight, some women and many children should choose seafood lowest in methylmercury or eat less seafood than the amounts in the Healthy US-Style Dietary Pattern. More information is available on the FDA and EPA websites at *FDA.gov/fishadviceandEPA.gov/fishadvice.*

[22] For children, salmon, sardines, and Atlantic mackerel are the only types of canned fish authorized.

[23] State agencies are required to offer both mature dry and canned legumes: 1 pound dry or 64 ounces canned. In Food Packages V and VII, both legumes and peanut butter must be provided. However, when individually tailoring these food packages for nutritional reasons (*e.g.,* food allergy, underweight, participant preference), State agencies have the option to authorize the following substitutions: 1 pound dry and 64 oz. canned legumes (and no peanut butter); or 2 pounds dry or 128 oz. canned legumes (and no peanut butter); or 36 oz. peanut butter (and no legumes).

(11) *Maximum monthly allowances of supplemental foods for children and women with qualifying conditions in Food Package III.* The maximum monthly allowances, options and substitution rates of supplemental foods for participants with qualifying conditions in Food Package III are stated in table 3 to this paragraph (e)(11) as follows:

TABLE 3 TO PARAGRAPH (e)(11)—FOOD PACKAGE III: MAXIMUM MONTHLY ALLOWANCES (MMA) OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN WITH QUALIFYING CONDITIONS

Foods [1]	Children	Women		
	A: 12 through 23 months B: 2 through 4 years	A: Pregnant B: Partially (mostly) breastfeeding (up to 1 year postpartum) [2]	Postpartum (up to 6 months postpartum) [3]	Fully Breastfeeding (up to 1 year postpartum) [4 5]
Juice, single strength [6 7]	64 fl oz	64 fl oz	N/A	64 fl oz.
WIC formula [8 9]	Up to 455 fl liquid concentrate.	Up to 455 fl liquid concentrate.	Up to 455 fl liquid concentrate.	Up to 455 fl liquid concentrate.
Milk, fluid [10 11 12 13 14 15 16 17]	A: 12 qt [10 11 13 14 16] B: 14 qt [10 2 13 14 15 16].	16 qt [10 12 13 14 15 17]	16 qt [10 12 13 14 15 17]	16 qt [10 12 13 14 15 17]
Breakfast cereal [18 19]	36 oz	36 oz	36 oz	36 oz.
Eggs [20]	1 dozen	1 dozen	1 dozen	2 dozen.
Fresh fruits and vegetables [21 22 23].	$24.00 CVV	A: $43.00 CVV B: $47.00 CVV.	$43.00 CVV	47.00 CVV.
Whole wheat or whole grain bread [24].	24 oz	48 oz	48 oz	48 oz.
Fish (canned) [25 26]	A: N/A B: 5 oz.	A: 10 oz B: 15 oz.	10 oz	20 oz.
Legumes *and/or* Peanut butter [27].	1 lb dry, or 64 oz canned Or 18 oz.	1 lb dry, or 64 oz canned And 18 oz.	1 lb dry, or 64 oz canned Or 18 oz.	1 lb dry, or 64 oz canned And 18 oz.

Table 3 Footnotes (abbreviations in order of appearance in table): N/A = the supplemental food is not authorized in the corresponding food package; CVV= cash-value voucher.

[1] Table 4 to paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods. Food Package III is issued to participants with qualifying medical conditions that require use of a WIC formula and supplementary foods under the direction of a health care provider. Per paragraph (b)(2)(ii)(A) of this section, State agencies must make the full MMA of all foods available to participants by providing at least one package size (or combination of sizes) that add up to the full MMA. However, per paragraph (b)(1)(iii) of this section, State agencies may authorize other package sizes (excluding WIC formula) to increase participant variety and choice. The competent professional authority (CPA) is authorized to determine nutritional risk and prescribe supplemental foods as established by State agency policy.

[2] Food Package III–A for women is issued to women participants with singleton pregnancies. Food Package III–B for women is issued to two categories of participants: breastfeeding women whose partially (mostly) breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances, as appropriate for the age of the infant as described in table 1 to paragraph (e)(9) of this section, and women pregnant with two or more fetuses.

[3] This food package is issued to two categories of WIC participants: Non-breastfeeding postpartum women and breastfeeding postpartum women whose infants receive more than the maximum infant formula allowances, as appropriate for the age of the infant as described in table 1 to paragraph (e)(9) of this section.

[4] This food package is issued to three categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women partially (mostly) breastfeeding multiple infants from the same pregnancy; and pregnant women who are also fully or partially (mostly) breastfeeding singleton infants.

[5] Women fully breastfeeding multiple infants from the same pregnancy are prescribed 1.5 times the MMA.

[6] Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the MMA for single-strength juice.

[7] As determined appropriate by the health care provider per medical documentation, children and pregnant, partially, and fully breastfeeding women may: choose to substitute a $3 CVV for the full juice amount (64 fluid ounces)—a partial CVV substitution for juice is not authorized—or use their $3 CVV for jarred infant food fruits and vegetables. State agencies must use the conversion of $1 CVV = 6.25 ounce of jarred infant food fruits and vegetables.

[8] WIC formula means infant formula, exempt infant formula, or WIC-eligible nutritionals. Participants may receive up to 455 fluid ounces of a WIC formula (liquid concentrate) as determined appropriate by the health care provider per medical documentation. The number of fluid ounces refers to the amount as prepared according to directions on the container.

[9] Powder and ready-to-feed may be substituted at rates that provide comparable nutritive value.

[10] Regular and lactose-free milk must be authorized. ''Regular milk'' refers to milk that conforms to FDA standard of identity 21 CFR 131.110 and contains lactose exclusive of fat content (*e.g.,* low-fat milk).

[11] Whole milk is the standard milk for issuance to 1-year-old children (12 through 23 months). Whole fat or low-fat yogurts may be issued to 1-year-old children. Fat-reduced milks or nonfat yogurt may be issued to 1-year-old children as determined appropriate by the health care provider per medical documentation.

[12] Low-fat (1%) or nonfat milks are the standard milk for issuance to children ≥24 months of age and women. Whole milk or reduced-fat (2%) milk may be substituted for low-fat (1%) or nonfat milk for children ≥24 months of age and women as determined appropriate by the health care provider per medical documentation.

[13] Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk (a 1:2 fluid ounce substitution ratio). Dry milk may be substituted at an equal reconstituted rate to fluid milk.

[14] For children and women, 1 pound of cheese may substitute for 3 quarts of milk; 1 quart of yogurt may substitute for 1 quart of milk, with a maximum of 2 quarts of yogurt that may be substituted for 2 quarts of milk. Fully breastfeeding women may substitute 2 pounds of cheese for 6 quarts of milk. Children and other women may substitute no more than 1 pound of cheese. State agencies do not have the option to issue additional amounts of cheese or yogurt beyond these maximums even with medical documentation.

[15] For children ≥24 months of age (Food Package IV–B) and women, low-fat or nonfat yogurts are the only types of yogurts authorized. Whole or reduced-fat yogurt may be substituted for low-fat or nonfat yogurt for children ≥24 months of age and women as determined appropriate by the health care provider per medical documentation. At State agency option, soy-based yogurt and/or soy-based cheese substitutes are authorized yogurt and cheese options for individuals who have a milk allergy, are lactose intolerant, or consume a vegan diet as determined appropriate by the health care provider per medical documentation.

[16] For children, issuance of tofu and soy-based beverage may be substituted for milk as determined appropriate by the health care provider per medical documentation. Soy-based beverage may be substituted for milk for children on a quart for quart basis up to the total MMA of milk. Tofu may be substituted for milk for children at the rate of 1 pound of tofu per 1 quart of milk. Additional amounts of tofu may be substituted, up to the MMA of milk, as determined appropriate by the health care provider per medical documentation.

[17] For women, soy-based beverage may be substituted for milk on a quart for quart basis up to the total MMA of milk. Tofu may be substituted for milk at the rate of 1 pound of tofu per 1 quart of milk. Additional amounts of tofu may be substituted, up to the MMA of milk as determined appropriate by the health care provider per medical documentation.

[18] 32 dry ounces of infant cereal may be substituted for 36 ounces of breakfast cereal as determined appropriate by the health care provider per medical documentation.

[19] All cereals authorized on a State agency's food list must meet whole grain criteria (refer to table 4 to paragraph (e)(12) of this section and its footnotes).

[20] A substitution of dry legume (1 pound) or canned legumes (64 ounces) or peanut butter (18 ounces) for each 1 dozen eggs is permitted for individuals with an egg allergy or who consume a vegan diet. At State agency option, tofu (1 pound) may be substituted for each 1 dozen eggs for individuals with an egg allergy or who consume a vegan diet.

[21] State agencies must authorize fresh and one other form (*i.e.,* canned (shelf-stable), frozen, and/or dried) of fruits and vegetables. State agencies may choose to authorize additional or all processed forms of fruits and vegetables. The CVV may be redeemed for any eligible fruit and vegetable (refer to table 4 to paragraph (e)(12) of this section and its footnotes). Except as authorized in paragraph (b)(1)(i) of this section, State agencies may not selectively choose which fruits and vegetables are available to participants. For example, if a State agency chooses to offer dried fruits, it must authorize all WIC-eligible dried fruits.

[22] Children and women whose special dietary needs require the use of pureed foods may receive commercial jarred infant food fruits and vegetables in lieu of the CVV. For children and women who require jarred infant food fruits and vegetables in place of the CVV, State agencies must use the conversion of $1 CVV = 6.25 ounce of jarred infant food fruits and vegetables. Infant food fruits and vegetables may be substituted for the CVV as determined appropriate by the health care provider per medical documentation.

[23] The monthly value of the fruit/vegetable CVV will be adjusted annually for inflation as described in § 246.16(j).

[24] Whole wheat and/or whole grain bread must be authorized. State agencies have the option to also authorize other whole grain options as described in table 4 to paragraph (e)(12) of this section and its footnotes.

[25] Issuance of smaller container sizes is encouraged to reduce the likelihood of exceeding weekly safe consumption level of methylmercury. The U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) provide joint advice regarding seafood consumption to limit methylmercury exposure for children. Depending on body weight, some women and many children should choose seafood lowest in methylmercury or eat less seafood than the amounts in the Healthy US-Style Dietary Pattern. More information is available on the FDA and EPA websites at *FDA.gov/fishadviceandEPA.gov/fishadvice.*

[26] For children, salmon, sardines, and Atlantic mackerel are the only types of canned fish authorized.

[27] State agencies are required to offer both mature dry and canned legumes: 1 pound dry or 64 ounces canned. In food packages where both beans and peanut butter are provided, when individually tailoring these food packages for nutritional reasons (*e.g.,* food allergy, underweight, participant preference), State agencies have the option to authorize the following substitutions: 1 pound dry and 64 oz. canned legumes (and no peanut butter); or 2 pounds dry or 128 oz. canned legumes (and no peanut butter); or 36 oz. peanut butter (and no legumes).

(12) *Minimum requirements and specifications for supplemental foods.* Table 4 to this paragraph (e)(12) describes the minimum requirements and specifications for supplemental foods in all food packages:

TABLE 4 TO PARAGRAPH (e)(12)—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS

Categories/foods	Minimum requirements and specifications
WIC FORMULA:	
Infant formula	All authorized infant formulas must: (1) Meet the definition for an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 350a), and the regulations at 21 CFR parts 106 and 107; (2) Be designed for enteral digestion via an oral or tube feeding; (3) Provide at least 10 mg iron per liter (at least 1.5 mg iron/100 kilocalories) at standard dilution; (4) Provide at least 67 kilocalories per 100 milliliters (approximately 20 kilocalories per fluid ounce) at standard dilution. (5) Not require the addition of any ingredients other than water prior to being served in a liquid state.
Exempt infant formula	All authorized exempt infant formula must: (1) Meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 350a(h)), and the regulations at 21 CFR parts 106 and 107; and (2) Be designed for enteral digestion via an oral or tube feeding.
WIC-eligible nutritionals [1]	Certain enteral products that are specifically formulated and commercially manufactured (as opposed to a naturally occurring foodstuff used in its natural state) to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible nutritionals must serve the purpose of a food, meal, or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme.
MILK, MILK ALTERNATIVES, AND MILK SUBSTITUTIONS:	
Cow's milk [2]	Must conform to FDA standard of identity for whole, reduced-fat, low-fat, or nonfat milks (21 CFR 131.110). Must be pasteurized. Only unflavored milk is permitted. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dry. Dry whole milk must conform to FDA standard of identity (21 CFR 131.147). Nonfat dry milk must conform to FDA standard of identity (21 CFR 131.127). Cultured milks must conform to FDA standard of identity for cultured milk, *e.g.,* cultured buttermilk, kefir cultured milk, acidophilus cultured milk (21 CFR 131.112). Acidified milk must conform to FDA standard of identity for acidified milk, *e.g.,* acidified kefir milk, acidified acidophilus milk or acidified buttermilk (21 CFR 131.111). Whole, reduced-fat, low-fat, and nonfat cow's milk types and varieties must contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2,000 IU of vitamin A per quart (500 IU per cup).
Goat's milk	Must be pasteurized. Only unflavored milk is permitted. May be fluid, shelf-stable, evaporated, or dry (*i.e.,* powdered). Whole, reduced-fat, low-fat, and nonfat goat's milk must contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2,000 IU of vitamin A per quart (500 IU per cup).
Cheese	Domestic cheese made from 100 percent pasteurized milk. Must conform to FDA standard of identity (21 CFR part 133); Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, pasteurized process American, or blends of any of these cheeses are authorized. Cheeses that are labeled low, free, reduced, less or light in sodium, fat or cholesterol are WIC eligible.
Yogurt (cow's milk)	Must be pasteurized, conform to FDA standard of identity (21 CFR 131.200), and contain ≤30 g of total sugars and 100 IU (2.5 mcg) of vitamin D per 8 ounces (227 g). May be plain or flavored. Yogurts that are fortified with vitamin A and other nutrients may be allowed at the State agency's option. Yogurts sold with accompanying mix-in ingredients such as granola, candy pieces, honey, nuts, and similar ingredients are not authorized. Drinkable yogurts are not authorized.
Tofu	Must contain a minimum of 200 mg of calcium per 100 g of tofu. May not contain added fats, sugars, oils, or sodium.
Soy-based beverage	Must contain ≤12 g of total sugars per cup and be fortified to meet the following nutrient levels (amounts are provided per cup): 276 mg calcium, 8 g protein, 500 IU vitamin A, 100 IU vitamin D, 24 mg magnesium, 222 mg phosphorus, 349 mg potassium, 0.44 mg riboflavin, and 1.1 mcg vitamin B12, in accordance with fortification guidelines issued by FDA. May be flavored or unflavored.
Soy-based cheese	Must contain 250 mg of calcium and 6.5 g of protein per 1.5-oz. Soy curd cheeses are not authorized.
Soy-based yogurt	Must contain ≤30 g of total sugars, 250 mg of calcium, 6.5 g of protein, and 100 IU (2.5 mcg) vitamin D per 8 ounces (227 g). May be plain or flavored. Soy-based yogurts sold with accompanying mix-in ingredients such as granola, candy pieces, honey, nuts, and similar ingredients are not authorized. Drinkable yogurts are not authorized.
JUICE	Must be pasteurized 100% unsweetened fruit juice. Must contain at least 30 mg of vitamin C per 100 mL of juice. Must conform to FDA standard of identity as appropriate (21 CFR part 146) or vegetable juice must conform to FDA standard of identity as appropriate (21 CFR part 156). With the exception of 100% citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf stable. Blends of authorized juices are allowed. Vegetable juice may be regular or lower in sodium.
EGGS	Fresh shell domestic hens' eggs or dried eggs mix (must conform to FDA standard of identity in 21 CFR 160.105) or pasteurized liquid whole eggs (must conform to FDA standard of identity in 21 CFR 160.115). Hard boiled eggs, where readily available for purchase in small quantities, may be provided for homeless participants.
BREAKFAST CEREAL (READY-TO-EAT AND INSTANT AND REGULAR HOT CEREALS).	Must contain a minimum of 28 mg iron per 100 g dry cereal. Must contain ≤21.2 g sucrose and other sugars per 100 g dry cereal (≤6 g per dry oz). All cereals on the State agency authorized food list must contain whole grain as the first ingredient.

TABLE 4 TO PARAGRAPH (e)(12)—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS—Continued

Categories/foods	Minimum requirements and specifications
FRUITS AND VEGETABLES (FRESH AND PROCESSED)[3 4 5 6 7].	Any variety of fresh (as defined by 21 CFR 101.95) whole or cut fruit without added sugars. Any variety of fresh (as defined by 21 CFR 101.95) whole or cut vegetable without added sugars, fats, or oils. Any variety of canned fruits (must conform to FDA standard of identity as appropriate (21 CFR part 145)); including applesauce, juice pack or water pack without added sugars, fats, oils, or salt (*i.e.,* sodium). The fruit must be listed as the first ingredient.Any variety of frozen fruits without added sugars, fats, oils, or salt (*i.e.,* sodium). Any variety of canned or frozen vegetables, without added sugars, fats, or oils. Vegetable must be listed as the first ingredient. May be regular or lower in sodium. Must conform to FDA standard of identity as appropriate (21 CFR part 155). Any type of dried fruits or dried vegetables without added sugars, fats, oils, or salt (*i.e.,* sodium). Any type of immature beans, peas, or lentils, fresh or in canned[4] forms. Any type of frozen beans (immature or mature). Beans purchased with the CVV may contain added vegetables and fruits, but may not contain added sugars, fats, oils, or meat as purchased. Canned beans, peas, or lentils may be regular or lower in sodium content. State agencies must allow organic forms of WIC-eligible fruits and vegetables.
WHOLE WHEAT BREAD, WHOLE GRAIN BREAD, AND WHOLE GRAIN OPTIONS:	
Bread	*Whole wheat bread* must conform to FDA standard of identity (21 CFR 136.180). (Includes whole wheat buns and rolls.) ''Whole wheat flour'' and/or ''bromated whole wheat flour'' must be the only flours listed in the ingredient list. OR *Whole grain bread* must conform to FDA standard of identity (21 CFR 136.110) (includes whole grain buns and rolls). AND Must contain at least 50 percent whole grains with the remaining grains being either enriched or whole grains.[8]
Whole Grain Options	Brown rice, wild rice, quinoa, bulgur (cracked wheat), oats, whole-grain barley, millet, triticale, amaranth, cornmeal (including blue), corn masa flour, whole wheat macaroni (pasta) products, whole wheat bread products (*i.e.,* pita, English muffin, bagels, naan), soft corn or whole wheat tortillas, buckwheat, teff, kamut, sorghum, wheat berries without added sugars, fats, oils, or salt (*i.e.,* sodium). May be instant-, quick-, or regular-cooking. Corn meal (including blue) must conform to FDA standard of identity 21 CFR 137.260. Soft corn or whole wheat tortillas. Soft corn tortillas made from ground masa flour (corn flour) using traditional processing methods are WIC-eligible, *e.g.,* whole corn, corn (masa), whole ground corn, corn masa flour, masa harina, and white corn flour. For whole wheat tortillas, ''whole wheat flour'' must be the only flour listed in the ingredient list. States may offer tortillas made with folic acid-fortified corn masa flour. Whole wheat macaroni (pasta) products. Must conform to FDA standard of identity (21 CFR 139.138) and have no added sugars, fats, oils, or salt (*i.e.,* sodium). ''Whole wheat flour'' and/or ''whole durum wheat flour'' must be the only flours listed in the ingredient list. Other shapes and sizes that otherwise meet the FDA standard of identity for whole wheat macaroni (pasta) products (21 CFR 139.138), and have no added sugars, fats, oils, or salt (*i.e.,* sodium), are also authorized (*e.g.,* whole wheat rotini, and whole wheat penne).
FISH (CANNED)[5]	Canned only: Light tuna (must conform to FDA standard of identity (21 CFR 161.190)); Salmon (Pacific salmon must conform to FDA standard of identity (21 CFR 161.170)); Sardines; and Mackerel (N. Atlantic *Scomber scombrus;* Chub Pacific *Scomber japonicas*).[9] For children (2 through 4 years of age), salmon, sardines, and Atlantic mackerel are the only types of canned fish authorized. May be packed in water or oil. Pack may include bones or skin. Only boneless varieties of fish may be provided to children, at State agency option. Added sauces and flavorings, *e.g.,* tomato sauce, mustard, lemon, are authorized at the State agency's option. May be regular or lower in sodium content.
MATURE LEGUMES (DRY BEANS AND PEAS)[10]	Any type of mature dry beans, peas, or lentils in dry-packaged or canned[4] forms. Examples include but are not limited to black beans, black-eyed peas, garbanzo beans (chickpeas), great northern beans, white beans (navy and pea beans), kidney beans, mature lima (''butter beans''), fava beans, mung beans, pinto beans, soybeans/edamame, split peas, lentils, and refried beans. Does not include green beans or green peas. All categories exclude soups. May not contain added sugars, fats, oils, vegetables, fruits or meat as purchased. Canned legumes may be regular or lower in sodium content.[11] Baked beans may only be provided for participants with limited cooking facilities.[11]
PEANUT BUTTER	Peanut butter and reduced-fat peanut butter must conform to FDA standard of identity (21 CFR 164.150); creamy or chunky, regular, or reduced-fat, salted or unsalted forms are allowed. Peanut butters with added marshmallows, honey, jelly, chocolate or similar ingredients are not authorized.
INFANT FOODS:	
Infant Cereal	Infant cereal must contain a minimum of 45 mg of iron per 100 g of dry cereal.[12]
Infant Fruits	Any variety of single ingredient commercial infant food fruit without added fats, sugars, starches, or salt (*i.e.,* sodium). Texture may range from strained through diced. The fruit must be listed as the first ingredient.[13]
Infant Vegetables	Any variety of single ingredient commercial infant food vegetables without added fats, sugars, starches, or salt (*i.e.,* sodium). Texture may range from strained through diced. The vegetable must be listed as the first ingredient.[14]
Infant Meat	Any variety of commercial infant food meat or poultry, as a single major ingredient, with added broth or gravy. Added fats, sugars, or salt (*i.e.,* sodium) are not allowed. Texture may range from pureed through diced.[15]

Table 4 Footnotes: FDA = Food and Drug Administration of the U.S. Department of Health and Human Services. Daily Value and Percent Daily Value: Changes on the New Nutrition and Supplement Facts Labels (*fda.gov*).

[1] The following are not considered a WIC-eligible nutritional: Formulas used solely for the purpose of enhancing nutrient intake, managing body weight, addressing picky eaters or used for a condition other than a qualifying condition (*e.g.,* vitamin pills, weight control products, etc.); medicines or drugs, as defined by the Federal Food, Drug, and Cosmetic Act as amended; enzymes, herbs, or botanicals; oral rehydration fluids or electrolyte solutions; flavoring or thickening agents; and feeding utensils or devices (*e.g.,* feeding tubes, bags, pumps) designed to administer a WIC-eligible formula.

[2] All authorized milks must conform to FDA standards of identity for milks as defined by 21 CFR part 131 and meet WIC's requirements for vitamin fortification as specified in table 4 to paragraph (e)(12) of this section. Additional authorized milks include, but are not limited to: calcium-fortified, lactose-reduced, organic and UHT pasteurized milks. Other milks are permitted at the State agency's discretion provided that the State agency determines that the milk meets the minimum requirements for authorized milk.

[3] Processed refers to frozen, canned,[4] or dried.

[4] Canned refers to processed food items in cans or other shelf-stable containers, *e.g.,* jars, pouches.

[5] Fresh cut herbs are authorized. The following are not authorized: spices and dried herbs; seeds; potted plants with vegetables, fruits or herbs; creamed vegetables or vegetables with added sauces; fresh fruit and/or vegetable packaging with dips, sauces, or glazes; mixed vegetables containing noodles, nuts or sauce packets; vegetable-grain (pasta or rice) mixtures; fruit-nut mixtures; breaded vegetables; fruits and vegetables for purchase on salad bars; peanuts or other nuts; ornamental and decorative fruits and vegetables such as chili peppers on a string; garlic on a string; gourds; painted pumpkins; fruit baskets; decorative blossoms and flowers, and foods containing fruits such as blueberry muffins and other baked goods. Home-canned and home-preserved fruits and vegetables are not authorized.

[6] Excludes catsup or other condiments; pickled vegetables; olives; soups; juices; and fruit leathers and fruit roll-ups. Canned tomato sauce, tomato paste, salsa, and spaghetti sauce without added sugar, fats, or oils are authorized.

[7] State agencies have the option to allow only lower sodium canned vegetables for purchase with the cash-value voucher.

[8] One of the following criteria must be met to confirm the product provides 50% or more whole grains: (1) product labeling contains the FDA health claim ''Diet rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers'' OR ''Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease''; (2) meets the ''rule of three'' criteria (*i.e.,* the first ingredient (or second after water) must be whole grain, and the next two grain ingredients (if any) must be whole grains, enriched grains, bran or germ; (3) the manufacturer provides written documentation that product contains 50% or more whole grains by weight.

[9] King mackerel is not authorized.

[10] Mature legumes in dry or canned forms may be purchased with the WIC food instrument only. Immature varieties of fresh or canned beans and frozen beans of any type (immature or mature) may be purchased with the cash-value voucher only. Juices are provided as a separate WIC food category and are not authorized under the fruit and vegetable category.

[11] The following are not authorized in the mature legume category: soups; immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, yellow beans, and wax beans; baked beans with meat, *e.g.,* beans and franks; beans containing added sugars (with the exception of baked beans), fats, oils, meats, fruits or vegetables.

[12] Infant cereals containing infant formula, milk, fruit, or other non-cereal ingredients are not allowed.

[13] Mixtures with cereal or infant food desserts (*e.g.,* peach cobbler) are not authorized; however, combinations of single ingredients (*e.g.,* apple-banana) and combinations of single ingredients of fruits and/or vegetables (*e.g.,* apples and squash) are allowed.

[14] Combinations of single ingredients (*e.g.,* peas and carrots) and combinations of single ingredients of fruits and/or vegetables (*e.g.,* apples and squash) are allowed. Mixed vegetables with white potato as an ingredient (*e.g.,* mixed vegetables) are authorized.

[15] No infant food combinations (*e.g.,* meat and vegetables) or dinners (*e.g.,* spaghetti and meatballs) are allowed.

(f) *USDA purchase of commodity foods.* (1) At the request of a State agency, FNS may purchase commodity foods for the State agency using funds allocated to the State agency. The commodity foods purchased and made available to the State agency must be equivalent to the foods specified in table 4 to paragraph (e)(12) of this section.

(2) The State agency must:

(i) Distribute the commodity foods to its local agencies or participants; and

(ii) Ensure satisfactory storage facilities and conditions for the commodity foods, including documentation of proper insurance.

(g) *Infant formula manufacturer registration.* Infant formula manufacturers supplying formula to the WIC Program must be registered with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). Such manufacturers wishing to bid for a State contract to supply infant formula to the Program must certify with the State health department that their formulas comply with the Federal Food, Drug, and Cosmetic Act and regulations issued pursuant to the Act.

(h) *Rounding up.* State agencies may round up to the next whole container for either infant formula or infant foods (infant cereal, fruits, vegetables and meat). State agencies that use the rounding up option must calculate the amount of infant formula or infant foods provided according to the requirements and methodology as described in this section.

(1) *Infant Formula.* State agencies must use the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate infant formula as specified in table 1 to paragraph (e)(9) of this section as the full nutritional benefit (FNB) provided by infant formula for each food package category and infant feeding option (*e.g.,* Food Package I A fully formula fed, IA–FF).

(i) For State agencies that use rounding up of infant formula, the FNB is determined over the timeframe (the number of months) that the participant receives the food package. In any given month of the timeframe, the monthly issuance of reconstituted fluid ounces of infant formula may exceed the maximum monthly allowance or fall below the FNB; however, the cumulative average over the timeframe may not fall below the FNB. In addition, the State agency must:

(A) Use the methodology described in paragraph (h)(1)(ii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant formula in whole containers that are all the same size; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe with the largest monthly issuances given in the beginning of the timeframe.

(ii) The methodology to calculate rounding up and dispersing infant formula to the next whole container over the food package timeframe is as follows:

(A) Multiply the FNB amount for the appropriate food package and feeding option (*e.g.,* Food Package I A fully formula fed, IA–FF) by the timeframe the participant will receive the food package to determine the total amount of infant formula to be provided.

(B) Divide the total amount of infant formula to be provided by the yield of the container (in reconstituted fluid ounces) issued by the State agency to determine the total number of containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole container in order to issue whole containers.

(2) *Infant foods.* (i) State agencies may use the rounding up option to the next whole container of infant food (infant cereal, fruits, vegetables and meat) when the maximum monthly allowance cannot be issued due to varying container sizes of authorized infant foods.

(ii) State agencies that use the rounding up option for infant foods must:

(A) Use the methodology described in paragraph (h)(2)(iii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant foods in whole containers; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe (the number of months the participant will receive the food package).

(iii) The methodology to round up and disperse infant food is as follows:

(A) Multiply the maximum monthly allowance for the infant food by the timeframe the participant will receive the food package to determine the total amount of food to be provided.

(B) Divide the total amount of food provided by the container size issued by the State agency (*e.g.,* ounces) to determine the total number of food containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole container in order to issue whole containers.

(i) *Plans for substitutions.* (1) The State agency may submit to FNS a plan for substitution of food(s) acceptable for use in the Program to allow for different cultural eating patterns. The plan shall provide the State agency's justification, including a specific explanation of the cultural eating pattern and other information necessary for FNS to evaluate the plan as specified in paragraph (i)(2) of this section.

(2) FNS will evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria:

(i) Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace.

(ii) The proposed substitute food must be widely available to participants in

the areas where the substitute is intended to be used.

(iii) The cost of the substitute food must be equivalent to or less than the cost of the food it is intended to replace.

(3) FNS will make a determination on the proposed plan based on the evaluation criteria specified in paragraph (i)(2) of this section, as appropriate. The State agency shall substitute foods only after receiving the written approval of FNS.

■ 5. Amend § 246.11 by revising paragraph (a)(1) to read as follows:

§ 246.11 Nutrition education.

(a) * * *

(1) Nutrition education including breastfeeding promotion and support shall be considered a benefit of the Program and shall be made available at no cost to the participant. Nutrition education including breastfeeding promotion and support, shall be designed to be easily understood by participants, and it shall bear a practical relationship to participant nutritional needs, household situations, and cultural preferences including information on how to select food for themselves and their families as well as the maximum monthly allowances of authorized supplemental foods to which they are entitled as a Program participant.

* * * * *

■ 6. Amend § 246.12 by revising paragraphs (g)(3)(i) and (u)(2)(i) to read as follows:

§ 246.12 Food delivery methods.

* * * * *

(g) * * *

(3) * * *

(i) *Minimum variety and quantity of supplemental foods.* The State agency must establish minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized. These requirements include that the vendor stock at least two different fruits, three different vegetables, and at least one whole grain cereal authorized by the State agency. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant meets these minimums. The State agency may establish different minimums for different vendor peer groups. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources included on the State agency's list described in paragraph (g)(11) of this section.

* * * * *

(u) * * *

(2) * * *

(i) *General.* Except as provided in paragraphs (u)(2)(ii) and (iii) of this section, whenever the State agency assesses a claim of $1,000 or more, assesses a claim for dual participation, or assess a second or subsequent claim of any amount, the State agency must disqualify the participant for one year.

* * * * *

■ 7. Amend § 246.16 by revising paragraphs (j) introductory text and (j)(1) through (4)to read as follows:

§ 246.16 Distribution of funds.

* * * * *

(j) *Inflation adjustment of the fruit and vegetable voucher.* The monthly cash value of the fruit and vegetable voucher shall be adjusted annually for inflation. Adjustments are effective the first day of each fiscal year beginning on or after October 1 each year. The inflation-adjusted value of the voucher shall be equal to a base value increased by a factor based on the Consumer Price Index for All Urban Consumers (CPI–U) for fresh fruits and vegetables, as provided in this section.

(1) *Adjustment year.* The adjustment year is the fiscal year that begins October 1 of the current calendar year.

(2) *Base value of the fruit and vegetable voucher.* The base year for calculation of the value of the fruit and vegetable voucher is fiscal year 20[22]. The base value to be used equals:

(i) $24 for children;

(ii) $43 for pregnant and postpartum women; and

(iii) $47 for breastfeeding (fully and partially) women.

(3) *Adjusted value of the fruit and vegetable voucher.* The adjusted value of the fruit and vegetable voucher is the cash value of the voucher for adjustment years beginning on or after [October 1, 2022]. The adjusted value is the base value increased by an amount equal to the base value of the fruit and vegetable voucher:

(i) Multiplied by the inflation adjustment described in paragraph (j)(4) of this section; and

(ii) Subject to rounding as described in paragraph (j)(5) of this section.

(4) *Inflation adjustment.* The inflation adjustment of the fruit and vegetable voucher shall equal the percentage (if any) by which the annual average value of the Consumer Price Index for fresh fruits and vegetables, computed from monthly values published by the Bureau of Labor Statistics, for the twelve months ending on March 31 of the fiscal year immediately prior to the adjustment year, exceeds the average of the monthly values of that index for the twelve months ending on March 31, 2021.

* * * * *

Cynthia Long,

Administrator, Food and Nutrition Service.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix A—Regulatory Impact Analysis

Regulatory Impact Analysis

I. Statement of Need

Section 17 of the Child Nutrition Act of 1966 (Pub. L. 89–642) mandates that the USDA conduct a comprehensive scientific review of the WIC food packages at least every ten years and revise the foods available, as needed, to reflect nutritional science, public health concerns, and cultural eating patterns (42 U.S.C. 1786(f)(11)(C)). This rule proposes changes that are intended to provide WIC participants with a wider variety of foods that align with the latest nutritional science; provide WIC State agencies with greater flexibility to prescribe food packages that accommodate participants' personal and cultural food preferences and special dietary needs; provide more equitable access to supplemental foods; and better promote and support individual breastfeeding goals of participants to help establish successful long-term breastfeeding.

II. Background

Established in 1974, the mission of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is to safeguard the health of low-income pregnant, postpartum, and breastfeeding individuals, infants, and children ages 1 through 4 years who are at nutritional risk by providing nutritious foods to supplement diets, nutrition education (to include breastfeeding promotion and support), and referrals to health and other social services. Participation in WIC is associated with improved pregnancy outcomes and lower infant mortality. WIC participation is also associated with improved diet quality.[1] In Federal fiscal year (FY) 2020, WIC served an average of 6.25 million infants, children, and pregnant, breastfeeding and postpartum individuals per month.[2]

The monthly WIC food packages are prescribed to (1) address the prevalence of inadequate and excessive nutrient intakes for

[1] Caulfield, L., Bennett, W., Gross, S., Hurley, K., Ogunwole, S., Venkataramani, M., Lerman, J., Zhang, A., Sharma, R., Bass, E. (2022). Maternal and Child Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Comparative Effectiveness Review No. 253. Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 75Q80120D00003.) AHRQ Publication No. 22–EHC019. Rockville, MD: Agency for Healthcare Research and Quality. DOI: *https://doi.org/10.23970/AHRQEPCCER253.*

[2] U.S. Department of Agriculture Food and Nutrition Service. WIC Data Tables, 2021. Available online at: *https://www.fns.usda.gov/pd/wic-program.*

each WIC participant category, (2) contribute to an overall dietary pattern consistent with the Dietary Guidelines for Americans (DGA), and (3) deliver priority nutrients to participants to meet their supplemental nutrition needs. There are seven WIC food packages available for the following participant categories:

- *Food Package I:* Infants birth through 5 months (Fully Breastfed, Partially Breastfed, and Fully Formula Fed)
- *Food Package II:* Infants ages 6 through 11 months (Fully Breastfed, Partially Breastfed, and Fully Formula Fed)
- *Food Package III:* Medically Fragile Women, Infants, and Children
- *Food Package IV:* Children ages 1 through 4 years
- *Food Package V:* Pregnant & Partially Breastfeeding Women up to 1 year postpartum
- *Food Package VI:* Postpartum Women (minimally or non-breastfeeding) up to 6 months postpartum
- *Food Package VII:* Fully Breastfeeding Women up to 1 year postpartum

On December 13, 2010, Congress passed the Healthy, Hunger-Free Kids Act of 2010 (Pub. L. 111–296), amending section 17(f)(11) of the Child Nutrition Act by mandating that the USDA conduct a scientific review of the WIC food packages at least every ten years. In response to the mandate, in 2014, FNS contracted with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a comprehensive review of the current WIC food packages in relation to the current nutritional science, dietary guidance, and program administration considerations. In 2017, NASEM published its recommendations for WIC food package revisions in the report: ''Review of WIC Food Packages: Improving Balance and Choice'' (the ''NASEM report'').[3] In its report, NASEM recommended modifications to the current WIC food packages to reduce foods provided in more than supplemental amounts and increase foods needed to improve intakes of priority nutrients and food groups. After NASEM released its 2017 report, on December 29, 2020, the USDA and the Department of Health and Human Services released the Dietary Guidelines for Americans (DGA), 2020–2025,[4] which provide recommendations for healthy dietary patterns by life stage and for the first time since the 1985 edition, specific recommendations for infants and children up to 2 years of age.[5] The proposed revisions align the WIC food packages with the 2020–2025 DGA and largely reflect the recommendations in the 2017 NASEM Report with modifications the Department deemed necessary for program administration considerations.

In FY 2022, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act 2022 (Pub. L. 117–103) directed USDA to temporarily increase the WIC cash-value voucher (CVV), which participants use to purchase fruits and vegetables, to amounts consistent with NASEM recommendations, adjusted for inflation, through September 30, 2022. As a result, the CVV was increased to the same amounts that are proposed in this rule, equal to $24 for child participants, $43 for pregnant and postpartum participants, and $47 for fully and partially breastfeeding participants in FY 2022. The President's Budget Request for FY 2023 included the same CVV increase, which would set CVV values at $25 for child participants, $44 for pregnant and postpartum participants, and $49 for fully and partially breastfeeding participants through September 30, 2023, after adjusting for inflation. To date, these legislative provisions have only temporarily increased the CVV on a year-to-year basis. This proposed rule would make permanent the CVV increase enacted in FY 2022, and proposed in FY 2023, by revising the regulations governing the WIC food packages. Due to the temporary nature of the CVV increases in FY 2022 and as proposed for FY 2023, the following analysis presents both the total cost, in terms of increased Federal transfers, for the proposed rule as a whole (*i.e.,* compared to current regulations and with the cost of CVV included) and also for the proposed rule absent the CVV cost impact (*i.e.,* the cost of the rule compared to the current WIC food packages as enacted in FY 2022).

In its 2017 report, NASEM included a regulatory impact analysis of its recommended revisions. This impact analysis builds on NASEM's analysis to update cost estimates for the provisions outlined in the proposed rule and calculates new or revised estimates for provisions that expand or modify those recommended by NASEM to align with the 2020–2025 DGA and/or accommodate program administration considerations.

III. Summary of Provisions

Table 1 summarizes the proposed revisions to regulations governing the WIC food packages, alongside current requirements as described in Federal Regulations, absent the temporary CVV increase enacted in FY 2022 under Public Law 117–103.

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[3] National Academies of Sciences, Engineering, and Medicine. ''Review of WIC Food Packages: Improving Balance and Choice: Final Report,'' 2017. Available online at: *https://www.fns.usda.gov/wic/review-wic-food-packages-improving-balance-and-choice.*

[4] Referred to hereafter as ''2020–2025 DGA'' or ''DGA.''

[5] U.S. Department of Health and Human Services/U.S. Department of Agriculture, ''Dietary Guidelines for Americans, 2020–2025.'' Available online at: *https://www.dietaryguidelines.gov.*

Table 1: Current Food Package Requirements and Key Revisions under Proposed Rule

Revisions Under Proposed Rule	Current Food Package Requirements
Cash-Value Voucher **Increase the value of the cash-value voucher (CVV)** Revised amounts (starting in FY 2024): Children 1 through 4 years: $25 Pregnant: $45 Postpartum: $45 Partially BF: $50 Fully BF: $50 **Expand what can be purchased with CVV** Permit CVV eligible items to include fresh herbs and permit larger sizes of packaged fresh fruits and vegetables. Dried herbs and any packaged fruits and vegetables with added sugars, fats, or oils (including as dips, sauces, or glazes) remain prohibited. This change also codifies the eligibility of white potatoes into regulations, but this does not represent a program change as white potatoes are currently eligible under Pub. L. 113-235.	Current amounts (starting in FY 2024): Children 1 through 4 years: $9 Pregnant: $12 Postpartum: $12 Partially BF: $12 Fully BF: $12 Current regulations do not permit CVV purchases of fresh herbs and do not allow for packaged fresh fruits and vegetables under the term "party trays."
Canned Fish **Add canned fish for children 2 through 4 years and for pregnant, partially (mostly) breastfeeding and postpartum individuals; reduce fish amounts for fully breastfeeding individuals; and revise WIC-eligible varieties** Revised amounts: 6 through 11 months: none 12 through 23 months: none 2 through 4 years: 5 oz. Pregnant: 10 oz. Postpartum: 10 oz. Partially BF: 15 oz. Fully BF: 20 oz.	Current amounts: 6-11 months: none 12 - 23 months: none 2 through 4 years: none Pregnant: none Postpartum: none Partially BF: none Fully BF: 30 oz.

Revisions Under Proposed Rule	Current Food Package Requirements
Infant Fruits and Vegetables **Reduce infant jarred fruit and vegetable amounts for fully breastfed infants** Revised amounts: Fully BF: 128 oz. Partially BF: 128 oz. Fully Formula-Fed: 128 oz. **Expand allowable age range to substitute CVV for infant fruits and vegetables and increase substitution amounts*** Infants ages 6-11 months may receive a CVV to purchase any form of fruits and vegetables for half or all the jarred infant fruits and vegetables. Revised amounts and CVV value allowed: Fully BF, Partially BF and Fully Formula-Fed: $10 CVV and 64 oz., or $20 CVV and no jarred infant fruits and vegetables.	Current amounts: Fully BF: 256 oz. Partially BF: 128 oz. Fully Formula-Fed: 128 oz. Currently, only infants ages 9-11 months may receive a CVV to purchase fresh fruits and vegetables as a substitute for half of the jarred infant fruits and vegetables. Current amounts and CVV value allowed: Fully BF: $9 CVV and 128 oz. jarred infant fruits and vegetables. Partially BF and Fully Formula-Fed: $4 CVV and 64 oz. jarred infant fruits and vegetables.
Legumes **Require both dry and canned legumes be authorized** Require State agencies offer both dry and canned legumes.	Current legume food category specifies "dry"; State agencies have the option to allow canned.
Infant Meats **Reduce infant meats amounts** Revised amounts: Fully BF: 40 oz. Partially BF: none Fully Formula-Fed: none	Current amounts: Fully BF: 77.5 oz. Partially BF: none Fully Formula-Fed: none
Breakfast Cereal **Change whole grain criteria for breakfast cereals and require all breakfast cereals to be whole grain** Require WIC-eligible whole grain breakfast cereals to contain whole grain as the first ingredient and require that all cereals authorized by a State agency be whole grain.	Currently, WIC-eligible whole grain breakfast cereals must have whole grain as the primary ingredient by weight and meet the FDA labeling requirements for making a health claim as a "whole grain food with moderate fat content" and at least half of cereals must be whole grain.
Infant Formula	

Revisions Under Proposed Rule	Current Food Package Requirements
Increase infant formula amounts in the first month for partially (mostly) breastfed infants Increase amount of formula in first month to up to 364 fl. oz.	Currently, partially breastfed infants may receive up to 104 fl. oz.
Allow all prescribed infant formula quantities to be considered "up to" amounts The proposed change to "up to" amounts would emphasize the importance of assessing, by WIC staff, the actual need for formula of the breastfeeding mother-infant dyad	Currently in regulations there are only maximum monthly allowances and minimum or "full nutrition benefit" amounts.
Cheese **Remove cheese as a food category for fully breastfeeding participants** Remove cheese as a food category for fully breastfeeding participants. Retain cheese as a partial milk substitution option for child, pregnant, postpartum, and breastfeeding participants.	Currently, cheese is a food category for fully breastfeeding participants (1 lb./month). Cheese is also a partial milk substitution option for child, pregnant, postpartum, and breastfeeding participants.
Whole Wheat/Whole Grain Bread and Other Whole Grain options *Increase whole wheat/whole grain bread and other whole grain option amounts for* pregnant, postpartum, and breastfeeding participants, *reduce amounts for child participants, revise specifications for package sizes, and change criteria for whole grain bread.* Revised amounts: Children: 24 oz. Pregnant, postpartum, and breastfeeding individuals: 48 oz. A State agency must provide package sizes that equal or add up the full amount (24 oz. or 48 oz.) but may also allow package sizes that do not. Require whole grain bread contain at least 50 percent whole grains. **Expand whole grain options***	Current amounts: Children: 32 oz. Pregnant, postpartum, and breastfeeding individuals: 16 oz. A State agency must provide package size(s) that equal or add up to exactly the full amount Currently, WIC regulations require whole grain bread have a whole grain as the primary ingredient by weight and meet the FDA labeling requirements for making a health claim as a "whole grain food with moderate fat content."

Revisions Under Proposed Rule	Current Food Package Requirements
In addition to current options, also allow: quinoa; wild rice; millet; triticale; amaranth; kamut; sorghum; wheat berries; whole wheat: pita, English muffins, bagels, naan; tortillas made with folic acid-fortified corn masa flour; cornmeal meeting FDA SOI 21 CFR 137.260; teff; and buckwheat.	Current whole grain options include brown rice, bulgur, oats, whole-grain barley, and whole wheat macaroni products without added sugars, fats, oils, or salt, and soft corn (made from ground masa flour) or whole wheat tortillas.
Milk **Reduce milk amounts for women and children** Revised amounts: 12 through 23 months: 12 qt. 2 through 4 years: 14 qt. Pregnant: 16 qt. Partially BF: 16 qt. Postpartum: 16 qt. Fully BF: 16 qt.	 Current amounts: 1 through 4 years: 16 qt. Pregnant: 22 qt. Partially BF: 22 qt. Postpartum: 16 qt. Fully BF: 24 qt.
Require authorization of lactose-free milk	Currently State agency option to authorize lactose-free milk.
No longer allowing option for flavored milk Only permit unflavored milk.	Currently State agency option to authorize flavored milk.
Increase amount of yogurt available to substitute for milk, allow reduced-fat yogurt for 1-year-old children without restrictions, and revise specifications for package sizes* Revised State agency option: up to 2 qt. (64 oz.) yogurt may be substituted for 2 qt. milk for child, pregnant, postpartum, and breastfeeding participants. Allow reduced-fat yogurt to be issued to children 12 through 23 months of age without the need for consultation with the participant's health care provider. Require State agencies provide package sizes that equal or add up the full amount (32 oz. or 64 oz.) but may also allow package sizes that do not.	Current State agency option: 1 qt. (32 oz.) yogurt may be substituted for 1 qt. milk for child, pregnant, postpartum, and breastfeeding participants. Currently, low-fat or nonfat yogurt may be issued (at State agency option) to children 12 through 23 months of age with consultation with the child's health care provider, if necessary, per State agency policy. Currently, State agencies must provide package size(s) that equal or add up to exactly 1 qt. (32 oz.).
Add additional milk substitution options* and milk substitution specifications Revised milk substitution specifications:	Current milk substitution specifications: Yogurt:

Revisions Under Proposed Rule	Current Food Package Requirements
Yogurt: • Reduce the total sugar limit for yogurt to ≤30 grams per 1 cup. • Add vitamin D requirement of 160 IU (4 mcg) per 1 cup. • Add soy-based yogurt option with the criteria that it must contain at least 250 mg of calcium, 6.5 grams of protein per 8-oz. serving, and 160 IU (4 mcg) vitamin D. Tofu: • Tofu must provide a minimum of 200 mg of calcium per 100 grams of tofu. Soy-based beverage: • May not exceed 12 grams of added sugar per 8-oz. serving. Soy-based cheese: • Add soy-based cheese option with the criteria that it must contain at least 250 mg of calcium, 6.5 grams of protein per 1.5-ounce serving, and 160 IU (4 mcg) vitamin	• Total sugar limit for yogurt is ≤40 grams per 1 cup. • No vitamin D requirements • Only allow cow's milk yogurt. Tofu: • Must be calcium-set prepared with calcium salts. Soy-based beverage: • No sugar limits for soy-based beverage. Soy-based cheese: • No soy-based cheese option
Infant Cereal **Reduce infant cereal amounts for all infants** Revised amounts: Fully BF: 16 oz. Partially BF: 8 oz. Fully Formula-Fed: 8 oz.	Current amounts: Fully BF: 24 oz. Partially BF: 24 oz. Fully Formula-Fed: 24 oz.
Juice **Reduce juice amounts for children and most** pregnant, postpartum and breastfeeding individuals**; eliminate juice in postpartum food package** Revised amounts: Children 1 through 4 years: 64 fl. oz. Pregnant: 64 fl. oz. Postpartum: none Partially BF: 64 fl. oz. Fully BF: 64 fl. oz. **Allow $3 CVV juice substitution** Allow participants to substitute a $3 CVV for 64 fl. oz. of juice.	Current amounts: Children 1 through 4 years: 128 fl. oz. Pregnant: 144 fl. oz. Postpartum: 96 fl. oz. Partially BF: 144 fl. oz. Fully BF: 144 fl. oz. Currently no option for State agencies to authorize substituting a CVV in place of juice.

Revisions Under Proposed Rule	Current Food Package Requirements
Eggs **Add required and optional substitution options for eggs** Require legumes and peanut butter be available to substitute for eggs if a participant has an egg allergy or is vegan. Give State agencies the option to also allow tofu* as a substitution for eggs.	Current regulations do not allow substitutions for eggs.
Fruit and Vegetables Forms and Varieties **State agencies required to authorize an additional form of fruits and vegetables** Require State agencies to authorize fresh and at least one other form (frozen, canned, or dried) of fruits and vegetables for children, pregnant, postpartum and breastfeeding individuals, and infants 6-11 months. Dried will not be authorized for infants.	Currently, State agencies are only required to authorize fresh fruits and fresh vegetables and have the option to authorize other forms (e.g., canned, frozen, and/or dried).
Require vendors to stock at least 3 different vegetables Require vendors to stock at least 3 different vegetables.	Under current minimum stocking requirements, vendors must stock at least 2 different vegetables.

Notes:
BF = fully breastfeeding; CVV = Cash Value Voucher; IU = international units; mcg = micrograms; mg = milligrams; lb. = pound; qt. = quarts; oz. = ounces
*Proposed revision is a State agency option.

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IV. Impacts

A. Summary of Impacts

The following analysis describes the estimated impacts of the proposed rule on the Federal WIC spending, accounted for in terms of Federal transfer payments projected between FY 2024 and 2028, as well as the key health and nutrition benefits for WIC participants expected as a result of the changes. The description of impacts on Federal transfers and participant health benefits is followed by a discussion of impacts on administrative burden and associated costs to State agencies, participation, and specific food markets.

The Department estimates that the proposed rule to revise regulations governing the WIC food packages would result in a net increase in Federal WIC spending of $4.1 billion over five years from FY 2024 through FY 2028. This increase only reflects changes in overall Federal transfers for WIC food expenditures. WIC food expenditures are a function of the number of participants receiving each food package, the cost of WIC-eligible food items, the quantity of WIC foods issued to each participant, and the percentage of WIC foods redeemed by participants (known as the ''redemption rate''). These estimates are summarized at the food category level in Table 2, where all changes proposed under a given food category (*e.g.,* changes to quantity issued, expanded substitution options, and flexibility in package sizes) are collectively considered for their impacts on quantities redeemed and unit costs.

This increase in Federal WIC food expenditures is driven by the proposed increase in the CVV, which is estimated to increase WIC food expenditures by $4.9 billion over five years when compared to current CVV levels as outlined in 7 CFR 246.10. However, as explained above, the CVV levels proposed in this rule were recently enacted on a temporary basis for FY 2022 and the increases are proposed to continue through FY 2023 in the President's Budget Request. As a result, when compared to the FY 2022 enacted food packages, the CVV increase proposed in this rule would not impact Federal WIC expenditures. With the CVV impact zeroed out of the overall cost estimate for the proposed rule, the remaining provisions are expected to result in a net *decrease* in Federal WIC food spending of $821 million over five years when compared to the food packages as enacted in FY 2022.

TABLE 2—SUMMARY OF ESTIMATED FOOD COSTS AND SAVINGS OF PROPOSED RULE BY FOOD CATEGORY

[FY 2024 through FY 2028]

	Fiscal year ($ millions)					
	2024	2025	2026	2027	2028	5 Year Total
Cash-Value Voucher (CVV)	$913.8	$949.8	$975.2	$1,029.2	$1,075.5	$4,943.5
Fish	31.6	33.1	34.8	35.6	36.4	171.4
Infant Fruits and Vegetables	21.6	22.1	22.6	23.1	23.6	113.0
Legumes	3.4	3.6	3.8	3.9	3.9	18.5
Infant Meats	−2.9	−3.0	−3.0	−3.1	−3.2	−15.2
Breakfast Cereal	−4.5	−4.8	−5.1	−5.2	−5.3	−24.8
Infant Formula [a]	1.1	−7.8	−8.0	−8.2	−8.4	−31.3
Cheese	−7.3	−7.4	−7.6	−7.8	−8.0	−38.0
Whole Grains	−8.3	−10.9	−13.6	−13.9	−14.3	−61.0
Infant Cereal	−18.1	−18.5	−18.9	−19.3	−19.8	−94.7
Milk	−25.2	−26.3	−27.5	−28.1	−28.7	−135.8
Juice	−133.6	−140.9	−148.7	−152.1	−155.5	−731.0
Interaction of Infant Formula Change Across Food Packages [a]	0.0	2.0	2.0	1.9	1.9	7.8
Eggs	(**)	(**)	(**)	(**)	(**)	(**)
Fruit and Vegetables Forms and Varieties	(**)	(**)	(**)	(**)	(**)	(**)
Total projected cost: compared to food packages in current Federal Regulations (includes cost of CVV) [b]	771.5	791.0	805.9	855.9	898.2	4,122.5
Total projected cost: compared to food packages with CVV increase as enacted in FY 2022 (no cost impact of CVV) [b]	−142.3	−158.8	−169.3	−173.3	−177.3	−821.0

Notes:

[a] The proposed revisions to the amount of infant formula allowed in the partially (mostly) breastfed infant food package is estimated, by NASEM, to shift 5 percent of infant-mother dyads from fully formula fed to partially (mostly) breastfed food packages one year after implementation. The cost impact directly on infant formula spending is provided in the ''Infant Formula'' row. The overall cost impact of shifting infant-mother dyads into the partially breastfeeding food package is displayed separately as the ''*Interaction of Infant Formula Change Across Food Packages.*'' This interaction estimate reflects the increase in costs related to shifting postpartum participants into the more expensive partially breastfeeding food package. More details are provided in the cost impacts section of this analysis.

[b] In FY 2022, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act 2022 (Pub. L. 117–103) authorized USDA to increase the CVV to a level consistent with NASEM recommendations, adjusted for inflation. The CVV values temporarily authorized and enacted for FY 2022, which were also proposed in the President's Budget for FY 2023, are the same CVV values proposed in this proposed rule. This table provides overall cost estimates for the proposed rule when comparing to the value of the permanent WIC food packages in the current Federal Regulations (i.e., cost of CVV included) as well as the cost estimates when comparing to the food packages as enacted in FY 2022 and proposed in FY 2023 (i.e., cost of CVV excluded).

** Provisions not estimated to have a meaningful impact on overall food cost.

The overall change in the total Federal spending on WIC is summarized in Table 3. The Department estimates the total five-year Federal spending on WIC under the current food package to be $28.0 billion from FY 2024 through 2028, this estimate does not include the cost of the temporary increase in the CVV authorized under Public Law 117–103 for FY 2022 (see Table 4 for comparisons to FY 2022 enacted expenses). The additional food costs of $4.1 billion estimated under this proposed rule would bring total Federal WIC spending, in terms of Federal transfers, up to $32.2 billion in total from FY 2024 through 2028.

TABLE 3—TOTAL PROJECTED FEDERAL WIC EXPENDITURES

[FY 2024–2028]

	Fiscal year (millions)					Total
	2024	2025	2026	2027	2028	
Total Food Expenditures	$3,840.7	$4,002.7	$4,168.8	$4,281.9	$4,388.9	$20,683.0
Cost of Current Food Packages [a]	3,069.2	3,211.7	3,362.9	3,426.1	3,490.7	16,560.6
Cost of CVV Increase [b]	*913.8*	*949.8*	*975.2*	*1,029.2*	*1,075.5*	*4,943.5*
Incremental Cost of Proposed Rule Other than CVV Increase [c]	−142.3	−158.8	−169.3	−173.3	−177.3	−821.0
Total Nutrition Services & Administration Costs	2,157.6	2,224.5	2,293.4	2,364.5	2,437.8	11,477.8
Total Federal Expenditures	5,998.2	6,227.2	6,462.2	6,646.5	6,826.7	32,160.8

[a] Cost of current food packages reflects total annual cost attributable to spending on foods as currently described in 7 CFR 246.10—which, absent any legislative adjustments to the CVV, would have set CVV levels at $9 for children and $12 for women in FY 2024.

[b] Cost of CVV increase reflects the added cost of the CVV increase proposed in this rule, which is equal to the CVV increase temporarily enacted in FY 2022 under Public Law 117–103.

[c] Incremental cost of the proposed rule other than CVV increase reflects the net impact on Federal WIC expenditures of all other provisions in this rule absent the CVV increase to demonstrate how the costs would differ from the food packages as enacted in FY 2022 when CVV was temporarily increased.

In addition to the above increase in food expenditures accounted for in terms of Federal transfers, USDA also estimates that WIC State agencies and local agencies will incur an increase in administrative burden associated with administering the proposed changes (including estimated burden for State and local agency staff training) and explaining the revised food packages to participants. This additional administrative burden is expected to account for about $171 million in additional labor costs associated with the required State and local agency staff time over five years between FY 2024 and FY 2028. These administrative costs are considered allowable expenses for State agencies under their annually awarded Nutrition Services and Administration (NSA) grants. In general, USDA expects that State agencies will be able to absorb the costs associated with implementing the provisions under this proposed rule with current NSA funds.

The proposed changes to the WIC food packages are expected to improve dietary quality by increasing intake of foods currently under-consumed by WIC participants, specifically fruits and vegetables, whole grains, and seafood.[6] Increased consumption of these foods is expected to increase intakes of key nutrients, including dietary fiber, potassium, vitamin D, vitamin A, vitamin C, folate, and polyunsaturated fatty acids. Dietary fiber, potassium, and vitamin D, considered nutrients of public health concern in the general U.S. population, are currently also under-consumed by WIC participants.[7] [8] The proposed changes are also expected to improve dietary balance by reducing amounts of foods that are currently provided in quantities that exceed a moderate proportion of an individual's requirement for a nutrient or recommended amount of a food group.

B. Baseline for Estimate of Program Expenditures

The total projected baseline Federal cost of WIC under the current food package for FY 2024 through 2028 is shown in Table 4 below. At the Federal level, WIC expenditures are broadly split between grants to State agencies to fund food benefits (''food costs'') and Nutrition Service and Administration (NSA) grants to fund all approved non-food expenses (''NSA costs''). As described later in this analysis, the Department estimates that the changes under this proposed rule will result in a net increase to WIC food costs but will not affect the NSA costs of the Program. Table 4 provides the total cost of the current WIC food packages both with and without the CVV increase enacted in FY 2022 under Public Law 117–103.

WIC food costs are a function of the number of participants receiving each food package, the retail prices of WIC-eligible food items, the quantity of WIC foods issued to each participant, and the percentage of WIC foods issued that are redeemed by participants (known as the ''redemption rate''). The following describes how each of these factors are estimated for FYs 2024 through 2028 in this analysis.

TABLE 4—TOTAL PROJECTED BASELINE FEDERAL WIC EXPENDITURES, CURRENT FOOD PACKAGES

	Fiscal year (millions)					
	2024	2025	2026	2027	2028	Total
Total Food Cost	$3,982.9	$4,161.5	$4,338.1	$4,455.3	$4,566.2	$21,504.1
Cost of Current Food Packages[a]	3,069.2	3,211.7	3,362.9	3,426.1	3,490.7	16,560.6
Cost of CVV Increase[b]	913.8	949.8	975.2	1,029.2	1,075.5	4,943.5
Total Nutrition Services & Administration Costs	2,157.6	2,224.5	2,293.4	2,364.5	2,437.8	11,477.8
Total Federal Cost	6,140.5	6,386.0	6,631.5	6,819.8	7,004.0	32,981.8

Note: Figures may not sum due to rounding.

[a] Cost of current food packages reflects total annual cost attributable to spending on foods as currently described in 7 CFR 246.10—which, absent any legislative adjustments to the CVV, would have set CVV levels at $9 for children and $12 for women in FY 2024.

[b] Cost of CVV increase reflects the added cost of the CVV increase proposed in this rule, which is equal to the CVV increase temporarily enacted in FY 2022 under Public Law 117–103.

Participation

This analysis bases WIC participation projections on participation changes observed during FY 2020 and FY 2021 (including when program flexibilities were implemented in response to the Coronavirus Disease 2019 (COVID–19) pandemic), specifically, a fixed level of participation among infants and pregnant, postpartum, and breastfeeding individuals and annual increases in participation among children. Accordingly, growth in child participation is estimated at 2.08 percent annually between FY 2021 and 2023 and to rise to 4.82 percent annual growth between 2023 and 2026 before leveling off at the higher participation level in 2027 and 2028. In 2018, the most recent data available, only 44 percent of eligible children participated in WIC.[9] The estimated increases in child participation used in this analysis reflect a projected narrowing of the coverage gap among WIC-eligible children as a result of current and future efforts to improve retention among children ages 1 to 4 in WIC. While declining birth rates in the U.S. have contributed to a decrease in infants and pregnant, postpartum, and breastfeeding individuals participating in WIC each year since 2009, the Department projects

[6] Gleason, S., Hansen, D., & Wakar, B. (2021). Indicators of diet quality, nutrition, and health for Americans by program participation status, 2011–2016: WIC report. Prepared by Insight Policy Research, Contract No. GS–10F–0136X. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Michael Burke. *www.fns.usda.gov/research-and-analysis.*

[7] Ibid.

[8] Borger, C., Zimmerman, T., Vericker, T., et al. (2020). WIC Infant and Toddler Feeding Practices Study 2: Fourth Year Report. Prepared by Westat, Contract No. AG–3198–K–15–0033 and AG–3198–K–15–0050. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Courtney Paolicelli. Available online at: *www.fns.usda.gov/research-and-analysis.*

[9] Gray K., Meyers-Mathieu K., Johnson, P., and Giannarelli, L. (2021). National- and State-Level Estimates of WIC Eligibility and WIC Program Reach in 2018 With Updated Estimates for 2016 and 2017. Prepared by Insight Policy Research, Contract No AG–3198–D–16–0095. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Grant Lovellette. Available online at: *www.fns.usda.gov/research-analysis.*

participation among these groups level off due to future outreach efforts to increase participation.[10] Within each participant category, this analysis uses data from the WIC Participant and Program Characteristics 2018 Food Packages and Costs Report (WIC PC 2018 Food Costs Report) to estimate the distribution across specific WIC food packages, shown in Table 5.[11]

TABLE 5—WIC PARTICIPATION ESTIMATES BY CATEGORY AND FOOD PACKAGE[FY 2024—2028]

	Food package	Fiscal year participants				
		2024	2025	2026	2027	2028
Infants		1,468,664	1,468,664	1,468,664	1,468,664	1,468,664
FF 0–4 months	I–FF–A	223,294	223,294	223,294	223,294	223,294
FF 4–6 months	I–FF–B	158,365	158,365	158,365	158,365	158,365
BF/FF 0–1 months	I–BF/FF–A	7,918	7,918	7,918	7,918	7,918
BF/FF 1–4 months	I–BF/FF–B	68,097	68,097	68,097	68,097	68,097
BF/FF 4–6 months	I–BF/FF–C	42,759	42,759	42,759	42,759	42,759
BF 0–4 months	I–BF–A	60,179	60,179	60,179	60,179	60,179
BF 4–6 months	I–BF–B	31,673	31,673	31,673	31,673	31,673
FF 6–11 months	II–FF	547,942	547,942	547,942	547,942	547,942
BF/FF 6–11 months	II–BF/FF	101,353	101,353	101,353	101,353	101,353
BF 6–11 months	II–BF	93,435	93,435	93,435	93,435	93,435
FP III	III–I	133,648	133,648	133,648	133,648	133,648
Children		3,714,820	3,894,002	4,081,826	4,081,826	4,081,826
12–23 months	IV–A	1,066,153	1,117,579	1,171,484	1,171,484	1,171,484
2–4 years	IV–B	2,585,515	2,710,225	2,840,951	2,840,951	2,840,951
FP III	III–IV	63,152	66,198	69,391	69,391	69,391
Adults		1,381,305	1,381,305	1,381,305	1,381,305	1,381,305
Pregnant	V–A *	494,645	494,645	494,645	494,645	494,645
BF/FF	V–B *	304,163	304,163	304,163	304,163	304,163
Postpartum	VI	399,750	399,750	399,750	399,750	399,750
BF	VII	180,260	180,260	180,260	180,260	180,260
FP III	III–V/VI/VII	2,486	2,486	2,486	2,486	2,486
Total Participants		6,564,789	6,743,971	6,931,795	6,931,795	6,931,795

FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; FP = food package.
Source: Internal USDA Estimates.

Prices of WIC Foods

Baseline unit costs for WIC food categories are estimated using average national retail unit cost data calculated from the Information Resources, Inc. (IRI) Infoscan retail dataset.[12] Average per-unit costs were calculated using FY 2018 IRI Infoscan retail data on food categories that include WIC-eligible foods. The FY 2018 unit cost data are adjusted to account for inflation using the U.S. Bureau of Labor Statistics Consumer Price Index for Urban Consumers (CPI–U) with food-specific forecasts estimated by the USDA Economic Research Service (ERS) for FY 2019 through FY 2022.[13] Inflation for all food categories is estimated for FY 2023 through FY 2028 using the Office of Management and Budget's (OMB) food at home projections used in the most recent President's Budget request.[14]

Quantities of WIC Foods Purchased by Program Participants

The quantity of WIC foods purchased, or redeemed, by participants is estimated as the product of the Maximum Monthly Allowance (MMA) of each food item multiplied by the estimated redemption rate for that item. Baseline estimates use the MMAs under the current food packages while the projections for redemption under the proposed food package revisions use the MMAs defined under the proposed rule. Key changes to MMAs by food item under this proposed rule are summarized above in Table 1. Baseline redemption rates are estimated by food category using 2020 redemption data that FNS collected from 48 State agencies (see Appendix A–1, Tables A–1 through A–12 for redemption rate estimates by food category).[15]

C. Food Costs and Benefits of Proposed Rule by Food Category

The following section describes the benefits to WIC participants and the estimated impact on the cost of the food packages of the proposed changes for each WIC food category. As described previously, all cost estimates are adjusted for annual inflation. Apart from the CVV, USDA applies NASEM's estimates of the relative impacts of the proposed revisions under each food category on redemption rates and unit costs, where applicable. NASEM's estimates of the impacts on redemption rates are based on a number of factors including changes to the amount of a food category prescribed, changes to the substitution options available, and changes to nutrient requirements that may affect participant preferences.

In general, the most consistent impact on redemption rates was driven by changes in the amount of a food item prescribed in the revised food packages. To consider this impact, NASEM first used EBT data from

[10] The provisional number of U.S. births in 2020 declined 4 percent compared to 2019. This is the lowest number of births since 1979 and the sixth consecutive year of a decline. Source: Hamilton BE, Martin JA, Osterman MJK. Births: Provisional data for 2020. Vital Statistics Rapid Release; no 12. Hyattsville, MD: National Center for Health Statistics. May 2021. DOI: *https://doi.org/10.15620/cdc:104993.*

[11] U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support. Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Participant and Program Characteristics 2018 Food Packages and Costs Report, by Nicole Kline, Kevin Meyers Mathieu, and Jeff Marr. Project Officer: Grant Lovellette. Alexandria, VA., November 2020. Available online at: *www.fns.usda.gov/research-and-analysis.*

[12] More information about this dataset is available here: *https://www.ers.usda.gov/topics/food-markets-prices/food-prices-expenditures-and-establishments/using-scanner-data/.*

[13] ERS food-specific inflation estimates are current as of June 26, 2022.

[14] As of March 2022, OMB projects annual food at home inflation to be around 2.26 percent annually for FY 2023–FY 2028. For more information, see *https://www.whitehouse.gov/wp-content/uploads/2022/03/budget_fy2023.pdf.*

[15] According to internal USDA data collected in March 2021 covering monthly WIC redemptions for all months in calendar year 2020. Data were requested from all State agencies, but only full year data for 2020 were provided by 48 State agencies. While redemption data may not be nationally representative, the 48 State agencies that reported data serve about 3.48 million WIC participants (or around 56 percent of all WIC participants in 2020).

three State agencies (Kentucky, Michigan, and Nevada) for a 2014 report by Altarum to understand three different types of WIC redemption patterns: (1) full redemption, (2) partial redemption, and (3) non-redemption.[16] The effect of a decrease in the MMA for an item is not computed equally for all three groups, because we would expect less of a change, if any, in the redemption rate among the share of full redeemers and those not redeeming the food item at all. Therefore, NASEM used the EBT data collected by Altarum to compute what they call an ''implied redemption rate'' based on the relative share of partial redeemers unique to each food item and the amount of the MMA being reduced. Beyond the implied redemption rates calculated based on changes to the MMA amounts, to account for other behavioral changes NASEM made upward or downward adjustments to the implied redemption rates based on changes in substitution options (such as allowing more yogurt to be substituted for milk) and product specifications (including package size flexibilities or whole-grain requirements). Explicit details on any calculations behind these adjustments are limited in NASEM's report, but they are generally based on assumptions of expected consumer behavior based on the changes—*e.g.,* increasing substitution options would expand options in a particular food category and therefore is expected to make that food category more popular and increase redemption rates. NASEM applied these changes to redemption data provided by FNS for 5 unidentified State agencies as well as redemption data NASEM collected directly from 6 State agencies to expand the representativeness of the estimates.

NASEM's approach poses a number of limitations. Without much of a precedent for such changes and without the opportunity to conduct a viable pilot, NASEM had limited data upon which to base their redemption rate adjustments. Another limitation is that these estimates do not account for variations based on demographic groups because of a lack of availability of EBT redemption data matched with participant characteristics. While USDA acknowledges these limitations, the Department finds NASEM's approach to be reasonable and sufficient for these estimates given the lack of available data. While this analysis relies on NASEM's methodology to estimate the relative impact of the proposed rule on redemption rates for each food item, the Department applies these relative impacts to a larger set of redemption data collected from 48 State agencies in 2020.

Although the food costs presented here are updated with the best available information and to reflect the food package revisions as defined in this proposed rule, including where the Department's proposals differ from NASEM's recommendations, NASEM's impact analysis provides additional background information, analyses, and discussion of rationales (see Appendix U of the 2017 NASEM report, p. 869–988).

Cash Value Voucher (CVV)

Summary of Proposed Change:

- Increase CVV maximum monthly allowances for child, pregnant, postpartum, and breastfeeding participants.
- Expand what can be purchased with CVV.

The proposed increases to the CVV maximum monthly amounts reflect the amounts recommended by NASEM to provide approximately half of the recommended daily amounts of fruits and vegetables for adults and children. The proposed increases also reflect 2020–2025 DGA recommendations for the applicable life stages of WIC adult participants (postpartum, pregnant, and lactating) based on the average caloric needs of these various groups (2,000 kcal, 2,200 kcal, and 2,400 kcal, respectively).

Context, Behavior Change, and Benefits:

Fruits and vegetables are nutrient dense and associated with a reduced risk of chronic diseases,[17] including high blood pressure,[18] [19] stroke,[20] heart disease,[21] diabetes,[22] and specific types of cancer.[23] A recent study found that adult consumption of 5 servings of fruits and vegetables per day (and specifically 3 servings of vegetables and 2 servings of fruit) is associated with a decrease in the risk of premature death and death due to cardiovascular disease, cancer, and respiratory disease.[24] In addition, studies suggest that increasing fruit and vegetable intakes or replacing foods of high energy density with foods of lower energy density, such as fruits and vegetables, can help with management of body weight.[25] [26] [27] Despite the importance of fruits and vegetables to a healthy dietary pattern, nearly 90 percent of the U.S. population does not meet the daily recommended intake of vegetables, and around 80 percent do not meet recommendations for fruit.[28] Among children participating in WIC, average intakes of fruits and vegetables are also below recommended levels.[29] The DGA emphasize the importance of building a healthy dietary pattern in early childhood when taste preferences are acquired and maintaining a health dietary pattern across the lifespan. WIC can play an important role in supporting families to establish and maintain healthy dietary patterns that are rich in nutrient-dense fruits and vegetables.

The proposed changes to regulations governing the CVV are likely to increase fruit and vegetable consumption among WIC participants. Increasing fruit and vegetable consumption would also increase intake of potassium and fiber, both of which USDA identifies in the 2020–2025 DGA as dietary components of public health concern for underconsumption. An increase in fruit and

[16] Phillips, D., Bell, L., Morgan, R., & Pooler, J. (2014). Transition to EBT in WIC: Review of impact and examination of participant redemption patterns: Final report. Retrieved from *https://altarum.org/sites/default/files/uploaded-publication-files/Altarum_Transition%20to%20WIC%20EBT_Final%20Report_071614.pdf.*

[17] While the publications cited in this section employ a variety of study designs, many lean on the data available in a few large prospective cohort studies. These prospective cohort studies, such as the well-known Nurses' Health Study, are often limited to a predominately White and socioeconomically homogenous sample—while this limitation has the benefit of controlling confounding factors for this reason, it may also limit the generalizability of findings. Moreover, it is relatively rare for the cited studies to control for income (which presumably matters because fruits and vegetables can be more expensive than many other foods); as such, concern about omitted variable bias may be warranted. We request comment on these methodological issues, as well as the extent to which the relevant literature appropriately sets null hypotheses prior to performing statistical tests.

[18] Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, Bray GA, Vogt TM, Cutler JA, Windhauser MM, Lin PH. A clinical trial of the effects of dietary patterns on blood pressure. *New England Journal of Medicine.* 1997 Apr 17;336(16):1117–24.

[19] Borgi L, Muraki I, Satija A, Willett WC, Rimm EB, Forman JP. Fruit and Vegetable Consumption and the Incidence of Hypertension in Three Prospective Cohort Studies. Hypertension. 2016 Feb;67(2):288–93. doi: 10.1161/HYPERTENSIONAHA.115.06497. Epub 2015 Dec 7. PMID: 26644239; PMCID: PMC5350612.

[20] Guo, N., Zhu, Y., Tian, D. *et al.* Role of diet in stroke incidence: an umbrella review of meta-analyses of prospective observational studies. *BMC Med* 20, 194 (2022). *https://doi.org/10.1186/s12916-022-02381-6.*

[21] Hung HC, Joshipura KJ, Jiang R, Hu FB, Hunter D, Smith-Warner SA, Colditz GA, Rosner B, Spiegelman D, Willett WC. Fruit and vegetable intake and risk of major chronic disease. *Journal of the National Cancer Institute.* 2004 Nov 3;96(21):1577–84.

[22] Muraki I, Imamura F, Manson JE, Hu FB, Willett WC, van Dam RM, Sun Q. Fruit consumption and risk of type 2 diabetes: results from three prospective longitudinal cohort studies. *BMJ.* 2013 Aug 29;347:f5001.

[23] Wiseman M. The Second World Cancer Research Fund/American Institute for Cancer Research Expert Report. Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective: Nutrition Society and BAPEN Medical Symposium on 'Nutrition support in cancer therapy'. *Proceedings of the Nutrition Society.* 2008 Aug;67(3):253–6.

[24] Dong D. Wang, Yanping Li, Shilpa N. Bhupathiraju, Bernard A. Rosner, Qi Sun, Edward L. Giovannucci, Eric B. Rimm, JoAnn E. Manson, Walter C. Willett, Meir J. Stampfer, Frank B. Hu. Fruit and Vegetable Intake and Mortality: Results From 2 Prospective Cohort Studies of U.S. Men and Women and a Meta-Analysis of 26 Cohort Studies. Circulation, 2021; DOI: 10.1161/CIRCULATIONAHA.120.048996.

[25] Tohill BC, Seymour J, Serdula M, Kettel-Khan L, Rolls BJ. What epidemiologic studies tell us about the relationship between fruit and vegetable consumption and body weight. Nutr Rev. 2004;62:365–374.

[26] Rolls BJ, Ello-Martin JA, Tohill BC. What can intervention studies tell us about the relationship between fruit and vegetable consumption and weight management? Nutr Rev. 2004;62(1):1–17.

[27] Bertoia ML, Mukamal KJ, Cahill LE, Hou T, Ludwig DS, Mozaffarian D, Willett WC, Hu FB, Rimm EB. Changes in intake of fruits and vegetables and weight change in United States men and women followed for up to 24 years: analysis from three prospective cohort studies. *PLoS medicine.* 2015 Sep 22;12(9):e1001878.

[28] See 2020–2025 DGA, p. 30–32.

[29] Gleason, S., Hansen, D., & Wakar, B. (2021). Indicators of diet quality, nutrition, and health for Americans by program participation status, 2011–2016: WIC report. Prepared by Insight Policy Research, Contract No. GS–10F–0136X. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Michael Burke. *www.fns.usda.gov/research-and-analysis.*

vegetable consumption would also increase intakes of vitamin A, vitamin C, and folate, all of which NASEM reported at inadequate levels among pregnant, postpartum, and breastfeeding participants.

NASEM estimated that WIC participants would need to spend $25, $45, or $50 (adjusted for inflation to FY 2024), depending on participant category, to meet 50 percent of the DGA-recommended intakes for vegetables and fruits. This suggests that the current CVV levels of $9 for children and $11 for pregnant, postpartum, and breastfeeding individuals only provide enough for around 19 percent and 12 percent of recommended fruit and vegetable intakes for these groups, respectively. Increasing the value of the CVV to the levels proposed by NASEM to meet 50 percent of the recommended fruit and vegetable intake is likely to increase fruit and vegetable purchases and consumption among WIC participants.

The WIC CVV provides participants with flexibility to purchase fruits and vegetables that meet their dietary, taste, and cultural preferences. Expanding CVV-eligible items further to include fresh herbs and larger packages of fruits and vegetables is intended to encourage healthier dietary patterns and support increased convenience. Increased use of fresh herbs in diets can help enhance the flavor of foods in place of added sugar, fats, and sodium. Packaged fruits and vegetables provide a more convenient option for participants that see preparation time as a barrier to consumption.

Federal Budgetary Costs:

The increase in value of the CVV accounts for most of the increased Federal spending under the proposed rule, adding around $4.9 billion in costs over five years compared to the CVV levels as currently established in WIC regulations at 7 CFR 246.10. This estimate assumes that the redemption rate of the increased CVV will continue at the 2020 level (71.6 percent) and accounts for annual inflation adjustments. Table 6 compares the projected CVV values for the current food packages outlined in 7 CFR 246.10 and revised food packages under this proposed rule for child, pregnant, postpartum, and breastfeeding participants between FY 2024 through 2028, accounting for annual inflation and rounding down to the nearest whole dollar.[30] As described earlier in this analysis, the CVV levels proposed in this rule were temporarily enacted in FY 2022 and have been proposed to continue through FY 2023 in the President's Budget Request. Therefore, compared to WIC food packages as enacted in FY 2022, the changes described in this section would have no impact on Federal spending, but would instead simply establish the FY 2022 CVV levels as the new permanent CVV levels in WIC regulations.

The CVV cost estimates only include costs associated with the changes to the CVV for child, pregnant, postpartum, and breastfeeding participants described above. Any costs associated with the CVV substitution option for infants are accounted for under the infant fruit and vegetable estimates. Similarly, costs associated with the $3 CVV substitution option for juice are accounted for in the juice cost estimates.

TABLE 6—CHANGES TO CVV AMOUNT BY PARTICIPANT CATEGORY
[FY 2024 through FY 2028]

Participant category (food package)	2024		2025		2026		2027		2028	
	Cur.	Rev.	Cur.	Rev.	Cur.	Rev.	Cur.	Rev.	Cur.	Rev.
Children (IV)	$9	$25	$9	$26	$10	$26	$10	$27	$10	$28
Pregnant (V–A)	12	45	12	46	12	47	13	49	13	50
Partially BF (V–B)	12	50	12	51	12	52	13	53	13	54
Postpartum (VI)	12	45	12	46	12	47	13	49	13	50
Fully BF (VII)	12	50	12	51	12	52	13	53	13	54

Notes:
CVV = Cash-value voucher; Cur. = Current food packages; Rev. = Revised food packages.
CVV values are set using a specific rounding methodology described in 7 CFR 246.16(j) where, after adjusting for inflation annually, the benefit level is always rounded down to the nearest whole dollar (*e.g.*, $24.99 would be rounded down to $24). In this analysis, the benefit levels before rounding down for the current food package begin in at $9.74 for children and $12.18 for pregnant, postpartum and breastfeeding individuals in FY 2024 to be consistent with current budget projections. The benefit levels for the revised food package begin in FY 2022 at $24, $43, and $47 and begin adjusting for inflation in FY 2023. Current food packages reflect the permanent CVV levels as currently set in 7 CFR 246.10. Revised food packages reflect the CVV levels proposed in this rule, which are equal to and make permanent the temporary levels enacted in FY 22, adjusted for inflation.

To better understand how the proposed increase to the CVV may impact CVV redemption rates, USDA collected CVV redemption data from nine large State agencies covering the period from April to August 2021, during the implementation of a temporary increase to CVV levels authorized under the American Rescue Plan Act (ARPA) of 2021 (Pub. L. 117–2).[31] Under ARPA authority, these State agencies increased the CVV for all food packages for child, pregnant, postpartum, and breastfeeding participants to $35. Redemption data during the months the increase was implemented indicate only about a 2-percentage point decrease in the CVV redemption rate following the increase.[32] The Department assumes that this 2-percentage point gap would further narrow as participants become more accustomed to the increased CVV and as WIC staff continue to promote use of the increased CVV through nutrition education. Based on these assumptions, the Department assumes there will be no change in CVV redemption rates under the proposed CVV levels in this rule.

Canned Fish

Summary of Proposed Change:

- Add canned fish to food packages for children (ages 2 through 4 years) and specify WIC-eligible varieties for children.
- Add canned fish in food packages for pregnant, partially (mostly) breastfeeding and postpartum participants not currently receiving canned fish, revise amounts for fully breastfeeding participants, and revise WIC-eligible varieties.

In 2021, the FDA and EPA updated their joint advice about eating fish, which incorporates 2020–2025 DGA recommendations; identifies fish types and serving sizes safe for consumption based on estimated methylmercury exposure; and newly includes advice for children age 1 year–11 years (previous advice included recommendations for children 2 to 11 years). The advice includes a subset of ''Best Choices'' that contain lower methylmercury (as also noted in the DGA 2020–2025 Table A3–1 (12–23 months) footnote (e)) to support children age 1 year in consuming 3 ounces per week recommended in the Healthy U.S.-Style Dietary Pattern without exceeding limits for estimated methylmercury exposure and indicates that many commonly consumed fish types, including light canned tuna, a WIC-eligible variety, should not be consumed in amounts of 3 ounces per week by this age group due to their methylmercury content. Therefore, the proposed changes for canned fish in the food packages does not include canned light tuna for children.

Context, Behavior Change, and Benefits:

The proposed revisions add select varieties of canned fish to food packages for children ages 2 through 4 years and for pregnant, postpartum and breastfeeding participants to

[30] This is consistent with the requirements for inflating the WIC CVV as described in 7 CFR 246.16(j).

[31] WIC Policy Memorandum #2021–3: Implementation of the American Rescue Plan Act of 2021 (Pub. L. 117–2), State Agency Option to Temporarily Increase the Cash-Value Voucher/Benefit for Fruit and Vegetable Purchases. March 24, 2021. Available at: *https://www.fns.usda.gov/wic/policy-memorandum-2021-3.*

[32] Data collected from 9 State agencies indicated a 68.4 percent CVV redemption rate during July and August 2021 under the temporary increase to $35 authorized by ARPA. The redemption rate for these months was expected to be around 70.5 percent if the CVV increase had not occurred, based on CVV redemption data trends in 2020 and earlier in 2021 for these State agencies. Therefore, we attributed approximately a 2-percentage point decrease in CVV redemption rates under the $35 CVV.

better align the WIC food packages with the DGA and generally follow NASEM recommendations. These revisions would greatly increase the number of WIC participants receiving fish (currently only breastfeeding participants receive fish), an important dietary source of polyunsaturated fatty acids and other key nutrients and would create more equitable access to this under-consumed food.

The amount of fish offered in the revised food packages would provide a supplemental quantity of between 15 to 47 percent of the DGA-recommended amounts, depending on participant category. This change represents an improvement over the current packages, which do not offer fish to child, pregnant, postpartum, or partially breastfeeding participants.

Federal Budgetary Costs:

The proposed changes to the quantities of canned fish represent the second largest increase in cost under this proposed rule, accounting for an estimated $171 million increase over five years compared to the cost of canned fish in the current food packages. This estimate is based on NASEM's assumption that the current redemption rate for fish in the food package for fully breastfeeding participants, just under 44 percent in 2020, will be slightly lower for all food packages receiving fish under the revised food package. The Department estimates the redemption rate for fish will be around 43 percent across all food packages under the proposed revisions.

Infant Fruits and Vegetables

Summary of Proposed Change:

- Reduce infant jarred fruit and vegetable amounts for fully breastfed infants.
- Expand allowable age range to substitute CVV for infant fruits and vegetables and increase substitution amounts.

The amounts of jarred fruits and vegetables currently provided for fully breastfed infants far exceed what is needed. Further, fully breastfed infants do not have a greater need for fruits and vegetables compared to other infants. Thus, the proposed reduced amounts of jarred fruits and vegetables for fully breastfed infant will be the same amounts currently provided to partially (mostly) breastfed or fully formula fed infants.

Context, Behavior Change, and Benefits:

NASEM found that the current food package for fully breastfed infants provides an excessive amount of jarred fruits and vegetables per day—more than one cup-equivalent, which is an amount difficult for infants 6 through 11 months old to consume daily. Furthermore, the more generous amount for fully breastfed infants was not based on a nutritional rationale (the DGA and the American Academy of Pediatrics (AAP) do not have specific recommendations for the quantity of fruit and vegetable consumption for this age group), but was recommended by the 2006 Institute of Medicine (IOM) committee to promote full breastfeeding (2006 IOM report, page 103).

Reducing the amount of jarred infant fruits and vegetables provided to fully breastfeeding infants better aligns this food package with the concept of supplemental, particularly since fully breastfed infants do not have a greater need for fruits and vegetables than infants fed infant formula or a combination of infant formula and human milk.

Expanding the age range at which infants are eligible to substitute CVV for infant fruits and vegetables (specifically, by lowering the eligible age from 9 to 6 months old) and increasing substitution amounts would provide additional choice to WIC participants to accommodate cultural and personal preferences without compromising the nutritional integrity of the infant food packages. In addition, by permitting the purchase of more fruits and vegetables through the CVV, a parent or caretaker has the opportunity to introduce a wider variety and texture of fruits and vegetables (compared to the jarred variety) to the infant according to the infant's developmental readiness for textures.[33] NASEM expects that allowing additional CVV substitutions for this age group will increase redemption and consumption of fruits and vegetables among this group of WIC participants.

Federal Budgetary Costs:

Although this proposed rule would decrease the maximum monthly allowance of jarred infant fruits and vegetables issued to fully breastfed infants, the Department estimates that the proposed changes to infant fruits and vegetables under this rule would result in a net increase of $113 million in costs over five years. These costs are the cumulative costs associated with both infant jarred fruit and vegetable redemptions and the infant CVV substitution option (*i.e.,* the infant CVV costs are reflected here and are separate from the costs associated with the CVV increase for child, pregnant, postpartum, and breastfeeding participants described above). This estimated increase in costs is driven by the expansion of the age range and amounts allowed for the CVV substitution option for jarred fruits and vegetables. In its report, NASEM estimates that this expansion of the infant CVV substitution option, coupled with the decrease in jarred fruits and vegetables issued to fully breastfed infants, will increase the redemption rate by slightly more than 27 percent (approximately 15 percentage points, given the 53 percentage point baseline rate).[34] By applying NASEM's analysis to current redemption rates, the Department estimates that the redemption rate for jarred infant fruits and vegetables will increase from just over 53 percent in 2020 to around 68 percent under the proposed rule.

Breakfast Cereal

Summary of Proposed Change:

- Change whole grain criteria for breakfast cereals.
- Require all breakfast cereals meet whole grain criteria.

As recommended by NASEM, the proposed revisions would change the criteria for whole grain breakfast cereals and require that all breakfast cereals meet the criteria for whole grain. These changes are designed to increase the amount of whole grains in the food packages that provide whole grains and improve consistency with FNS Child Nutrition Programs (CACFP, the National School Lunch Program, and the National School Breakfast Program).

Context, Behavior Change, and Benefits:

These provisions are expected to help address inadequate consumption of whole grains (and excess consumption of refined grains) among WIC participants. NASEM's analysis of National Health and Nutrition Examination Survey (NHANES) data concluded that the consumption of whole grains by WIC participants was poor and that consumption of refined grains by WIC participants was excessive. An updated analysis of NHANES data for years 2011–2016 confirms low intakes of whole grains among young children participating in WIC. On a given day, 48 percent of WIC participants ages 1 through 4 years consumed whole grains, whereas 82 percent consumed refined grains. On average, less than half of grains consumed were whole grains.[35]

The DGA recommend that at least half of grain intake consist of whole grains, as whole grains are nutrient-dense and contribute more fiber to a healthy diet than refined grains, but according to the DGA, 98 percent of Americans fail to eat enough whole grains, and 74 percent of Americans consume too many refined grains.

Prior revisions to the WIC food package did not fully implement IOM's 2006 recommendation that all breakfast cereals meet the criteria for whole grain cereals due to concerns at the time that the recommendation would have eliminated corn- and rice-based cereals, which are alternatives for people with allergies or intolerances, and it would have limited participant choice due to a relatively lack of availability of whole-grain cereals in the marketplace when the prior rule was published.

During its most recent review, the NASEM committee reviewed product information provided by two large national breakfast cereal manufacturers and found that manufacturers are now producing a sufficient number of different breakfast cereals across the country that meet the whole-grain rich criteria (including gluten-free varieties to address celiac disease, allergies, or intolerances) to provide sufficient choice to WIC participants; therefore, these requirements are expected to increase whole grain consumption and decrease refined grain consumption among WIC participants.

Federal Budgetary Costs:

While the maximum monthly allowances for breakfast cereal will not change under the proposed rule, the Department estimates that the revisions to whole grain requirements for cereal will decrease costs by approximately

[33] See the DGA recommendations for infants regarding developmental readiness for solid foods on p. 57 of the DGA 2020–2025.

[34] This estimate is based on a combined redemption rate for both redemption of infant jarred fruit and vegetables and redemption of the infant CVV substitution.

[35] Gleason, S., Hansen, D., & Wakar, B. (2021). Indicators of diet quality, nutrition, and health for Americans by program participation status, 2011–2016: WIC report. Prepared by Insight Policy Research, Contract No. GS–10F–0136X. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Michael Burke. *www.fns.usda.gov/research-and-analysis.*

$18 million over five years. The decrease in cost is driven by the estimated impact of these changes on redemption rates. While the changes to breakfast cereal requirements are expected to increase whole grain consumption overall amongst WIC participants, the Department, like NASEM, expects some participants will reduce cereal redemptions as a result of the changes in whole grain requirements. NASEM estimated that the changes will decrease redemption rates by 10 percent, based on reduction in allowable cereal options and its analysis showing that whole grain cereals are less preferred by participants in some States.[36] By applying NASEM's findings, the Department estimates that the redemption rates across all food packages for breakfast cereals will decrease from 48 to 43 percent. This estimate also accounts for a slight increase in unit costs. NASEM estimates that the proposed changes will increase the unit cost of breakfast cereals in the WIC food packages by about 9 percent. The Department estimates that, starting in FY 2024, unit costs for cereal under the proposed rule will rise from $0.18 to $0.21 per ounce, after adjusting for inflation.

Infant Formula

Summary of Proposed Change:

- Increase infant formula amounts in the first month for partially breastfed infants.
- Allow all prescribed infant formula quantities to be considered ''up to'' amounts.

As recommended by NASEM, the proposed rule would increase maximum monthly infant formula amounts in the first month for partially (mostly) breasted infants from 104 fluid ounces to up to 364 fluid ounces. Consistent with current requirements, the amount of formula provided would be tailored based on an individual nutrition and breastfeeding assessment and would not exceed the maximum 364 fluid ounces per month. Tailored issuance of formula in the first month, and nutrition and breastfeeding education and support from WIC staff, not only maximizes the potential for women to achieve exclusive breastfeeding goals, but also to achieve successful partial breastfeeding when exclusive breastfeeding is not possible or desired.

Context, Behavior Change, and Benefits:

This provision would increase the maximum monthly infant formula amount in the first month of life for partially (mostly) breastfed infants, consistent with NASEM's recommendations. As NASEM notes, while current regulations intend to encourage participants who initiate breastfeeding to do so exclusively, the current approach may cause infants who need more than 104 fluid ounces of formula in the first month to be prematurely categorized as fully formula fed (and the mother as ''postpartum'') in order to obtain additional formula from the Program.

Breastfeeding is associated with several improved health outcomes for both infants and breastfeeding mothers. Women who breastfeed have a reduced risk of breast and ovarian cancer, hypertension, and type 2 diabetes, and their infants have a lower risk of asthma, Type-1 diabetes, sudden infant death syndrome (SIDS), and gastrointestinal, ear, and lower respiratory infections.[37]

The proposed change would increase participant flexibility and provide better support for any amount of breastfeeding during the first month by providing partially (mostly) breastfeeding infants any amount of formula (up to the maximum 364 fluid ounces allowed) to support the participant's desired level of breastfeeding. It is possible that this provision may extend the duration of breastfeeding for some mothers who were previously categorized as ''postpartum'' prematurely and discontinued breastfeeding. NASEM specifically estimates that this proposed increase to the infant formula amounts allowed during the first month of an infant's life would result in a 5 percent shift in infant-mother dyads moving from the fully formula feeding to partially (mostly) breastfeeding food packages after the first year of implementation.

The proposed change to consider all formula quantities to be issued as ''up to'' amounts will encourage and enable WIC staff to assess the actual formula needs of participants and tailor the quantities of infant formula provided accordingly. This change, as recommended by NASEM, is intended to reduce interference with the successful establishment of the mother's desired breastfeeding behavior while appropriately issuing formula amounts that meet infants' nutritional needs.

Federal Budgetary Costs:

By increasing the amount of infant formula allowed in the first month of life for partially breastfed infants, the Department assumes a shift of 5 percent of fully formula fed infants into the partially breastfed infant category after one full year of implementation, based on NASEM's analysis.[38] Because the partially breastfed infant food packages are less costly than the fully breastfed infant food packages, this shift would result in an estimated decrease of around $29 million in total Federal spending on infant formula in the WIC food packages over five years.

The revised amounts of infant formula prescribed under this proposed rule are also estimated to impact spending in other food categories. As described above, NASEM estimates these changes would result in a 5 percent shift of fully formula fed infants into the partially breastfed infant category. This would correspond with a shift of 5 percent of participants from the postpartum food package (VI) category into the partially breastfeeding category (V–B). In this analysis, the Department estimates the impact of this shift in participant categories separately from the other food-specific cost estimates (*e.g.,* the cost estimate provided in Table 2 for the CVV does not take this interaction into account), to account for the discrete impacts of each. In total, the shift of 5 percent of participants from the postpartum food package to the partially breastfeeding food package is estimated to increase WIC food costs by $8 million over five years. These changes are accounted for by calculating the difference in spending between the slightly more expensive food package V–B compared to food package VI resulting from the 5 percent shift in participants from the postpartum to partially breastfeeding category.

Revising the regulatory language to permit formula quantities prescribed as ''up to'' amounts rather than only setting a minimum amount for full nutrition benefit is not projected by NASEM to have a significant impact on the cost of the food packages. While the effect on cost is expected to be minimal, the impact of this provision will ultimately depend upon the extent to which it is used—both in terms of how frequently formula quantities are tailored and the extent to which tailoring formula amounts changes the quantities prescribed.

Whole Wheat/Whole Grain Bread and Other Whole Grain Options

Summary of Proposed Change:

- Increase whole wheat/whole grain bread and other whole grain option amounts for pregnant, postpartum and breastfeeding individuals, reduce amounts for children, and revise specifications for package sizes.
- Require that whole grain breads contain at least 50 percent whole grains.
- Expand whole grain options.

Context, Behavior Change, and Benefits:

The proposed revisions largely reflect NASEM's recommendations and would provide whole wheat bread, whole grain bread, and whole grain options in supplemental amounts that better align with the DGA, particularly for women. The DGA recommend that at least half of grain intake consist of whole grains, as whole grains are nutrient-dense and contribute more fiber to a healthy diet than refined grains, but according to the DGA, 98 percent of Americans fail to eat enough whole grains, and 74 percent of Americans consume too many refined grains.

The reduced amount for children represents the upper end of NASEM's recommended range of 16 to 24 ounces and would provide 27 to 53 percent of DGA recommended amounts, better aligning the children's food packages with the concept of supplemental and offsetting cost increases elsewhere in the revised food packages.

[36] While the NASEM Report acknowledges the increasing market availability of allowable cereal options, the actual impact on redemption rates of breakfast cereals may vary slightly as the market has continued to evolve in the years since NASEM's analysis.

[37] For a review of recent scientific literature on breastfeeding and maternal health outcomes, see *https://effectivehealthcare.ahrq.gov/sites/default/files/cer-210-breastfeeding-summary.pdf.* For evidence on breastfeeding and infant outcomes, see Ip S, Chung M, Raman G, et al; Tufts-New England Medical Center Evidence-based Practice Center. Breastfeeding and maternal and infant health outcomes in developed countries. Evid Rep Technol Assess (Full Rep). 2007;153(153):1–186 and American Academy of Pediatrics. Breastfeeding and the Use of Human Milk. *Pediatrics* 2017;129(3):e827–e841.

[38] From the NASEM RIA (p. 973): ''A key assumption of the primary analysis is that, under the proposed revisions, 5 percent of fully formula-fed mother-infant dyads will shift to corresponding fully (mostly) breastfeeding food packages. The committee considered the 5 percent shift conservative, given evidence that the 2009 food package, which allowed women to either choose between formula-feeding or fully breastfeeding in the infant's first month of life, resulted in an approximately 7 to 11 percent shift of dyads from breastfeeding to formula-feeding.''

The proposed increased amount for pregnant, postpartum and breastfeeding participants exceeds NASEM's recommended amount (24 ounces). Specifically, the Department's proposed amount for would provide 40 to 53 percent of the DGA recommended whole grain amounts, while the amount recommended by NASEM would provide 13 to 27 percent. The increased amount would provide and encourage consumption of whole grains, consistent with the DGA and in quantities closer to NASEM's definition of a supplemental amount. The proposed changes also better align the Program with common package sizes found in the marketplace.

Changing the allowable package sizes will increase the whole wheat/whole grain bread choices available for State agencies to authorize as WIC-eligible, thereby increasing choice for participants. When WIC adopted the 16-ounce bread size, very few products on the market adhered to this specification, which required manufacturers to produce a relatively limited number of products sized specifically for WIC; consequently, WIC participants had relatively few choices among different types of WIC-approved breads. Although this availability has become less of a problem since the implementation of the 2009 WIC food package revisions, far more whole wheat/whole grain breads available in the marketplace still come in either a 20-ounce or 24-ounce package size as compared to a 16-ounce package size.[39] Therefore, allowing State agencies to authorize 20- and 24-ounce bread package sizes will decrease burden on participants, increase product availability, and likely promote intake of whole grains, if participants are able to select whole grain products that more closely align with their personal or cultural preferences. This change may also decrease burden on small vendors who have experienced difficulty stocking the 16-ounce package size currently required by WIC.

Finally, the proposed expansion of whole grain options is responsive to participant requests for more choices for bread substitutions, while still providing priority nutrients, and is intended to increase whole grain consumption by offering a greater variety of grains to WIC participants.

Federal Budgetary Costs:

The revisions under the whole wheat bread, whole grain bread, and other whole grain options contribute to both costs and savings under the proposed rule. Overall, these changes result in an estimated decrease of about $61 million in food costs over five years.

NASEM estimates that expanding the number of allowable substitution options and providing greater flexibility in package sizes would increase the overall redemption rate for whole grains by around 13 percent. The proposed rule differs from NASEM's recommendation to allow a specific range of package sizes under this category, and instead proposes to allow State agencies to authorize a greater variety of package sizes to increase variety and choice, while still providing participants with package sizes that ensure they can receive the full benefit amount. Despite this variation, the effect on redemption rates is expected to be consistent with NASEM's projections. By applying NASEM's projections to current rates, the Department estimates the proposed rule would increase redemption rates for whole wheat bread, whole grain bread, and other whole grain options from 44 percent in 2020 to nearly 50 percent after implementation of the proposed rule. The increase in the maximum monthly allowance for pregnant, postpartum, and breastfeeding participants from 16 ounces to 48 ounces is also expected to increase overall food costs associated with whole grains in the pregnant, postpartum and breastfeeding food packages.

The increases in costs described above are more than offset by the estimated decrease in unit costs for whole grain products in all food packages and the proposed decrease in the maximum monthly allowance of whole grains in the food packages for children from 32 ounces to 24 ounces. In its report, NASEM estimates that the cost of 16 ounces of whole wheat bread to be $2.35 under the current food package. To account for allowing 24-ounce package sizes in the revised food package and the addition of alternative whole grain substitutions, NASEM computes a composite cost of $2.67 for 24 ounces of whole grain products under the revised food package.[40] On a per ounce basis, NASEM's projections amount to a 24.4 percent decrease in the unit cost of whole grains in the revised food package (from $0.147 per ounce in 16-ounce packages to $0.111 per ounce in 24-ounce packages).

Cheese

Summary of Proposed Change:

- Remove cheese as a food category for fully breastfeeding participants.

As recommended by NASEM, this proposed rule would remove cheese as a separate food category for fully breastfeeding participants (Food Package VII). This change aligns with the DGA recommendation for reducing saturated fat consumption.

Context, Behavior Change, and Benefits:

Removing cheese as a separate food category for fully breastfeeding participants aligns with the DGA recommendation for reducing saturated fat consumption. However, cheese remains a milk substitution option in the food packages for child, pregnant, postpartum, and breastfeeding participants, meaning that cheese can be substituted for a portion of the maximum monthly allowance of milk. Even with the removal of the standalone cheese category, fully breastfeeding participants would still be able to receive two pounds of cheese as a partial substitute for milk.

Federal Budgetary Costs:

Removing cheese as a standalone food category is estimated to decrease WIC food costs by $38 million over five years.

Infant Meats

Summary of Proposed Change:

- Reduce infant meats amounts.

Context, Behavior Change, and Benefits:

This provision reduces the maximum monthly allowance of infant meat for fully breastfed infants from 77.5 to 40.0 ounces. The NASEM committee found that the current food package II–BF provides fully breastfed infants with approximately 130 percent of the maximum amount of infant meat recommended by the AAP. The Committee also found that the redemption rate for infant meat, an important source of heme iron and zinc for fully breastfed infants, was only about 20 percent. The proposed rule reduces the amount of infant meat provided to a level representing approximately 65 percent of the AAP recommended maximum amount. This revision better aligns with the concept of providing a supplemental amount of infant meat to fully breastfeeding infants.

Federal Budgetary Costs:

Reducing the maximum monthly allowance of infant meats in the fully breastfed 6 through 11-month-old infant food package is estimated to reduce WIC food costs by $15 million over 5 years. NASEM estimates that reducing the quantity of infant meats prescribed to fully breastfed infants will increase the overall redemption rate—this is largely based on the assumption that when a smaller amount is prescribed, a larger proportion of that amount will be redeemed by partial redeemers. Applying NASEM's estimates, this cost savings assumes a 39 percent increase in the redemption rate of infant meats—increasing from around 23 percent in 2020 to 32 percent under the proposed rule.

Infant Cereal

Summary of Proposed Change:

- Reduce infant cereal amounts for all infants.

Context, Behavior Change, and Benefits:

This provision reduces the maximum monthly allowance of infant cereal to fully breastfed infants from 24 to 16 ounces. For partially breastfed and fully formula fed infants, the amount is reduced from 24 to 8 ounces. The NASEM committee found that the current food packages provide approximately 150 percent of the maximum amount of infant cereal recommended by the AAP. The proposed revisions better align with AAP recommendations for fully breastfed infants and with the Program's intent to provide supplemental amounts of food for all other infants. The revised infant cereal quantities would provide approximately 100 percent of the AAP-recommended amount for fully breastfeeding infants because fortified infant cereal is an important source of the iron and zinc that fully breastfed infants need from a commentary food source starting at age 6 months. The revised quantities would provide 50 percent of the AAP recommended amount for partially (mostly) breastfed and fully formula fed infants.

[39] According to an ERS analysis, in 2015, 16 oz while grain bread packages had a market share of 17 percent, while 20 and 24 oz whole grain bread package had market shares of 29 and 28 percent, respectively. For more information, see: *https://www.ers.usda.gov/amber-waves/2020/april/usda-approved-whole-wheat-bread-package-size-is-now-more-common-and-less-costly-for-the-special-supplemental-nutrition-program-for-women-infants-and-children-wic/.*

[40] NASEM's composite cost for whole grain products is weighted to 0.76 for whole wheat bread, 0.19 for corn tortillas, and 0.06 for oatmeal based on available redemption data from selected States.

Federal Budgetary Costs:

Reducing infant cereals in all infant food packages is estimated to reduce WIC food costs by around $95 million over five years. NASEM estimates the reduction in the maximum monthly allowance of infant cereals will result in a 21 percent increase in the redemption rate. Applying NASEM's projections, the Department estimates that the redemption rate for infant cereals across all infant food packages will increase from 43 percent in 2020 to 53 percent under the proposed rule.

Milk

Summary of Proposed Change:

- Reduce milk amounts for child, pregnant, postpartum, and breastfeeding participants.
- Require authorization of lactose-free milk.
- No longer allow the option for flavored milk.
- Increase amount of yogurt available to substitute for milk and revise specifications for package sizes.
- Add milk substitution options and milk substitution specifications.

The proposed quantities reflect NASEM recommendations, are more consistent with the supplemental nature of the Program, and are consistent with nutrition education messages to consume a balanced diet that meets, but does not exceed, recommended amounts of foods and nutrients to prevent overweight/obesity and/or displace other healthy and important food groups and nutrients.

Context, Behavior Change, and Benefits:

The proposed revisions to reduce the amount of milk prescribed to WIC participants would better align the amount given to participants to the Program's intent to provide a supplemental amount of food. The current food packages provide 85 to 128 percent of the DGA recommendations for dairy products. The revision recommended by NASEM and proposed by the Department would provide 71 to 96 percent of the amounts recommended by DGA.

Furthermore, the revised quantities are more consistent with nutrition education messages to consume a balanced diet that meets, but does not exceed, recommended amounts of food to prevent excess weight gain and displacement of other foods that provide key nutrients.

The proposed rule allows only unflavored milk and specifies limits on sugar for milk substitutions to better align the WIC food package with the DGA, which emphasize nutrient dense foods and beverages that provide vitamins, minerals, and other health-promoting components with little or no added sugars. As noted in the DGA, nutrient dense foods are particularly important during the first two years of life when nutrient requirements are high relative to body size, leaving virtually no room for added sugars in the diet. The DGA also recommend that beverages with no added sugars be the primary choice for children to assist in the establishment of healthy food choices early in life. The proposed revisions align the milk offering with CACFP provision of milks to children less than 5 years of age.

The proposed option for substitution of two quarts of yogurt in place of two quarts of milk may improve intakes for participants who prefer dairy in this form. In addition, the proposed rule would allow fortified soy cheese and beverage options as well as require authorization of lactose-free milk for participants with lactose intolerance, a milk allergy, and those who consume a vegan diet.[41] The options are intended to provide participants with flexibility to select substitutions that better meet cultural needs and personal preferences while still providing critical nutrients to WIC participants.

The revised specifications for yogurt and other dairy substitutions will help ensure that WIC participants receive the most nutritionally dense dairy or dairy substitute products without unnecessary added sugars.

Federal Budgetary Costs:

Reducing the maximum monthly allowance of milk as described is estimated to reduce WIC food costs by $136 million over five years. This large cost savings contributes to improving the balance and supplemental nature of the WIC food packages by offsetting some of the costs associated with increased amounts provided in other food categories.

The decrease in costs is driven by the decrease in the maximum monthly allowance for milk in most food packages under the proposed rule. The savings associated with the reduction in milk quantities are expected to be partially offset by the proposed changes to milk substitution options, which are expected to increase both redemption rates and the composite unit cost of milk and milk alternatives. To estimate a composite unit cost for milk redemptions that considers the combined costs of redeeming milk amounts for fluid milk, cheese, and yogurt, this analysis derives a composite unit cost for milk redemptions using the same approach that NASEM applies in its report and updates NASEM's model with WIC unit cost data for whole and reduced-fat milk (accounting for lactose-free and soy substitutions, see Table 7 notes below), cheese, and yogurt from the WIC PC 2018 Food Costs Report. NASEM's composite milk cost model represents ''high-cost'' substitution scenarios, within allowable substitution limits for cheese and yogurt, across food packages for child, pregnant, postpartum, and breastfeeding participants. The Department applies current unit cost estimates to this model, maintaining NASEM's substitution scenarios, and finds that, consistent with NASEM, revisions under the proposed rule are expected to increase the composite unit cost for milk across almost all food packages, as shown below in Table 7. The increase in this composite unit cost reflects an expected shift towards an increase in the proportion of milk that is substituted for yogurt. The increase in yogurt redemptions, relative to milk, is the combined result of three factors: (1) reduction in quantity of milk in most food packages, (2) an increase in the amount of yogurt participants are allowed to substitute for milk, and (3) increased flexibility in allowable yogurt package sizes.

TABLE 7—COMPOSITE UNIT PRICE FOR MILK AND MILK ALTERNATIVES IN CURRENT AND REVISED FOOD PACKAGES

Food package	Current			Revised		
	MMA	Substitution scheme	Composite cost ($/qt)	MMA	Substitution scheme	Composite cost ($/qt)
IV–A	16	12 qt milk + 1 lb cheese + 1 qt yogurt.	1.1240	12	8 qt milk + 1 lb cheese + 1 qt yogurt.	1.2021
IV–B	16	12 qt milk + 1 lb cheese + 1 qt yogurt.	1.0709	14	11 qt milk + 0.5 lb cheese + 1.5 qt yogurt.	1.0977
V–A	22	18 qt milk + 1 lb cheese + 1 qt yogurt.	0.9900	16	13 qt milk + 0.5 lb cheese + 1.5 qt yogurt.	1.0605
V–B	22	18 qt milk + 1 lb cheese + 1 qt yogurt.	0.9900	16	13 qt milk + 0.5 lb cheese + 1.5 qt yogurt.	1.0605
VI	16	12 qt milk + 1 lb cheese + 1 qt yogurt.	1.0709	16	13 qt milk + 0.5 lb cheese + 1.5 qt yogurt.	1.0605
VII	24	19 qt milk + 1 lb cheese + 1 qt yogurt.	0.9856	16	12 qt milk + 1 lb cheese + 1 qt yogurt.	1.0709

Notes:

[41] Although, currently an option (not a requirement) all States and most ITOs already authorize some kind of lactose-free milk, and therefore, USDA does not estimate an additional cost attributable to this requirement.

Unit costs for milk come from the FY 2018 IRI Infoscan retail dataset and already account for the price of lactose-free milk. Adjustments to the unit cost for milk are also adjusted to account for substitutions of soy beverages applying weights of 0.992 to whole milk and 0.008 to soy beverages for food package IV–A and weights of 0.989 to reduced-fat milk and 0.011 to soy beverages for all other food packages. Baseline, unweighted unit costs in 2018 (per ounce) were $0.027 for whole milk, $0.025 for reduced-fat milk, $0.053 for soy beverages, $0.088 for yogurt, and $0.292 for cheese.

(Source: IRI Infoscan dataset analysis).

Table adapted from NASEM Report (Appendix U, p. 950–955).

Cost estimates for milk also apply NASEM's assumptions about the impact of the revisions on redemption rates. NASEM estimates that the revisions under the proposed rule, particularly the additional amount of yogurt authorized for substitution, is expected to increase redemption rates across all food packages (see Appendix A–1, Table A–10 for detailed redemption rates). As of FY 2015 (the most recent data available), flavored milk was only authorized by three States and 14 Indian Tribal Organizations—collectively covering only around 3 percent of total WIC participants. As a result, the provision to no longer allow is not expected to have a significant impact on overall costs or redemptions because this only represents a policy change for a small proportion of participants.

Juice

Summary of Proposed Change:

- Reduce juice amounts for child, pregnant, and breastfeeding participants and eliminate juice for postpartum participants.
- Allow CVV juice substitution.

Context, Behavior Change, and Benefits:

The proposed reduction of juice in food packages for child, pregnant, and breastfeeding participants better aligns the food packages with the latest dietary guidance and with the supplemental intent of the Program. The current food packages provide between 96 and 144 fluid ounces (depending on participant category), or 40 to 107 percent of DGA-recommended limits for juice. The reduced quantities would provide approximately 26 to 53 percent of DGA-recommended limits.

The DGA emphasize the consumption of whole forms of fruits and vegetables over juice. While the DGA include 100 percent juice as part of the fruit and vegetable food category, it emphasizes whole fruit and a variety of vegetables from all subgroups, and it places limits on juice amounts that should contribute towards an overall dietary pattern, and juice is not a recommended food. Also, juice is neither a separate food category nor a subgroup (like dark-green vegetables) in the dietary patterns that Americans should consume each day.

As noted by the NASEM committee, the AAP recommends that most fruit intake should be from whole fruit because whole fruit also contributes fiber and other important plant-based compounds that are removed during fruit juice processing.

The option for CVV substitution of juice aligns with both the AAP and DGA recommendations and provides additional flexibility to WIC participants by allowing them to select from options that may better meet their cultural needs and personal preferences. These proposed changes will likely increase the consumption of whole fruits and vegetables among participants that prefer this substitution over juice.

All juice offered through the WIC program (across food packages) would be 64 fluid ounces, potentially decreasing vendor burden by streamlining options across food packages.

Finally, the cost savings from the reduction of juice partially offsets the cost of increasing the value of the CVV.

Federal Budgetary Costs:

The reduction of juice in all food packages represents the largest source of cost savings under the proposed rule—accounting for an estimated net decrease of $731 million in WIC food costs over five years. This estimate also accounts for an expected increase in the redemption rate of the juice benefit as a result of the added $3 CVV juice substitution option, which slightly offsets cost savings. Specifically, NASEM estimates that the CVV substitution, combined with the overall decrease in amounts of juice issued, will increase the redemption rate of juice by about 13 percent. Applying NASEM's estimate to current rates, the Department estimates that redemption rates for juice, including the $3 CVV juice substitution, will increase from 63 percent in 2020 to 71 percent under the proposed rule. Like the estimates for infant jarred fruit and vegetable redemptions, the estimated redemption rate for juice in the revised food packages accounts for both redemption of juice and redemption of the $3 CVV substitution for juice.

Legumes

Summary of Proposed Change:

- Require both dry and canned legumes be allowed.

As recommended by NASEM, this proposed change would require State agencies to authorize dried and canned legumes. Currently only dried legumes are required, and it is a State agency option to allow canned legumes.

Context, Behavior Change, and Benefits:

The NASEM committee noted that consumption of legumes, a source of fiber, protein, B vitamins, iron, zinc, and other nutrients, was below recommended amounts across WIC participant subgroups. To help address under-consumption of this nutrient-rich food, this proposed provision will require State agencies to authorize both dried and canned legumes for WIC participants. States are currently only required to authorize dried legumes, and allowing canned legumes is a State option.[42] Requiring canned legumes would reduce burden for those participants who currently do not have access to canned legumes and who do not have the time or ability to prepare dried legumes.

Federal Budgetary Costs:

Requiring all State agencies to authorize canned legumes is expected to increase food costs by around $18 million over five years. This increase in costs is the result of both an estimated increase in the composite unit cost of legumes and a slight increase in redemption rates. The Department estimates that requiring State agencies to authorize canned legumes will slightly increase redemption rates from 38 percent in 2020 up to 39 percent under the proposed rule. This increase is less than the increase that NASEM projects because NASEM's estimate also considers the effect of reducing the amounts of legumes issued—which is not changed in this rule. The estimated increase in redemption rates for legumes is also small because this provision only represents a policy change for an estimated 15 percent of WIC participants.[43] Similarly, the expanded availability of canned legumes to this group of participants is also estimated to slightly increase the composite unit price of legumes from $2.57 in the current food package to $2.62 under the proposed rule as canned legumes are generally more expensive than dry legumes.[44]

Eggs

Summary of Proposed Change:

- Add required and optional substitution options for eggs.

Context, Behavior Change, and Benefits:

Based on NASEM's recommendations, with modification, the proposed changes would require that State agencies allow the substitution of eggs with legumes or peanut butter if a participant has an egg allergy, is vegan, or for other reasons (*e.g.,* cultural preferences) as determined by State agency policy. The changes would also allow State agencies the option to authorize tofu as a substitute for eggs. Like eggs, legumes and peanut butter (to a lesser extent) are sources of choline, and both are sources of iron. Given iron's role in growth and development,

[42] According to the 2015 WIC Food Packages Policy Options report, 85 percent of State agencies authorized canned legumes in FY 2015. For more information, see: Thorn, B., Huret, N., Bellows, D., Ayo, E., Myers, R., & Wilcox-Cook, E. (2015). WIC Food Packages Policy Options Study II. Project Officer: Grant Lovellette. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support. Available online at: *www.fns.usda.gov/research-analysis.*

[43] Thorn, B., Huret, N., Bellows, D., Ayo, E., Myers, R., & Wilcox-Cook, E. (2015). WIC Food Packages Policy Options Study II. Project Officer: Grant Lovellette. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support. Available online at: *www.fns.usda.gov/research-analysis.*

[44] Composite unit price of legumes represents the weighted average price per ''allotment''—either 16 ounces of dry beans, 64 ounces of canned beans, or 18 ounces of peanut butter. Replicating NASEM's analysis, weights of 0.5, 0.31, and 0.19 were applied to peanut butter, dry beans, and canned beans, respectively, in the composite unit cost for legumes in the current food packages. To account for an increase in canned bean purchasing, weights of 0.5, 0.29, and 0.21 are applied to peanut butter, dry beans, and canned beans, respectively, under the revised food packages.

the prevalence of inadequate intake among the WIC population, and the health consequences of inadequate intake, offering foods with iron is critical to WIC participants' health.

In addition, peanut butter and legumes are required foods in the food packages, therefore the Department anticipates no additional administrative effort related to identifying and authorizing these foods as substitutes for eggs. Requiring peanut butter and legumes as substitutes for eggs is nutritionally appropriate, will not result in increased administrative burden, and increases equity in program delivery.

The Department also proposes to allow State agencies the option to authorize tofu as a substitute for eggs. Similar to eggs, tofu is a source of choline. If implemented, appropriate food package tailoring and nutrition education would need to address other food sources of iron, especially for participants determined to have low iron levels.

Federal Budgetary Costs:

Requiring that State agencies offer legumes or peanut butter as a substitution for eggs is not projected to have a significant impact on food costs. The substitution is limited to participants with an egg allergy, are vegan, or for reasons defined by the State agency. In 2018, only 1 percent of WIC participants in a study sample representative of 12 State agencies reported having an egg allergy.[45] The same study found only around 2 percent of participants reported being vegetarian—although USDA does not have data on prevalence of vegan diets among WIC participants, data on the general U.S. population suggest that vegan diets are even less common than vegetarian diets.[46] Therefore, while this policy change provides an important substitution option, its use is expected to be rare as it will likely only apply to a small number of participants.

Fruit and Vegetables Forms and Varieties

Summary of Proposed Change:

- State agencies required to authorize an additional form of fruits and vegetables.
- Require vendors to stock at least 3 different vegetables.

Context, Behavior Change, and Benefits:

As recommended by NASEM, the proposed rule would require State agencies to authorize fresh and at least one other form (frozen, canned, and/or dried) of both fruits and vegetables for the food packages for child, pregnant, postpartum, and breastfeeding participants and require fresh and at least one other form (frozen or canned) for the CVV substitution for infant (ages 6 through 11 months) food packages.

Currently, WIC State agencies are not required, but may choose, to authorize other forms of fruits and vegetables in addition to fresh for child, pregnant, postpartum, and breastfeeding participants. In 2021, only eight of 89 State agencies did not authorize a form other than fresh. Therefore, the Department anticipates that the proposed change would have minimal impact on most State agencies, while ensuring greater participant choice in those State agencies currently not authorizing other forms of fruits and vegetables. Additionally, with the proposed increase in the CVV, having the option to buy other forms that are not as perishable as fresh may encourage fuller redemption and consumption of the fruits and vegetables.

As recommended by NASEM, the proposed rule would also require vendors to stock at least three varieties of vegetables. Currently, vendors are required to stock two varieties of vegetables. NASEM recommended the requirement for stocking a greater variety of vegetables as opposed to fruits because its review noted higher redemption of fruits compared to vegetables in two State agencies.[47] NASEM also cited the lower intake of vegetables (particularly in contrast to fruits) in all WIC participant categories and recommended increased stocking requirements for vegetables.

Thus, the proposed change is intended to increase the purchase and consumption of vegetables among WIC participants, particularly given the proposed increase to the value of the CVV, by requiring vendors to offer more variety for participants to select from. If participants have more vegetables from which to select, they may redeem their CVV for more vegetables and increase their vegetable consumption. In addition, the proposed change is intended to promote equity by ensuring all participants, regardless of where they redeem benefits, have access to a variety of vegetables, while incurring minimal additional burden on small vendors.

This proposed revision could also increase general availability of different types of vegetables in areas served by small WIC vendors, as those additional vegetable types would be available for retail purchase by the general public.

Federal Budgetary Costs:

The requirement for State agencies to authorize at least one additional form of fruits and vegetables other than fresh and the requirement that vendors stock at least three varieties of vegetables are not expected to increase the food costs in WIC. Both provisions may incur some initial administrative burden on State agencies and vendors (as discussed in the Administrative Impacts section below), however, these administrative impacts are expected to be minimal and short-lived. Further, because only 81 out of 89 State agencies already authorize at least one form of fruits and vegetables other than fresh, the impact of this provision will only impact a small number of State agencies.

D. Impacts on Amounts of Food Groups Issued

As described above, the proposed changes to the WIC food packages will improve the balance of nutritious foods to align with recommendations from NASEM, the 2020–2025 DGA, and the AAP. The proposed changes also better reflect the supplemental nature of the WIC food package. Table 8 and Table 9 below summarize the estimated proportions of DGA daily recommended intakes for child (ages 2 through 4 years) and for pregnant participants, respectively, to provide examples of the impacts of the proposed rule on the food package contents.

The 2020–2025 DGA identified average daily food group intakes of vegetables, seafood, and whole grains as falling below the recommended intake ranges for women and children across the general population. The DGA and the AAP[48] also emphasize the consumption of whole fruits and vegetables over juice. A recent FNS study using 2011–2016 National Health and Nutrition Examination Survey (NHANES) data found that children participating in WIC under the current food package report overall inadequate intake levels for vegetables, seafood, and whole grains.[49] The same study also found that children participating in WIC are less likely to consume any amount of whole fruits on a given day than higher income children (73 compared to 93 percent), but are also significantly more likely to consume 100 percent fruit juice (73 compared to 47 percent). As described in the previous section, and illustrated in Table 8 and Table 9 below, this proposed rule will help WIC participants narrow these gaps in intake by increasing the amounts of whole grains, fish, and whole fruits and vegetables available in the WIC food packages.

To estimate the level of fruits relative to vegetables that should be accounted for when considering the proportion of DGA recommendations provided in the WIC food packages, NASEM based its estimates on the assumption that 67 percent of the CVV is typically spent on fruits while 33 percent is spent on vegetables—based on data collected from Wyoming and Texas at the time of NASEM's analysis. This ratio of CVV redemption for fruits relative to vegetables is consistent with more recent internal USDA data collected from Ohio, Wyoming, and Texas in 2018 as part of a forthcoming study on CVV redemption patterns. Therefore, USDA maintains NASEM's assumptions on relative CVV redemptions to the calculations for fruit and vegetable coverage under the current food packages in Table 8 and Table 9. However, USDA projects that the share of vegetables to fruits purchased with the CVV will even out at the increased CVV levels in

[45] This information is not yet published. Data will be publicly available in the forthcoming report from the WIC Food Cost-Containment Practices Study, expected to be published in early-2022.

[46] Gallup. ''Snapshot: Few Americans Vegetarian or Vegan.'' August 1, 2018. Available at: *https://news.gallup.com/poll/238328/snapshot-few-americans-vegetarian-vegan.aspx.*

[47] Other data sources (*e.g., WIC Infant and Toddler Feeding Practices Study 2,* available at *https://www.fns.usda.gov/wic/infant-and-toddler-feeding-practices-study-2-fourth-year-report*) also find that intake of vegetables among WIC participants is lower than the intake of fruits.

[48] Heyman MB, Abrams SA, AAP SECTION ON GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION, AAP COMMITTEE ON NUTRITION. Fruit Juice in Infants, Children, and Adolescents: Current Recommendations. Pediatrics. 2017;139(6):e20170967.

[49] Gleason, S., Hansen, D., & Wakar, B. (2021). Indicators of diet quality, nutrition, and health for Americans by program participation status, 2011–2016: WIC report. Prepared by Insight Policy Research, Contract No. GS–10F–0136X. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Michael Burke. *www.fns.usda.gov/research-and-analysis.*

this proposed rule.[50] USDA estimates that 50 percent of CVV spending will be used to purchase fruits and 50 percent used to purchase vegetables at the revised benefit levels.

The proposed rule will decrease the amount of total dairy and refined grains in the food packages for child, pregnant, postpartum, and breastfeeding participants. The decrease in the proportion of refined grains is the result of the revised whole grain breakfast cereal requirements described above. This change improves the balance between whole and refined grains and aligns with DGA guidelines that emphasize that at least half of total grain intake should be in the form of whole grains. The decrease in total dairy, as described in the previous section, will better align the food packages with the supplemental nature of WIC. Although the maximum monthly allowance for legumes exceeds the DGA daily recommended intakes for children and the allowance for peanut butter exceeds daily recommended intakes for children and women, USDA chose not to decrease the amounts provided for either food. This decision was made partly due to market availability, as it is more difficult to find package sizes for beans or peanut butter that fall below the current maximum allowances.

TABLE 8—PROPORTION OF 2020–2025 DGA-RECOMMENDED DAILY AMOUNTS OF FOOD GROUPS IN THE CURRENT AND REVISED FOOD PACKAGES FOR CHILDREN AGES 2 THROUGH 4 YEARS ASSUMING FULL REDEMPTION: FOOD PACKAGE IV–B

WIC food category	DGA food group	Units/day	DGA daily intake [a]	Current		Revised		Change in % of DGA met [c]
				WIC MMA [b]	% of DGA	WIC MMA	% of DGA	
Total fruit	Total Fruit	c-eq	1.25	0.86	72	0.99	76	4
Juice, 100%		c-eq	0.63	0.53	85	0.27	43	−43
Fruit (CVV) [c]		c-eq	0.63	0.37	58	0.68	109	51
Total vegetables	Total Vegetables	c-eq	1.50	0.31	20	0.81	54	34
Vegetables (CVV) [d]	Vegetables (CVV)	c-eq	1.50	0.18	12	0.68	46	34
Legumes	Legumes	c-eq	0.07	0.13	177	0.13	177	0
Total dairy	Total dairy	c-eq	2.50	2.13	85	1.87	75	−10
Total grains	Total grains	oz-eq	4.50	2.27	50	2.00	44	−6
Breakfast cereal	Refined grains	oz-eq	2.25	0.97	43	0.60	27	−17
Breakfast cereal	Whole grains	oz-eq	2.25	0.23	58	0.60	62	5
Bread	Whole grains	oz-eq	.....	1.07	.....	0.80	.....	.....
Total protein foods	Total protein foods	oz-eq	3.50	1.00	28	1.16	33	5
Peanut butter	Nuts, seeds, and soy	oz-eq	0.36	0.60	167	0.60	167	0
Eggs	Meat, poultry, eggs	oz-eq	2.36	0.40	17	0.40	17	0
Fish	Seafood	oz-eq	0.71	0.00	0	0.17	23	23

Notes:
DGA = *Dietary Guidelines for Americans;* MMA = Maximum monthly allowance; c-eq = cup-equivalent; oz-eq = ounce equivalent.
[a] DGA daily intake recommendations based on a 1,300 calorie diet.
[b] For alignment with DGA daily intake recommendations, WIC MMA represented in terms of daily amounts rather than monthly.
[c] Change in % of DGA met is displayed as percentage point change.
[d] CVV MMA in current food package assumes 67 percent redeemed on fruits and 33 percent redeemed on vegetables; CVV MMA in revised food package assume 50 percent redeemed on fruits and 50 percent redeemed on vegetables.
CVV intake estimates are based on assumption of fruit and vegetable unit cost of $0.55/cup-equivalent and $9 CVV in FY 2018, around the time of NASEM's estimates, under current food package compared to unit cost of $0.61/cup-equivalent, accounting for inflation, and $25 CVV in revised package in FY 2024.

TABLE 9—PROPORTION OF 2020–2025 DGA-RECOMMENDED AMOUNTS OF FOOD GROUPS IN THE CURRENT AND REVISED FOOD PACKAGES FOR PREGNANT PARTICIPANTS ASSUMING FULL REDEMPTION: FOOD PACKAGE V–A

WIC food category	DGA food group	Units/day	DGA daily intake [a]	Current		Revised		Change in % of DGA met [c]
				WIC MMA [b]	% of DGA	WIC MMA	% of DGA	
Total fruit	Total Fruit	c-eq	2.00	1.05	52	1.50	75	22
Juice, 100%		c-eq	1.00	0.60	60	0.27	27	−33
Fruit (CVV) [c]		c-eq	1.00	0.45	45	1.23	123	78
Total vegetables	Total Vegetables	c-eq	3.00	0.47	16	1.48	49	34
Vegetables (CVV) [d]	Vegetables (CVV)	c-eq	3.00	0.22	7	1.23	41	34
Legumes	Legumes	c-eq	0.29	0.25	88	0.25	88	0
Total dairy	Total dairy	c-eq	3.00	2.93	98	2.13	75	−23
Total grains	Total grains	oz-eq	7.00	1.73	25	2.80	40	15
Breakfast cereal	Refined grains	oz-eq	3.50	0.97	28	0.60	17	−11
Breakfast cereal	Whole grains	oz-eq	3.50	0.23	22	0.60	63	41
Bread	Whole grains	oz-eq	.....	0.53	.....	1.60	.....	.....
Total protein foods	Total protein foods	oz-eq	6.00	1.60	27	1.93	32	6
Peanut butter	Nuts, seeds,and soy	oz-eq	0.71	1.20	168	1.20	168	0
Eggs	Meat, poultry, eggs	oz-eq	4.43	0.40	9	0.40	9	0
Fish	Seafood	oz-eq	1.29	0.00	0	0.33	26	26

Notes:
DGA = *Dietary Guidelines for Americans;* MMA = Maximum monthly allowance; c-eq = cup-equivalent; oz-eq = ounce equivalent.
[a] DGA daily intake recommendations based on a 2,200 calorie diet.
[b] For alignment with DGA daily intake recommendations, WIC MMA represented in terms of daily amounts rather than monthly.
[c] Change in % of DGA met is displayed as percentage point change.
[d] CVV MMA in current food package assumes 67 percent redeemed on fruits and 33 percent redeemed on vegetables; CVV MMA in revised food package assume 50 percent redeemed on fruits and 50 percent redeemed on vegetables.
CVV intake estimates are based on assumption of fruit and vegetable unit cost of $0.55/cup-equivalent and $11 CVV in FY 2018, around the time of NASEM's estimates, under current food package compared to unit cost of $0.61/cup-equivalent, accounting for inflation, and $45 CVV in revised package in FY 2024.

[50] USDA expects that fruit and vegetable purchasing will be redeemed at closer to 50/50 split at the revised CVV level. This projection is based on the DGA coverage level for fruit in the current food package and the expectation that participants would not exceed DGA recommended fruit intakes under the higher CVV level (as would be the case if fruit continued to account for 67 percent of CVV redemption). If participants continued to use 67 percent of the increased CVV towards fruit and 33 percent towards vegetables, then children ages 2 to 4 years would receive 109 percent of the DGA recommended intake for fruits.

E. Administrative Impacts

Participant Burden

The proposed rule is not expected to substantially change the administrative burden on participants. The general benefits and requirements of the Program are not changing. There will be a one-time burden on participants, estimated to account for an additional 5 minutes per participant, to become familiar with the new food packages and with new foods (*e.g.,* nutrition education around canned fish consumption). In addition, the Department expects the revised may take longer to explain than the current food packages on an ongoing basis because it may take longer to explain the expanded substitution options and package size flexibilities—to account for this, the Department estimates participants will spend an additional 3 minutes learning about the food package options at each certification appointment.

WIC Local Agency Burden

The proposed rule is not expected to substantially change the long-term administrative burden on local WIC agencies. The general benefits and requirements of the Program are not changing. The Department estimates there will be a one-time 1 hour burden for local agencies to attend State Agency provided training on the food package changes. The food package changes are also expected to have both a short-term and ongoing impact on the length of WIC appointments. There will be a one-time burden on local WIC agencies for helping WIC participants become familiar with the new food package and with new foods, which is estimated to take local agencies about 5 minutes per participant in the first year the food package revisions are implemented (estimated to be FY 2024). In addition, the Department expects the revised food packages may take longer to explain than the current food packages on an ongoing basis because of the additional food package size flexibilities and additional substitution options—to account for this, USDA estimates local agencies will spend an additional 3 minutes explaining the food packages at each WIC certification appointment. The Department sought input from FNS Regional office staff in making these estimates. The Department is seeking comments from local agencies on the type and scope of administrative burden that may be associated with implementing the provisions in this proposed rule in this manner to better estimate the burden in the final rule.

WIC State Agency Burden

The general benefits and requirements of the Program are not changing. However, the proposed rule includes additional requirements and options for WIC-authorized foods that will impact State agencies' identification of foods, substitutions, brands, and packaging acceptable for use in the Program. The Department estimates a slight increase (5 to 10% increase, or about 3 hours per State agency) in the amount of time it takes annually for State agencies to identify foods that are acceptable for use in the Program in their State. In addition, the Department estimates 5 hours of training activities added to the burden in the first year related to the food package changes (this includes attending FNS training, developing guidance materials and providing other technical assistance to local agencies. Also, there may be a small one-time burden on State WIC agencies for programming the new food packages into their MIS, but the Department expects that these activities can be absorbed into existing State WIC agency administrative processes for system maintenance and program administration, and the Department expects that the long-term administrative burden on State WIC agencies to be minimal. The Department is seeking comments from State agencies on the type and scope of administrative burden that may be associated with implementing the provisions in this proposed rule in this manner.

Vendor Burden

The proposed rule is not expected to change the administrative burden on most vendors. The general benefits and requirements of the Program are not changing. There may be a small one-time burden on small vendors if they currently only stock two varieties of vegetables, as the proposed rule would require them to stock at least three varieties of vegetables, but the Department expects that the long-term administrative burden on vendors will remain substantially unchanged. The Department notes that other provisions of the rule may decrease burden, at least on some vendors—for example, allowing 20 or 24 ounce package sizes for whole grain breads may lessen the burden on small vendors that have difficulty stocking the less common 16 ounce package size currently required by WIC, or allowing canned legumes to be stocked instead of dry legumes. Therefore, the total burden change to the average vendor will likely be minimal, though the burden changes may vary from vendor to vendor. The Department estimates that 150 small vendors will decide to discontinue participation in the Program (out of more than 41,000 total vendors) as a result of the implementation of this rule. The Department is seeking public comment from vendors to better understand the impact of and potential barriers to implementing the proposed changes.

Food Manufacturer Burden

The changes to the food packages were selected to align with products currently available on the market, so the Department expects that the new food package implementation to have exceedingly minimal effects on food manufacturers' need to reformulate products or create new products or package sizes. The Department expects that most manufacturers will not have to reformulate any products to meet the requirements of this rule; in those rare cases where minor reformulation or repackaging may be necessary, USDA does not expect this burden to be more pronounced than the burden of regularly reviewing and reformulating products within a competitive marketplace, so USDA expects the long-term administrative burden on food manufacturers to remain substantially unchanged. The Department is seeking comments from food manufacturers on the type and scope of burden that may be associated with implementing the provisions in this proposed rule in this manner.

Administrative Costs

As described above, USDA expects any administrative burden and costs associated with this rule to be highly localized, most will be one-time and minimal, and/or to be absorbed within current programmatic overhead. Specifically, USDA only expects slight measurable administrative costs for State agencies and local agencies to account for the added time for the identification of authorized foods and for the explanation of the food package changes to WIC participants. USDA estimates total administrative costs to State agencies and local agencies to a one-time amount of about $17.9 million in FY 2024.

A detailed accounting of the State agency and local agency burden (OMB 0584–0043) is provided in the annual burden adjustment estimates published with this rule. Information provided by FNS Regional Office staff (with direct, routine contact with State agencies) was used to determine the burden estimates. In total, USDA estimates that each of the 89 State agencies will spend an additional 3 hours identifying acceptable foods in the first year the provisions are implemented, or about 267 total hours across all State agencies. This increase in burden is estimated to increase State agency administrative costs by around $16,000 in FY 2024. As described above, State and local WIC agencies are also expected to incur some burden for training activities related to the proposed changes. The 5 hours estimated for State agency training activities is estimated to increase administrative costs by around $26,000 while the 1 hour of training for each of the 1,808 local agencies is estimated to increase administrative costs by around $94,000. USDA also estimates that in the first year following the food package changes, WIC staff at the local agency level will take an additional 5 minutes per participant to explain the food package changes to all participants. Multiplying this time by the over 6 million annual WIC participants, accounts for approximately 572,000 add burden hours at a cost of $29.9 million in FY 2024. As described above, the Department also expects local agency staff will take an additional 3 minutes to explain the options in the revised food packages at each WIC certification appointment on an ongoing basis. While this is a small change at the individual level, when applied to all approximately 10 million WIC certifications estimated per year, this additional staff time is estimated to account for an additional $141 million in administrative costs over five years. Taken together, the administrative burden for State and local agency staff is estimated to amount to 1,085,018 hours at a total cost of $171 million over five years from FY 2024 through FY 2028.

TABLE 10—ADMINISTRATIVE COSTS ASSOCIATED WITH STAFF BURDEN

	Additional burden hours	Fiscal year					Total
		2024	2025	2026	2027	2028	
		Annual cost (millions)					
State Agency Staff Burden:							
Identifying acceptable foods	267	$0.016	n/a	n/a	n/a	n/a	$0.016
State agency training activities	445	0.026	n/a	n/a	n/a	n/a	0.026
Local Agency Staff Burden:							
Local agency training activities	1,808	0.094	n/a	n/a	n/a	n/a	0.094
Explaining food package changes (one-time)	572,282	29.855	n/a	n/a	n/a	n/a	29.855
Explaining revised food package options (ongoing)	510,216	26.618	$27.416	$28.239	$29.086	$29.958	141.316
Total	1,085,018	56.609	27.416	28.239	29.086	29.958	171.308

Notes:
Hourly labor costs are based on Bureau of Labor and Statistics (BLS) estimates for total compensation and inflated to FY 2024–FY 2028 according to the CPI–W projections in OMB's economic assumptions for the FY2023 President's Budget request.
State agency staff labor costs use BLS Hourly Total Cost of Compensation for all State and Local workers, series CMU3010000000000D, available at: *https://data.bls.gov/timeseries/CMU3010000000000D.*
Local agency staff labor costs use BLS Hourly Total Cost of Compensation for state and local workers in healthcare and social assistance industries, series CMU3016200000000D, available at: *https://beta.bls.gov/dataViewer/view/timeseries/CMU3016200000000D.*

F. Participation Impacts

The baseline and revised costs presented in this analysis both assume a change in WIC participation from historical participation trends as a result of the $390 million in additional WIC funding made available in the American Rescue Plan Act of 2021 (ARPA, Pub. L. 117–2) to carry out outreach, innovation, and program modernization efforts to increase participation and redemption of benefits. Implementation of projects made possible by this ARPA funding assume a leveling-off of infant, pregnant, postpartum, and breastfeeding participants and an eventual increase in participation among children followed by a leveling off at the higher rate of child participation.

As noted in the above analysis, the Department's primary estimate does include a shift of 5 percent of fully formula-fed infant-mother dyads to partially breastfeeding dyads, similar to the assumptions made in the NASEM cost analysis.

Other than the shift towards increased breastfeeding under the revised food packages (as described above), NASEM projects the rest of the food package changes will not have a meaningful impact on participation. However, because the proposed rule goes beyond NASEM's cost neutral recommendations (particularly in the proposed increases to the CVV), the rule may be more likely to have an impact on participation. However, given planned efforts to increase participation and retention under ARPA, as described above, USDA is uncertain at this time how much of an increase in participation may be attributable solely to the proposed rule. To better understand how the proposed rule, and specifically the increase to the CVV benefit, will impact participation, USDA is tracking WIC participation trends under the temporary CVV increase recently extended under the *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2022* (Pub. L. 117–103). As described in WIC Policy Memorandum #2022–3, the current WIC CVV levels will be set at $24 for child participants, $43 for pregnant and postpartum participants, and $47 for fully and partially breastfeeding participants until September 30, 2022.[51] As FY 2022 participation data become available, USDA will analyze changes in participation trends to better project the potential impact of the proposed changes on participation and will incorporate this, as well as public comment, into the estimates in the final rule. USDA presents additional cost estimates in the Uncertainties section below, which demonstrate how the cost of the rule would be affected if participation remains flat compared to our primary estimate.

G. Market Impacts

Generally, the changes proposed by this rule attempt to align with products widely available in the current marketplace and to provide WIC participants with additional choices to meet their cultural and personal preferences, and special dietary needs, while at the same time providing food packages that supply appropriate, supplemental amounts of key nutrient-dense foods. For example, the proposed package size flexibilities, and the addition of canned legumes, milk substitutions, forms of fruit and vegetables, etc. are all designed to increase product choice in line with products currently available in the U.S. food marketplace and should not result in additional burden on food manufacturers. The Department anticipates that the general impact of this proposed rule on the wider U.S. food market will be small and easily absorbed by the competitive marketplace. Nevertheless, the Department is seeking public comment from U.S. food market suppliers and participants on the type and scope of market impacts that may be associated with implementing the provisions in this proposed rule.

The dollar impacts of the proposed rule on the different food categories are presented in our primary estimate in Table 2. For all food categories, the Department expects that the change in food purchases attributable to the rule will comprise only a small fraction of the total market for each food category in the United States. For example, the Department estimates that the total net change to the U.S. baby food market will be less than $100 million over 5 years; however, the baby food market in the United States was estimated to be approximately $13 billion in 2018, growing to $17 billion by 2026,[52] so the changes represent less than 0.2% of the total U.S. baby food market over the estimate period. Similarly, the U.S. canned fish market was estimated to be approximately $5 billion in 2021, so the proposed increase in fish represents approximately one-half percentage point of the total U.S. canned fished market. The proposed changes would cause even smaller impacts to the breakfast cereal, grain, and dairy markets. The Department expects that the competitive marketplaces for the various food items will easily absorb the changes in purchasing patterns attributable to this rule without disruption or significant price changes.

The two biggest cost provisions affect the juice market (the decrease in juice) and the fruit and vegetable market (the increase in CVV value). Even in these instances, the Department expects the competitive marketplaces to absorb these changes with minimal disruption. The U.S. juice market was estimated to be $24 billion in 2021, growing to $27 billion by 2026.[53] Even though the decrease in juice attributable to WIC may seem substantial, it accounts for only 0.5% of the total U.S. juice market over the estimate period. Furthermore, many fruit juice manufacturers produce alternate products that will be purchasable with the CVV in many States (*e.g.,* frozen fruits, canned fruits, dried fruits, etc.), so many fruit juice manufacturers will have the opportunity to substitute at least some of the

[51] WIC Policy Memorandum #2022–3: Implementation of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2022 (Pub. L. 117–103), Extending the Temporary Increase in the Cash-Value Voucher/Benefit for Fruit and Vegetable Purchases. March 18, 2022. Available online at: *https://www.fns.usda.gov/wic/wpm-2022-3.*

[52] For more information, see *https://www.alliedmarketresearch.com/us-baby-food-market.*

[53] For more information, see *https://www.statista.com/outlook/cmo/non-alcoholic-drinks/juices/united-states.*

decrease in spending on their juice products with increased spending on other products.

Similarly, the Department anticipates that the U.S. fruit and vegetable market is large and varied enough to absorb the increased purchasing power of the CVV with minimal disruptions. The total size of the U.S. fruit and vegetable market is difficult to estimate with non-proprietary data sources (the Department did not have access to the necessary proprietary data sources on the U.S. fruit and vegetable market when preparing this analysis); however, ERS estimates that farm cash receipts for ''vegetables and melons,'' ''fruits and nuts,'' and ''mushrooms'' combined was approximately $47 billion in 2020.[54] The value of the processed fruit and vegetable market in North America may have been approximately $90 billion in 2020.[55] Just as examples, the increase in the CVV value would account, separately, for less than 2% of the value of farm cash receipts, and for less than 1% of the processed fruit and vegetable market.

The increase in economic activity attributable to the rule will also increase revenues to farmers, farmers' markets (to the extent that WIC participants choose to redeem their additional CVV benefits at farmers' markets), food processors, food distributors, and food retailers. The Department does not attempt to estimate separate, direct effects for each of these economic sectors, such an estimate would be too complex and too uncertain to estimate with precision.

H. Uncertainties

WIC Participation Trends

As stated above, the primary analysis assumes WIC participation growth is consistent with current projections. These estimates assume a fixed level of infant, pregnant, postpartum, and breastfeeding participants and annual increases in child participants through FY 2026. Growth in child participation is estimated at 2.08 percent annually between FY 2021 and FY 2023 and rises to 4.82 percent annual growth between FY 2023 and FY 2026 before leveling off at the higher participation rate in FY 2026 and FY 2028. WIC participation declined each year between 2009 and 2020. There was an increase in participation among children in 2020 during the COVID–19 pandemic; however, participation among adults and infants continued to decline. Table 11, below, compares the cost of the proposed rule under current participation projections compared to a model that assumes flat WIC participation across all categories between FY 2021 to FY 2028. As shown below, the projected increase in participation accounts for $297.0 million of the food cost of the proposed rule over five years.

TABLE 11—PROJECTED FOOD COST OF PROPOSED RULE BY PARTICIPATION CHANGE

	Fiscal year (millions)					Total
	2024	2025	2026	2027	2028	
Primary Analysis: No growth among pregnant, postpartum and breastfeeding individuals and children, annual growth among children of 2.1 percent, FYs 2021–2023, 4.82 percent FYs 2023–2026, and flat participation FYs 2026–2028	$771.48	$791.00	$805.88	$855.86	$898.25	$4,122.5
No Growth: Flat WIC participation among all participant categories, FYs 2021–2028	740.07	742.06	738.84	783.64	820.85	3,825.5
Difference	31.4	48.9	67.0	72.2	77.4	297.0

Cash-Value Voucher Redemption Rate

Compared to the current food packages outlined in 7 CFR 246.10, the proposed increase to the CVV accounts for the largest share of the costs associated with the proposed rule, and as such, even small variations in the model for the CVV cost estimates can result in large changes to the cost of the rule. Redemption rates for all WIC-eligible foods, including the CVV, vary by State agency and by month or season. Redemption rate data is also relatively new, as many States have only fully implemented electronic benefits transfer (EBT) in WIC over the past few years.[56] USDA does not have a routine process in place for collecting EBT data on an ongoing basis. There also remains some uncertainty around how such a large increase to the CVV amount will impact CVV redemption rates. Preliminary data, described earlier in this analysis, suggest that CVV redemption rates in selected States have remained close to typical levels even under the temporary increase to a $35 CVV for all participants authorized under ARPA. Based on the data collected during the ARPA temporary CVV increase, the Department estimates in this analysis assume CVV redemption rates will maintain at 71.6 percent in both the current and revised food packages. Table 12, below, illustrates the impact on the food cost of the rule if the actual CVV redemption rate is just 2 percentage points higher or 2 percentage points lower than the current projections. A 2-percentage point change in the CVV redemption rate under this model is estimated to account for a $138 million change in the cost of the revised CVV benefit amounts under this proposed rule.

TABLE 12—PROJECTED FOOD COST OF CVV INCREASE AT DIFFERENT REDEMPTION RATES

	Fiscal year (millions)					Total
	2024	2025	2026	2027	2028	
Higher (+2): 73.6 percent	$797.0	$817.6	$833.1	$884.6	$928.3	$4,260.6
Current: 71.6 percent	771.5	791.0	805.9	855.9	898.2	4,122.5
Lower (−2): 69.6 percent	746.0	764.4	778.6	827.1	868.2	3,984.3

[54] See *https://data.ers.usda.gov/reports.aspx?ID=17845.*

[55] For more information, see *https://www.gminsights.com/industry-analysis/processed-fruits-and-vegetables-market.*

[56] EBT redemption data allows for analysis of redemptions at the food item level. Prior to the onset of EBT, data on redemption of paper WIC food vouchers were generally limited to overall redemption of WIC benefit values.

V. Alternatives

Different CVV Values

The Department considered permanently implementing ARPA's temporary increase of the WIC CVV to $35 for all participant categories instead of NASEM's proposed values.[57] State agencies and participants are already familiar with the $35 benefit value, and $35 CVV benefit is much closer to NASEM's recommendations than the pre-ARPA CVV benefit.

The Department decided to reject this alternative for both nutrition security and cost reasons. A permanent $35 benefit would provide approximately 75 percent of the DGA recommended quantity of fruits and vegetables for children, while at the same time providing only 36 to 39 percent of the DGA recommended quantity of fruits and vegetables for women. A $35 CVV benefit to all participants would also be more expensive than the proposed rule, costing approximately $6.1 billion over 5 years compared to the proposed rule's CVV cost of $4.9 billion because of the high number of child participants who would receive the higher amount of CVV.

NASEM's Proposed Fish and Legumes Rotation

NASEM recommended adding canned fish to the child, pregnant, postpartum, and partially breastfeeding participant food packages on a three-month rotation, alternating with peanut butter and legumes. The Department decided to reject this alternative in favor of providing canned fish to all pregnant, postpartum and breastfeeding participants and most child participants while keeping the existing peanut butter and legume benefits.

In evaluating the three-month rotation recommendation, the Department determined that this would be too confusing to participants and would be administratively challenging to implement. There are currently no WIC foods provided on a three-month rotation. In addition, the cost neutrality constraints that NASEM applied in making its recommendations are outweighed by the Department's goals of promoting nutrition security and equitable access to foods.

VI. Accounting Statement

As required by OMB Circular A–4, we have prepared an accounting statement summarizing the annualized estimates of benefits, costs and transfers associated with the provisions of this rule.

The benefits of the rule include better alignment of the WIC food packages with the latest available science as described by NASEM, the DGA, and AAP and increased choice and flexibility for WIC participants. Health benefits are not specifically quantified in this analysis but were considered upfront in the detailed nutrient gap analysis conducted to develop the recommendations for the food package.

The net transfers associated with provisions of the rule are incurred by the Federal government. These include the following:

- Increasing the value of the CVV
- Increasing the amount of fish prescribed to WIC participants
- Decreasing the amount of juice prescribed to WIC participants
- Other changes as noted in the above analysis

TABLE 13—UNDISCOUNTED COST AND TRANSFER PAYMENT STREAM

	Fiscal year ($ millions)					Total
	2024	2025	2026	2027	2028	
Nominal Federal Transfer Payment Stream	$771.5	$791.0	$805.9	$855.9	$898.2	$4,122.5
Nominal State Agency Cost Stream	56.6	27.4	28.2	29.1	30.0	171.3

Applying 3 percent and 7 percent discount rates (plus our annual assumed inflation factor) to these nominal streams gives present values (in 2023 dollars):

TABLE 14—DISCOUNTED COST STREAMS

	Fiscal year ($ millions, 2023 dollars)					Total
	2024	2025	2026	2027	2028	
Discounted Federal Transfer Payment Stream:						
3 percent	$732.8	$714.0	$690.9	$697.1	$695.2	$3,530.0
7 percent	706.0	662.7	617.7	600.5	576.9	3,163.8
Discounted State Agency Cost Stream:						
3 percent	53.8	25.8	25.8	25.8	25.8	157.1
7 percent	51.8	23.9	23.1	22.2	21.4	142.4

Table 15 takes the discounted streams from Table 14 and computes annualized values in FY 2023 dollars.

TABLE 15—ACCOUNTING STATEMENT

Benefits	Range	Estimate	Year dollar	Discount rate (%)	Period covered
Qualitative: Better alignment of the WIC food packages with the latest available science as described by NASEM, the DGA, and AAP and increased choice and flexibility for WIC participants.					

[57] See WIC Policy Memorandum #2021–3, ''State Agency Option to Temporarily Increase the Cash-Value Voucher/Benefit for Fruit and Vegetable Purchases,'' available online at *https://www.fns.usda.gov/wic/policy-memorandum-2021-3.*

TABLE 15—ACCOUNTING STATEMENT—Continued

Benefits	Range	Estimate	Year dollar	Discount rate (%)	Period covered
Program participants, farmers, food processors, food distributors, food retailers					
Annualized Monetized ($ millions/year)	n.a.	n.a.	n.a.	n.a.	FY 2024–2028.
Costs	Range	Estimate	Year dollar	Discount rate (%)	Period covered
Quantitative: Net increase in State agency administrative costs associated with increased State agency and local agency administrative burden required to implement proposed changes to the food packages. Administrative cost increases are only expected to be one-time costs in the first year the changes are implemented (estimate for FY 2024).					
State Agencies					
Annualized Monetized ($ millions/year)	n.a.	$136.0 158.3	2023 2023	7 3	FY 2024.
Transfers	Range	Estimate	Year dollar	Discount rate (%)	Period covered
Quantitative: Net increase in WIC food expenditures associated with proposed changes to the food packages.					
Federal Government					
Annualized Monetized ($ millions/year)	n.a.	$749.4 780.1	2023 2023	7 3	FY 2024–2028.

Appendix A–1: Detailed Cost Estimates

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Table A-1: Cash-Value Voucher (CVV), Detailed Cost Estimate

Food Package	Baseline vs. Revised	MMA ($)	RR	Redeemed	Cost by Food Package ($, millions) 2024	2025	2026	2027	2028	Cost Difference, Revised vs. Baseline ($, millions) 2024	2025	2026	2027	2028	Total
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline	9	71.6%	6.44	82.4	96.0	100.7	100.7	100.7	146.6	153.6	161.0	171.1	181.2	813.5
	Revised	25	71.6%	17.90	229.0	249.7	261.7	271.8	281.8						
IV-B	Baseline	9	71.6%	6.44	199.9	232.9	244.1	244.1	244.1	355.4	372.6	390.6	415.0	439.4	1,972.9
	Revised	25	71.6%	17.90	555.4	605.4	634.6	659.1	683.5						
V-A	Baseline	12	71.6%	8.59	51.0	51.0	55.2	55.2	55.2	140.2	144.5	144.5	153.0	157.2	739.5
	Revised	45	71.6%	32.22	191.2	195.5	199.7	208.2	212.5						
V-B	Baseline	12	71.6%	8.59	31.4	31.4	34.0	34.0	34.0	99.3	101.9	101.9	104.5	107.1	514.8
	Revised	50	71.6%	35.80	130.7	133.3	135.9	138.5	141.1						
VI	Baseline	12	71.6%	8.59	41.2	41.2	44.7	44.7	44.7	113.3	116.8	116.8	123.6	127.1	597.6
	Revised	45	71.6%	32.22	154.6	158.0	161.4	168.3	171.7						
VII	Baseline	12	71.6%	8.59	18.6	18.6	20.1	20.1	20.1	58.9	60.4	60.4	62.0	63.5	305.1
	Revised	50	71.6%	35.80	77.4	79.0	80.5	82.1	83.6						
									Total:	**$ 913.8**	**$ 949.8**	**$ 975.2**	**$ 1,029.2**	**$ 1,075.5**	**$ 4,943.5**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-2: Canned Fish, Detailed Cost Estimate

Cost by Food Package ($, millions) | Cost Difference, Revised vs. Baseline ($, millions)

Food Package	Baseline vs. Revised	MMA (oz.)	RR	Redeemed	2024	2025	2026	2027	2028	2024	2025	2026	2027	2028	Total
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline	0	43.6%	0.00	0.0	0.0	0.0	0.0	0.0	16.6	17.8	19.1	19.6	20.0	93.1
	Revised	5	43.0%	2.15	16.6	17.8	19.1	19.6	20.0						
V-A	Baseline	0	43.6%	0.00	0.0	0.0	0.0	0.0	0.0	6.4	6.5	6.7	6.8	7.0	33.3
	Revised	10	43.0%	4.30	6.4	6.5	6.7	6.8	7.0						
V-B	Baseline	0	43.6%	0.00	0.0	0.0	0.0	0.0	0.0	5.9	6.0	6.1	6.3	6.4	30.7
	Revised	15	43.0%	6.45	5.9	6.0	6.1	6.3	6.4						
VI	Baseline	0	43.6%	0.00	0.0	0.0	0.0	0.0	0.0	5.1	5.3	5.4	5.5	5.6	26.9
	Revised	10	43.0%	4.30	5.1	5.3	5.4	5.5	5.6						
VII	Baseline	30	43.6%	13.08	7.1	7.2	7.4	7.6	7.7	-2.4	-2.5	-2.5	-2.6	-2.6	-12.7
	Revised	20	43.0%	8.59	4.6	4.7	4.9	5.0	5.1						
									Total:	**$ 31.6**	**$ 33.1**	**$ 34.8**	**$ 35.6**	**$ 36.4**	**$ 171.4**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-3: Infant Jarred Fruits and Vegetables, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	Baseline vs. Revised	MMA (oz.)	RR	Redeemed	2024	2025	2026	2027	2028	2024	2025	2026	2027	2028	Total

I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline	128	53.4%	68.35	107.1	109.5	112.0	114.6	117.2	29.4	30.1	30.8	31.4	32.2	153.8
	Revised	128	68.1%	87.12	136.5	139.6	142.8	146.0	149.3						
II-BF/FF	Baseline	128	53.4%	68.35	19.8	20.3	20.7	21.2	21.7	5.4	5.6	5.7	5.8	5.9	28.5
	Revised	128	68.1%	87.12	25.3	25.8	26.4	27.0	27.6						
II-BF	Baseline	256	53.4%	136.70	36.5	37.4	38.2	39.1	40.0	-13.3	-13.6	-13.9	-14.2	-14.5	-69.3
	Revised	128	68.1%	87.12	23.3	23.8	24.3	24.9	25.5						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VI	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VII	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
									Total:	**$ 21.6**	**$ 22.1**	**$ 22.6**	**$ 23.1**	**$ 23.6**	**$ 113.0**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-4: Legumes, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (unit)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline	1	38.4%	0.38	15.3	16.4	17.6	18.0	18.4	0.7	0.7	0.8	0.8	0.8	3.9
	Revised	1	39.2%	0.39	16.0	17.2	18.4	18.8	19.2						
IV-B	Baseline	1	38.4%	0.38	37.2	39.8	42.7	43.7	44.7	1.7	1.8	1.9	2.0	2.0	9.4
	Revised	1	39.2%	0.39	38.8	41.6	44.6	45.6	46.7						
V-A	Baseline	1	38.4%	0.38	7.1	7.3	7.4	7.6	7.8	0.3	0.3	0.3	0.3	0.3	1.7
	Revised	1	39.2%	0.39	7.4	7.6	7.8	7.9	8.1						
V-B	Baseline	1	38.4%	0.38	4.4	4.5	4.6	4.7	4.8	0.2	0.2	0.2	0.2	0.2	1.0
	Revised	1	39.2%	0.39	4.6	4.7	4.8	4.9	5.0						
VI	Baseline	1	38.4%	0.38	5.7	5.9	6.0	6.1	6.3	0.3	0.3	0.3	0.3	0.3	1.4
	Revised	1	39.2%	0.39	6.0	6.1	6.3	6.4	6.6						
VII	Baseline	2	38.4%	0.77	5.2	5.3	5.4	5.5	5.7	0.2	0.2	0.2	0.2	0.3	1.2
	Revised	2	39.2%	0.78	4.8	4.9	5.0	5.2	5.3						
									Total:	**$ 3.4**	**$ 3.6**	**$ 3.8**	**$ 3.9**	**$ 3.9**	**$ 18.5**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
MMA for legumes is defined in terms of units, where 1 unit equals either: 18 oz. peanut butter, 16 oz. dried legumes, or 64 oz. canned legumes
Figures may not sum due to rounding.

Table A-5: Infant Meats, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline	77.5	23.1%	17.90	10.2	10.5	10.7	11.0	11.2	-2.9	-3.0	-3.0	-3.1	-3.2	-15.2
	Revised	40	32.0%	12.82	7.3	7.5	7.7	7.8	8.0						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VI	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VII	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
									Total:	**-$ 2.9**	**-$ 3.0**	**-$ 3.0**	**-$ 3.1**	**-$ 3.2**	**-$ 15.2**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-6: Breakfast Cereal, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline	36	47.9%	17.24	45.4	48.7	52.2	53.4	54.6	-0.9	-1.0	-1.0	-1.1	-1.1	-5.1
	Revised	36	43.1%	15.52	44.5	47.7	51.2	52.3	53.5						
IV-B	Baseline	36	47.9%	17.24	110.2	118.1	126.6	129.5	132.4	-2.2	-2.4	-2.5	-2.6	-2.7	-12.4
	Revised	36	43.1%	15.52	108.0	115.7	124.1	126.9	129.7						
V-A	Baseline	36	47.9%	17.24	21.1	21.6	22.0	22.5	23.0	-0.4	-0.4	-0.4	-0.5	-0.5	-2.2
	Revised	36	43.1%	15.52	20.7	21.1	21.6	22.1	22.6						
V-B	Baseline	36	47.9%	17.24	13.0	13.3	13.6	13.9	14.2	-0.3	-0.3	-0.3	-0.3	-0.3	-1.4
	Revised	36	43.1%	15.52	12.7	13.0	13.3	13.6	13.9						
VI	Baseline	36	47.9%	17.24	17.0	17.4	17.8	18.2	18.6	-0.3	-0.3	-0.4	-0.4	-0.4	-1.8
	Revised	36	43.1%	15.52	16.7	17.1	17.5	17.9	18.3						
VII	Baseline	36	47.9%	17.24	7.7	7.9	8.0	8.2	8.4	-0.2	-0.2	-0.2	-0.2	-0.2	-0.8
	Revised	36	43.1%	15.52	7.5	7.7	7.9	8.0	8.2						
									Total:	**-$ 4.3**	**-$ 4.6**	**-$ 4.8**	**-$ 4.9**	**-$ 5.0**	**-$ 323.7**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-7: Infant Formula, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline	806	80.8%	651.25	401.0	410.0	419.3	428.8	438.5	0.0	-20.5	-21.0	-21.4	-21.9	-84.8
	Revised	806	80.8%	651.25	401.0	389.5	398.3	407.3	416.6						
I-FF-B	Baseline	884	80.8%	714.27	311.9	318.9	326.2	333.5	341.1	0.0	-15.9	-16.3	-16.7	-17.1	-66.0
	Revised	884	80.8%	714.27	311.9	303.0	309.8	316.9	324.0						
I-BF/FF-A	Baseline	104	80.8%	84.03	1.8	1.9	1.9	2.0	2.0	4.6	5.7	5.8	5.9	6.0	28.0
	Revised	364	80.8%	294.11	6.4	7.5	7.7	7.9	8.1						
I-BF/FF-B	Baseline	364	80.8%	294.11	55.2	56.5	57.7	59.1	60.4	0.0	8.3	8.5	8.7	8.9	34.3
	Revised	364	80.8%	294.11	55.2	64.8	66.2	67.7	69.3						

I-BF/FF-C	Baseline	442	80.8%	357.14	42.1	43.1	44.0	45.0	46.0	0.0	8.0	8.2	8.3	8.5	33.0
	Revised	442	80.8%	357.14	42.1	51.0	52.2	53.4	54.6						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline	624	80.8%	504.19	761.8	778.9	796.6	814.6	833.0	0.0	-38.9	-39.8	-40.7	-41.7	-161.2
	Revised	624	80.8%	504.19	761.8	740.0	756.8	773.9	791.4						
II-BF/FF	Baseline	312	80.8%	252.10	70.5	72.0	73.7	75.3	77.0	0.0	19.5	19.9	20.4	20.8	80.6
	Revised	312	80.8%	252.10	70.5	91.5	93.6	95.7	97.9						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VI	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VII	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
									Total (pre-rebate):	$ 4.6	-$ 34.0	-$ 34.8	-$ 35.6	-$ 36.4	-$ 136.1
									Total (post-rebate):	**$ 1.1**	**-$ 7.8**	**-$ 8.0**	**-$ 8.2**	**-$ 8.4**	**-$ 31.3**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate. Figures may not sum due to rounding. Formula costs reflect shift of 5 percent of infant-mother dyads from fully formula fed to partially breastfed food packages one year after implementation.

Table A-8: Cheese, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VI	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VII	Baseline	16	62.1%	9.94	7.3	7.4	7.6	7.8	8.0	-7.3	-7.4	-7.6	-7.8	-8.0	-38.0
	Revised	0	0.0%	0.00	0.0	0.0	0.0	0.0	0.0						
									Total:	**-$ 7.3**	**-$ 7.4**	**-$ 7.6**	**-$ 7.8**	**-$ 8.0**	**-$ 38.0**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-9: Whole Wheat/Whole Grain Bread, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline	32	44.0%	14.08	39.1	41.9	44.9	45.9	47.0	-14.0	-15.0	-16.1	-16.4	-16.8	-78.3
	Revised	24	49.8%	11.95	25.1	26.9	28.8	29.5	30.2						
IV-B	Baseline	32	44.0%	14.08	94.8	101.6	108.9	111.4	113.9	-33.9	-36.4	-39.0	-39.9	-40.8	-190.0
	Revised	24	49.8%	11.95	60.9	65.2	69.9	71.5	73.1						
V-A	Baseline	16	44.0%	7.04	9.1	9.3	9.5	9.7	9.9	14.2	14.5	14.9	15.2	15.5	74.4
	Revised	48	49.8%	23.91	23.3	23.8	24.3	24.9	25.5						
V-B	Baseline	16	44.0%	7.04	5.6	5.7	5.8	6.0	6.1	8.7	8.9	9.1	9.3	9.6	45.7
	Revised	48	49.8%	23.91	14.3	14.6	15.0	15.3	15.7						
VI	Baseline	16	44.0%	7.04	7.3	7.5	7.7	7.8	8.0	11.5	11.7	12.0	12.3	12.6	60.1
	Revised	48	49.8%	23.91	18.8	19.2	19.7	20.1	20.6						
VII	Baseline	16	44.0%	7.04	3.3	3.4	3.5	3.5	3.6	5.2	5.3	5.4	5.5	5.7	27.1
	Revised	48	49.8%	23.91	7.8	8.0	8.1	8.3	8.5						
									Total:	**-$ 8.3**	**-$ 10.9**	**-$ 13.6**	**-$ 13.9**	**-$ 14.3**	**-$ 61.0**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-10: Milk and Milk Alternatives, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (qt.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-A	Baseline	16	70.6%	11.30	216.1	231.7	248.4	254.0	259.7	-15.0	-16.1	-17.3	-17.7	-18.1	-84.2
	Revised	12	81.9%	9.83	201.1	215.6	231.1	236.3	241.6						
IV-B	Baseline	16	56.1%	8.98	383.8	411.4	441.0	451.0	461.2	4.1	4.4	4.7	4.8	4.9	22.8
	Revised	14	63.2%	8.85	387.9	415.8	445.7	455.8	466.1						
V-A	Baseline	22	56.1%	12.34	93.3	95.4	97.6	99.8	102.1	-7.6	-7.8	-8.0	-8.2	-8.4	-40.0
	Revised	16	66.1%	10.58	85.7	87.6	89.6	91.6	93.7						
V-B	Baseline	22	56.1%	12.34	57.4	58.7	60.0	61.4	62.8	-4.7	-4.8	-4.9	-5.0	-5.1	-24.6
	Revised	16	66.1%	10.58	52.7	53.9	55.1	56.4	57.6						
VI	Baseline	16	56.1%	8.98	59.3	60.7	62.1	63.5	64.9	2.6	2.6	2.7	2.7	2.8	13.4
	Revised	16	59.1%	9.46	61.9	63.3	64.7	66.2	67.7						
VII	Baseline	24	56.1%	13.46	36.9	37.8	38.6	39.5	40.4	-4.4	-4.5	-4.7	-4.8	-4.9	-23.3
	Revised	16	68.1%	10.90	28.5	29.1	29.8	30.5	31.2						
									Total:	**-$ 25.2**	**-$ 26.3**	**-$ 27.5**	**-$ 28.1**	**-$ 28.7**	**-$ 135.8**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate

Table A-11: Infant Cereals, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline	24	43.4%	10.42	24.5	25.1	25.6	26.2	26.8	-14.6	-14.9	-15.3	-15.6	-16.0	-76.3
	Revised	8	52.6%	4.21	9.9	10.1	10.4	10.6	10.8						

II-BF/FF	Baseline	24	43.4%	10.42	4.5	4.6	4.7	4.8	5.0	-2.7	-2.8	-2.8	-2.9	-3.0	-14.1
	Revised	8	52.6%	4.21	1.8	1.9	1.9	2.0	2.0						
II-BF	Baseline	24	43.4%	10.42	4.2	4.3	4.4	4.5	4.6	-0.8	-0.8	-0.8	-0.9	-0.9	-4.2
	Revised	16	52.6%	8.42	3.2	3.3	3.4	3.5	3.5						
IV-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
IV-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
V-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VI	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
VII	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
									Total:	**-$ 18.1**	**-$ 18.5**	**-$ 18.9**	**-$ 19.3**	**-$ 19.8**	**-$ 94.7**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

Table A-12: Juice, Detailed Cost Estimate

					Cost by Food Package ($, millions)					Cost Difference, Revised vs. Baseline ($, millions)					
Food Package	**Baseline vs. Revised**	**MMA (oz.)**	**RR**	**Redeemed**	**2024**	**2025**	**2026**	**2027**	**2028**	**2024**	**2025**	**2026**	**2027**	**2028**	**Total**
I-FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF/FF-C	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-A	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
I-BF-B	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
II-BF/FF	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Revised			0.00	0.0	0.0	0.0	0.0	0.0						

	Baseline			0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
II-BF	Revised			0.00	0.0	0.0	0.0	0.0	0.0						
	Baseline	128	63.2%	80.90	58.4	62.6	67.1	68.6	70.2	-25.4	-27.3	-29.2	-29.9	-30.6	-142.4
IV-A	Revised	64	71.3%	45.65	32.9	35.3	37.9	38.7	39.6						
	Baseline	128	63.2%	80.90	141.6	151.8	162.7	166.4	170.1	-61.7	-66.1	-70.9	-72.5	-74.1	-345.4
IV-B	Revised	64	71.3%	45.65	79.9	85.6	91.8	93.9	96.0						
	Baseline	144	63.2%	91.01	30.5	31.2	31.9	32.6	33.3	-15.2	-15.5	-15.9	-16.2	-16.6	-79.5
V-A	Revised	64	71.3%	45.65	15.3	15.6	16.0	16.3	16.7						
	Baseline	144	63.2%	91.01	18.7	19.2	19.6	20.0	20.5	-9.3	-9.6	-9.8	-10.0	-10.2	-48.9
V-B	Revised	64	71.3%	45.65	9.4	9.6	9.8	10.1	10.3						
	Baseline	96	63.2%	60.67	16.4	16.8	17.2	17.6	18.0	-16.4	-16.8	-17.2	-17.6	-18.0	-85.9
VI	Revised	0	71.3%	0.00	0.0	0.0	0.0	0.0	0.0						
	Baseline	144	63.2%	91.01	11.1	11.4	11.6	11.9	12.1	-5.5	-5.7	-5.8	-5.9	-6.1	-29.0
VII	Revised	64	71.3%	45.65	5.2	5.3	5.5	5.6	5.7						
									Total:	**-$ 133.6**	**-$ 140.9**	**-$ 148.7**	**-$ 152.1**	**-$ 155.5**	**-$ 731.0**

Notes: FF = formula fed; BF/FF = partially (mostly) breastfeeding; BF = fully breastfeeding; MMA = maximum monthly allowance; RR = redemption rate
Figures may not sum due to rounding.

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Part IV

Department of Labor

Employee Benefits Security Administration

29 CFR Parts 2560 and 2570

Voluntary Fiduciary Correction Program; Proposed Rule

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2560 and 2570

RIN 1210–AB64

Voluntary Fiduciary Correction Program

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Proposed program amendments; request for comment.

SUMMARY: This document contains an amended and restated Voluntary Fiduciary Correction Program (VFC Program or Program) under Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA) and a request for comment. The VFC Program is designed to encourage correction of fiduciary breaches by permitting persons to avoid potential Department of Labor (Department) civil enforcement actions and civil penalties if they voluntarily correct eligible transactions in a manner that meets the requirements of the Program. Based on its experience since the last revision of the Program in 2006, the Employee Benefits Security Administration (EBSA) has identified certain changes that will both simplify and expand the original VFC Program, thereby making the Program easier for, and more useful to, employers and others who wish to avail themselves of the relief provided by the Program. Specifically, the Program amendments add a self-correction feature, clarify some existing transactions eligible for correction under the Program, expand the scope of other transactions currently eligible for correction, and simplify certain administrative or procedural requirements for participation in and correction of transactions under the VFC Program.

DATES: Written comments on the amended and restated VFC Program should be submitted on or before January 20, 2023. The Department will notify the public of the availability of the amended and restated VFC Program in a subsequent **Federal Register** document.

ADDRESSES: You may submit written comments, identified by RIN 1210–AB64, to one of the following addresses:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: Amendment and Restatement of Voluntary Fiduciary Correction Program.

Instructions: Persons submitting comments electronically are encouraged not to submit paper copies. Comments will be available to the public, without charge online at *www.regulations.gov,* at *www.dol.gov/agencies/ebsa,* and at the Public Disclosure Room, EBSA, U.S. Department of Labor, Suite N–1513, 200 Constitution Avenue NW, Washington, DC 20210.

Warning: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records and can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: Yolanda R. Wartenberg, Office of Regulations and Interpretations, EBSA, (202) 693–8500, for questions regarding the VFC Program amendments in this document. Susan Wilker, Office of Exemption Determinations, EBSA, (202) 693–8540, for questions regarding the proposed amendments to the associated class exemption PTE 2002–51. James Butikofer, Office of Research and Analysis, EBSA, (202) 693–8410, for questions regarding the regulatory impact analysis. (These are not toll-free numbers.)

For general questions regarding the VFC Program: contact Dawn Miatech-Plaska, Office of Enforcement, EBSA, (202) 693–8691. For questions regarding specific applications and self-corrections under the VFC Program: contact the appropriate EBSA Regional Office listed in Appendix C. (These are not toll-free numbers.)

Customer Service Information: Individuals interested in obtaining information from the Department concerning ERISA and employee benefit plans may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline, at 1–866– 444–EBSA (3272) or visit the Department's website (*www.dol.gov/ebsa*).

SUPPLEMENTARY INFORMATION:

A. Summary Overview

The Department of Labor's (Department) authority to establish the Voluntary Fiduciary Correction Program (VFC Program or Program) derives from its authority to enforce the fiduciary standards in Title I of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1132(a)(2) and 1132(a)(5), and thereby to establish policies on how this authority will be implemented. The Department also has the authority under section 408(a) of ERISA (29 U.S.C. 1108) to issue exemptions from the prohibited transaction rules in sections 406 and 407 of ERISA (29 U.S.C. 1106 and 1107) and in section 4975 of the Internal Revenue Code (Code).[1]

The Employee Benefits Security Administration (EBSA) originally adopted the VFC Program in 2002, and later revised it in 2005 and 2006.[2] EBSA designed the VFC Program to encourage employers and plan fiduciaries to voluntarily comply with ERISA and allow those potentially liable for certain specified fiduciary breaches under ERISA to voluntarily apply for relief from civil enforcement actions and certain civil penalties, provided they meet the Program's criteria and follow the procedures outlined in the Program. The existing VFC Program describes how to apply for relief, lists the specific transactions covered, and sets forth acceptable methods for correcting fiduciary breaches under the Program.[3] It also provides examples of potential breaches and related permissible corrective actions. The Program defines the term ''Breach'' to mean any transaction that is or may be a violation of the fiduciary responsibilities contained in Part 4 of Title I of ERISA. The Program also provides a model application form, a checklist, and an Online Calculator for determining correction amounts. Eligible applicants that satisfy the terms and conditions of the existing VFC Program receive a no action letter from EBSA and are not subject to civil monetary penalties for the corrected transactions. Excise tax relief for six specific VFC Program transactions is conditionally available under an associated class exemption, PTE 2002–51.[4] The VFC Program has been, and will continue to be, administered in EBSA Regional Offices.

While the VFC Program continues to be successful in encouraging and facilitating the correction of violations

[1] Under Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 252 (2020), the authority of the Secretary of Treasury to issue exemptions pursuant to section 4975 of the Internal Revenue Code was transferred, with certain exceptions not relevant here, to the Secretary of Labor.

[2] 70 FR 17516 (2005), 71 FR 20262 (2006).

[3] EBSA acknowledges, based on its experience, that certain transactions may fit within one or more of the listed categories of transactions, even if not specifically named in the category, for example certain transactions involving contributions in kind under Section 7.4(a) of the Program. EBSA encourages potential applicants to discuss eligibility and similar issues with the appropriate regional VFC Program coordinator.

[4] PTE 2002–51 at 67 FR 70623 (2002); amended at 71 FR 20135 (2006). The current exemptive relief for these six transactions remains available while the proposed amendments to the exemption are being finalized.

of ERISA's fiduciary responsibility and prohibited transaction rules, based on a review of the current VFC Program, which was last revised in 2006,[5] the Department concluded that certain revisions to the Program would facilitate more efficient and less costly corrections of fiduciary breaches under the Program, encourage greater participation in the Program, and respond to requests from stakeholders for adjustments based on their experiences using the Program.

The most significant change to the Program is the addition of a new self-correction feature contained in section 7.1(b) of the VFC Program for certain failures to timely transmit participant contributions (and participant loan repayments) to pension plans. Delinquent participant contributions is the type of transaction most frequently corrected under the Program. The Department has received input from stakeholders who said the time and expense required to file a VFC Program application with the Department is a disincentive to use the Program to correct these transactions, especially when they involve small dollar amounts. After carefully considering the issue, the Department agrees that a self-correction feature for delinquent participant contributions to pension plans that includes appropriately designed safeguards would encourage more voluntary corrections by offering plan officials and other responsible fiduciaries a streamlined correction process. It would also enable EBSA to better allocate resources currently dedicated to processing VFC Program applications for these transactions. The other Program amendments contained in this document (1) clarify existing transactions eligible for correction under the Program, (2) expand the scope of certain transactions currently eligible for correction, and (3) simplify certain administrative or procedural requirements for participation in the VFC Program and correction of transactions under the Program. A more detailed summary of the Program revisions is set forth below in the section of this preamble entitled ''VFC Program 2022 Amendments.''[6]

In tandem with today's publication of amendments to the VFC Program, EBSA is publishing a proposed amendment to PTE 2002–51, the Program's associated class exemption, to make certain conforming amendments to the class exemption. For a more comprehensive discussion of the proposed changes to the class exemption and the request for public comments on those proposed changes, see the proposed amendment to PTE 2002–51 published elsewhere in today's issue of the **Federal Register**.

As discussed in greater detail below in the section entitled ''Statement on Availability and Request for Comment,'' this amended and restated VFC Program will become available to the public following approval by the Office of Management and Budget (OMB) of the revised information collections in the Program in accordance with the Paperwork Reduction Act of 1995 (PRA). The availability will be announced by the Department in a subsequent **Federal Register** Notice. Further, the expanded excise tax relief afforded by the proposed amendments to PTE 2002–51 is not available until such amendments are adopted in final form, which also will be communicated in the **Federal Register**. However, the existing VFC Program and PTE 2002–51 remain available during the Department's consideration of the changes.

B. VFC Program 2022 Amendments

The VFC Program 2022 Amendments set forth in this document would retain the fundamentals of the current VFC Program. To facilitate reference to the Program, this document includes a restatement of the Program in its entirety. Stakeholders interested in a discussion of the existing components of the VFC Program should review the **Federal Register** notices announcing the original 2002 program and the 2005 and 2006 revisions to the Program.[7] The following is an overview of the VFC Program amendments contained in this document.

(1) Self-Correction Feature for Delinquent Participant Contributions to Pension Plans—Section 7.1(b)

A major change, prompted by input from the regulated community, is the addition of a new Self-Correction Component (SC Component or SCC) to section 7, ''Description of Eligible Transactions and Corrections Under the VFC Program.'' Specifically, section 7.1(b) ''Delinquent Participant Contributions and Loan Repayments to Pension Plans under the Self-Correction Component'' provides a new self-correction process for pension plans.[8]

In the past, as noted in the preamble to the April 2006 VFC Program Notice, EBSA was of the view that a self-correction feature would not give the Department sufficient information and certainty of correction compared to that afforded by the Program's application and approval process. However, based on its experience with the Program and input from stakeholders, EBSA is persuaded that delinquent participant contribution/loan repayment transactions are suitable for a self-correction procedure. EBSA expects that a well-designed self-correction feature will mean more voluntary corrections and more participant accounts receiving more timely correction amounts.

Certain other conditions apply to relief under the SC Component. Relief under the SC Component for delinquent participant contributions and delinquent plan loan repayments is available to any pension plan regardless of the size of the plan's participant population or amount of plan assets, but is limited to corrections where the amount of Lost Earnings is $1,000.00 or less excluding any excise tax paid to the plan under the associated class exemption, PTE 2002–51.[9] The delinquent participant contributions or loan repayments also must have been remitted to the plan no more than 180 calendar days from the date of withholding or receipt. These conditions are designed to exclude from the SCC delinquencies involving lost earning amounts that suggest the need for more active evaluation by EBSA of the circumstances surrounding the Breach and timing of the correction.

The Department considered but did not include at this time a limit on the frequency with which a self-corrector may use the SC Component versus

[5] 71 FR 20262 (2006); 71 FR 20135 (2006).

[6] As is the case under the current VFC Program, multiemployer plans and multiple employer plans would be permitted to use the amended VFC Program (including the new SC Component) when it becomes available. The preamble to the 2006 revision of the VFC Program stated that the definition of ''Plan official'' in cases of multiemployer plans or multiple employer plans was not limited so that an application could be made only by the ''plan administrator'' rather than by any contributing or adopting employer. 71 FR 20262, 20264 (April 19, 2006). The Department explained that the plan administrator of such a plan could apply on behalf of the entire plan, but any participating employer may apply on its own behalf. The Department solicits comments on whether additional guidance on those points would be helpful, and if so, what the guidance should provide.

[7] *See* 67 FR 15062 (March 28, 2002), 70 FR 17516 (April 6, 2005), and 71 FR 20262 (April 19, 2006). Prior to adoption in March 2002, the VFC Program was made available on an interim basis during which the Department invited and considered public comments on the Program. (*See* 65 FR 14164, March 15, 2000)).

[8] To reflect the inclusion of the SCC into the Program, section 6 in the amended program has been renamed ''VFC Program Application and Self-Correction Component Procedures'' and the prior section 6 has been renamed and re-designated as section 6.1 ''VFC Program Application Procedures.''

[9] *See* proposed amendments to PTE 2002–51 elsewhere in today's **Federal Register**.

following the application process for correcting delinquent participant contributions. For example, the Department considered adopting a three-year provision modeled on the provisions in the current VFC prohibited transaction exemption (PTE) that precludes reliance on the PTE to avoid excise taxes for similar VFC Program covered transactions more frequently than once every three years.[10] The Department concluded, however, that the PTE provision was not comparable because it does not preclude reliance on the VFC Program; it just limits relief from applicable excise taxes and even that limitation was subject to several exceptions. The Department was also concerned about a frequency limit unintentionally creating disincentives to use the VFC Program and encouraging corrections outside the VFC Program. Moreover, as discussed in greater detail in the proposed PTE amendment, the Department is soliciting public comments on a proposal to remove the three-year limitation provision from the PTE. As noted above, no similar frequency limitation applies to the use of the VFC Program so parties are able to obtain a ''no action'' letter from the Department even in the case of repeated use of the VFC Program for similar types of transactions. The preamble to the proposed amendments to the PTE also notes that the three-year provision was initially included in the PTE to prevent parties from becoming lax in efforts to comply with their fiduciary duties in connection with covered transactions because of the availability of the exemption. However, the Department's experience with the VFC Program and exemption indicated that the risk of such behavior was low. Also, the application and reporting requirements under the VFC Program and the SC Component together with the ''under investigation'' ineligibility condition provide the Department with a system under which it receives notice of repeat usage and a means of protecting against any potentially inappropriate use of the exemption in connection with covered transactions. Accordingly, the Department decided that it would solicit comments on whether a frequency limitation should be included in the PTE, and if so, what it should be and should any exceptions apply. Nonetheless, the Department will be monitoring for frequent use of the SCC and may communicate with repeat users or open investigations to identify and correct systemic issues leading to repeated failures to transmit participant contributions in a timely fashion.

Relief under the SCC is further conditioned on a particular correction method being used. Correction amounts under the SC Component consist of the (1) Principal Amount and (2) Lost Earnings. Specifically, the Principal Amount is the amount of participant contributions or loan repayments that would have been available to the plan if the employer had not retained such amounts, while Lost Earnings is the amount of earnings that would have been earned on the Principal Amount but for the failure to timely remit such amounts to the plan. The SC Component requires that Lost Earnings be paid from the ''Date of Withholding or Receipt,'' and mandates the use of the Online Calculator to determine the amount of the loss payable to the plan. For this transaction, Date of Withholding or Receipt means the date the amount would otherwise have been payable to the participant in cash in the case of amounts withheld by an employer from a participant's wages, or the day on which the participant contribution or loan payment is received by the employer in the case of amounts that a participant or beneficiary pays to an employer. Use of the Online Calculator and the Date of Withholding or Receipt—which is a stricter standard than the date on which participant contributions or loan repayments could reasonably have been segregated from the employer's general assets—are critical elements of the SCC that, in the Department's view, will help ensure full correction without the need for the protections afforded by the Program's application and approval process. These elements also will provide self-correctors with assurance of the accuracy of their calculations.

Under the SC Component, section 7.1(b)(2)(iii) details an electronically filed notice requirement (SCC notice) which replaces the paper application requirements in section 7.1(a)(3) of the Program. The required data elements in the SCC notice include: the name and an email address for the self-corrector; the plan name; the plan sponsor's nine-digit number (EIN) and the plan's three-digit number (PN); the Principal Amount; the amount of Lost Earnings and the date paid to the plan; the Loss Date (Date(s) of Withholding or Receipt); and the number of participants affected by the correction. The SCC notice must be submitted electronically to EBSA using a new online VFC Program web tool to be located on EBSA's website. Self-correctors using the web tool will receive an automatic EBSA email acknowledging the SCC notice submission.

Prior to submitting the SCC notice, self-correctors must calculate the Lost Earnings amount using the VFC Program's Online Calculator. The Lost Earnings calculation is intended to be a reasonable approximation of the amount that would have been earned on the delinquent participant contributions or loan repayments but for the employer's delinquent transmission of the contributions or repayments. Lost Earnings is calculated by entering the Principal Amount which is the total amount of the delinquent participant contributions or loan repayments, the Loss Date (Date of Withholding or Receipt) which may require multiple entries based on delinquencies in multiple pay periods, and the date the Lost Earnings amount is paid to the plan. The Date of Withholding or Receipt is the date the amount would otherwise have been payable to the participant in cash in the case of amounts withheld by an employer from a participant's wages, or the day on which the participant contribution or loan payment is received by the employer in the case of amounts that a participant or beneficiary pays to an employer. Detailed instructions for the VFC Program Online Calculator are on EBSA's website. Definitions of capitalized terms are contained in sections 5 and 7.1(b).

Self-correctors also must complete the SCC Retention Record Checklist in Appendix F, prepare or collect the documents listed in the Appendix, and provide the completed checklist and required documentation to the plan administrator as required by sections 6.2(d) and 7.1(b)(3). This obligation applies even if the employer is the plan administrator. Such ''dual role'' situations do not relieve the employer as plan administrator from fiduciary recordkeeping and obligations under ERISA. The plan administrator then must maintain these documents as part of the plan's records as required by law. Although self-correctors that satisfy the terms and conditions of the VFC Program do not receive a no action letter from EBSA, similar to a no action letter, the SCC provides that compliance with the SCC terms and conditions results in not being subject to civil monetary penalties or an EBSA civil enforcement action. As with an application under the Program, however, and in accordance with section 2(b) ''Verification,'' EBSA reserves the right to investigate and take other actions with respect to the transaction corrected through the SCC, including taking steps to confirm the

[10] The exemption is currently unavailable to VFC Program applicants that have, within the previous three years, taken advantage of the relief provided by the VFC Program or the exemption for a similar type of transaction.

corrective action was in fact taken. The relief does not extend to criminal investigations or to persons other than the self-corrector. Also, if EBSA determines that the terms and conditions of the SCC were not satisfied, the ''self-corrector'' would, obviously, not be exempt from civil penalties or EBSA enforcement actions related to relevant participant contributions.

Other procedural requirements for self-correction are detailed in section 6.2 ''VFC Program Self-Correction Component Procedures,'' including a Penalty of Perjury Statement. For convenience, a compliant Penalty of Perjury Statement is included as part of the SCC Retention Record Checklist in Appendix F.

EBSA is seeking comments from interested persons on the revisions to the Program set forth in this document, including comments on the SCC criteria and conditions and whether other criteria or conditions would adequately protect plans and participants while being less burdensome or less costly. For example, the Department invites public comments on whether the SCC should incorporate additional protections for pension plans that are classified as small based on their participant population (generally those covering fewer than 100 participants).[11] A possible additional protection would be to limit the participation of small plans to only those whose plan sponsors comply with the safe harbor standard in 29 CFR 2510.3–102(a)(2) for the timely handling of participant contributions. Compliance could require, for example, either an existing practice or an agreement to put in place a customary practice of depositing participant contributions and loan payments with the plan not later than the 7th business day following the day on which such amount would otherwise have been payable to the participant in cash in the case of amounts withheld by an employer from a participant's wages, or the 7th business day following the day on which the participant contribution or loan payment is received by the employer in the case of amounts that a participant or beneficiary pays to an employer. The additional protection that would result from requiring compliance with the safe harbor as a condition of SCC relief is that small employers would either have or agree to implement clear procedures for the timely handling of participant contributions. In the Department's view, the use of the small plan safe harbor standard for large plans would be inappropriate. EBSA expects that large plans generally can and should be depositing participant contributions with the plan sooner than 7 business days after the contributions are withheld or received by the employer.

(2) Conforming Revisions to Current Application Process Provisions for Delinquent Participant Contributions (Sections 7.1(a), (c) and (d))

Section 7.1(a) has been renamed ''Delinquent Participant Contributions and Loan Repayments to Pension Plans under VFC Program Applications'' to clarify that it applies only to corrections pursuant to Program applications in contrast to self-corrections under section 7.1(b). Additionally, section 7.1(a) has been revised to reflect the Department's amendment of its regulation defining plan assets in 2010 to include participant loan repayments within these regulatory principles. (See 29 CFR 2510.3–102(a)(1)). Language has also been added to sections 7.1(a)(3)(ii)(A) and (iii)(A) to explain that the required narrative in the application must include a description of any steps taken to prevent future delinquencies. Language referring to Restoration of Profits has been deleted from sections 7.1(a)(2)(i) and (ii) to simplify the Program because in the Department's experience no applicant has reported generating a profit through use of the delinquent amounts.

Sections 7.1(b) ''Delinquent Participant Contributions to Insured Welfare Plans'' and (c) ''Delinquent Participant Contributions to Welfare Plan Trusts'' are being re-designated as sections 7.1(c) and (d) respectively. A change also has been made to each of these sections to clarify that the participant contributions were remitted to the insurance provider in section 7.1(c)(3)(iii) and to the trust in section 7.1(d)(3)(ii) rather than the plan as previously stated. A change was also made to delete language referring to Restoration of Profits in sections 7.1(d)(2)(i) and (ii) to simplify the Program because, as stated above, no applicant has reported generating a profit through use of the delinquent amounts.

The VFC Program does not include a correction for delinquent matching employer contributions. Although some applications filed under the current VFC Program for delinquent participant contributions have sought relief for matching employer contributions, EBSA historically concluded that the different characteristics of the plan asset and fiduciary obligations that apply in the case of employer contributions make it inappropriate to include matching employer contributions as a transaction in a VFC Program. The Agency's position on that subject has not changed. Nonetheless, to the extent that a Program application provides that the employer will apply the same correction formula to the employer matching contributions that it is required to apply to the delinquent participant contributions, EBSA anticipates that it will not reject or refuse to process such applications even though the ''correction'' of the employer contribution is not a covered transaction under the VFC Program, is not entitled to any relief under the Program, and will not be covered by any no action letter.

(3) Loans—Sections 7.2(b), (c) and (d)

The original VFC Program included as an eligible transaction ''Loan at Below-Market Interest Rate to a Party in Interest with Respect to the Plan.'' The corrective action in section 7.2(b) under both the current and this amended and restated Program requires the payment of the loan in full, plus penalties, and the greater of the Lost Earnings or Restoration of Profits. In addition to the required section 6.1 documentation, an applicant currently must provide both a written copy of an independent commercial lender's fair market interest rate determination under section 7.2(b)(3)(ii) and a copy of an independent fiduciary's dated, written approval of the fair market interest rate determination under section 7.2(b)(3)(iii). To reduce applicants' costs, the VFC Program 2022 Amendments would amend section 7.2(b)(3)(iii) to eliminate the requirement that an independent fiduciary validate in writing the process used to determine the fair market interest rate determination for loans in the amount of $10,000 or less. Thus, under these amendments to the Program, in the case of below-market interest rate loans in the amount of $10,000 or less, a copy of the independent commercial lender's written fair market interest rate

[11] In determining whether a plan qualifies as a ''small'' plan, self-correctors can rely on the end of year participant count reported on the latest Form 5500 or Form 5500–SF filed for the plan because that would be the annual report count closest in time to use of the SCC. If there is no Form 5500 or Form 5500–SF for the prior year, the self-corrector should use the participant count for the end of the year that would have been reported if a Form 5500 or Form 5500–SF were required or that will be reported when the prior year Form 5500 or Form 5500–SF is filed. Images of the Form 5500 and Form 5500–SF filings for plan years after 2008 can be accessed on EBSA's website at *efast.dol.gov/5500search/*. The Department notes that potential self-correctors who fail to meet the SCC conditions for participating in the SCC may still be eligible to correct the delinquency violation through the normal application process under the VFC Program.

determination will now suffice to validate the interest rate.

As a further clarifying change, the wording in section 7.2(b)(3)(i) is being revised to require a narrative describing the process used to determine the interest rate at the time the loan was made.

Section 7.2(c) ''Loan at Below-Market Interest Rate to a Person Who is Not a Party in Interest With Respect to the Plan'' is also a transaction that dates from the original VFC Program. Sections 7.2(c)(2)(i) and (ii) are being re-organized to clarify the required correction for this transaction. Section 7.2(c)(2)(ii) also adds an alternative to payment of the present value of the Principal Amounts from the Recovery Date to the loan's maturity date. The present value payment method must be coupled with the borrower's continued payment of the outstanding loan balance under the original repayment schedule for the duration of the loan. The new alternative permits the borrower's payment of the amortized outstanding loan balance over the remaining payment schedule of the loan at the interest rate that would have been applicable if the loan had originally been made at the fair market interest rate. When this new alternative is used, the applicant must submit a copy of the loan repayment schedule for the re-amortized loan repayments under section 7.2(c)(3)(iii). Any fair market interest rate must be determined by an independent commercial lender.

The wording in section 7.2(c)(3)(i) is being revised in a similar fashion to the wording in section 7.2(b)(3)(i) to require a narrative describing the process used to determine the interest rate at the time the loan was made.

Section 7.2(d) ''Loan at Below-Market Interest Rate Solely Due to a Delay in Perfecting the Plan's Security Interest'' is another transaction dating back to the original 2002 Program. It provides a correction for when a plan made a purportedly secured loan to a non-party in interest, but a delay occurred in recording or otherwise perfecting the plan's interest in the loan collateral, resulting in the loan being treated as an unsecured loan until the plan's security interest was perfected. Section 7.2(d)(2) is being re-organized to clarify the correction. Section 7.2(d)(2)(ii) specifically requires that the plan's interest in the loan collateral be recorded or perfected. For situations where the delay in perfecting the loan's security caused a permanent change in the risk characteristics of the loan, section 7.2(d)(2)(iii) is being amended to add an alternative to the payment of the present value of the remaining Principal Amounts from the date the loan is fully secured to the maturity date of the loan. The present value payment method must be coupled with the borrower's continued payment of the outstanding loan balance under the original repayment schedule for the duration of the loan. The new alternative permits the borrower's payment of the amortized outstanding loan balance over the remaining payment schedule of the loan at the interest rate that would have been applicable for a loan with the changed risk characteristics. When this new alternative is used, the applicant must submit a copy of the loan repayment schedule for the re-amortized loan repayments under section 7.2(d)(3)(iii). Any fair market interest rate must be determined by an independent commercial lender.

In a related modification applicable to these three types of loans, section 5(a) is being revised to include a specific explanation in section 5(a)(5) for when a commercial lender will be considered to be ''independent'' using the same criteria as is used to determine the ''independence'' of an appraiser.

As an ongoing protection for plans and their participants, EBSA staff, as part of the application review process, will continue to monitor a commercial lender's interest rate determination process and will object if it appears that a lender is not truly ''independent'' or the interest rate determination process is otherwise flawed.

(4) Purchases, Sales and Exchanges—Section 7.4

Section 7.4(a) ''Purchase of an Asset (Including Real Property) by a Plan from a Party in Interest'' provides a method of correction for situations when the plan purchased an asset (including real property) from a party in interest in a transaction to which no prohibited transaction exemption applies. A plan's purchase from a party in interest can be corrected by reversing the transaction provided the plan receives the higher of the fair market value at resale or the Principal Amount plus the greater of either Lost Earnings or Restoration of Profits. As an alternative correction, a plan may retain the asset plus receive an amount resulting from application of a formulaic calculation, but only if an independent fiduciary determines that the plan will realize a greater benefit from this alternative correction than from the resale of the asset. Section 7.4(a)(2) is being amended by adding a new paragraph (iii) that provides a third method of correction in situations when the purchase cannot be reversed or the asset retained because the plan no longer owns the asset (*e.g.,* sales, maturity, destruction). Under this new correction, the plan can receive a ''cash settlement'' if the asset has been sold and a Plan Official provides a statement, as required by section 7.4(a)(3)(v), that the sale was upon the advice of an independent fiduciary and not in anticipation of applying for relief under the Program. The determination of the cash settlement amount is prescribed in section 7.4(a)(2)(iii) and takes into account, among other factors, whether the plan realized a profit on the resale of the asset, or a loss on the resale, maturity or destruction of the asset.

As a further clarifying change, the wording in section 7.4(a)(2)(ii), is being modified to permit the subtraction of any earnings received on the asset up to the Recovery Date from Lost Earnings.

EBSA is also amending section 7.4(b) ''Sale of an Asset (Including Real Property) by a Plan to a Party in Interest.'' Section 7.4(b) provides a method of correction in situations when the plan sold an asset for cash to a party in interest in a transaction to which no prohibited transaction exemption applies. The amendment adds a condition to the section 7.4(b)(2)(ii) correction to permit the plan to receive the correction amount rather than to repurchase the asset by permitting a Plan Official to determine that the asset cannot be repurchased (*e.g.,* destruction, maturity). This new condition in section 7.4(b)(2)(ii) is an alternative to the section's existing condition requiring an independent fiduciary to determine that the plan will recognize a greater benefit from this correction than the correction in section 7.4(b)(2)(i). As part of the required documentation under section 7.4(b)(3)(iv), the Plan Official making this determination must provide a written explanation of why the asset cannot be repurchased.

(5) Sales/Leasebacks—Section 7.4(c)

Section 7.4(c) ''Sale and Leaseback of Real Property to Employer'' provides a method of correction for a plan sponsor that sells a parcel of real property to the plan, which is then leased back to the plan sponsor and is not otherwise exempt. To more accurately reflect the statutory exemption provided by ERISA section 408(e), which does not limit the transaction to the plan sponsor, the VFC Program 2022 Amendments would explicitly expand the transaction to allow correction of leases to affiliates of the plan sponsor. Changes, where appropriate, to the associated class exemption are being proposed for consistency with these amendments.

(6) Illiquid Assets—Section 7.4(f)

The April 2005 Program revision added a correction for a transaction that permits a plan to divest, rather than continue to hold in its portfolio, a previously purchased asset that is determined to be illiquid and that had been acquired under three possible circumstances described in the transaction. The transaction was further expanded in 2006 by adding a fourth scenario reflecting the acquisition of an asset from a party in interest to which a statutory or administrative exemption applied. This amendment of the VFC Program retains the four scenarios that compose the transaction, as well as the correction method, which permits the sale of the asset to a party in interest, provided the plan receives the higher of (A) the fair market value of the asset at the time of resale, without a reduction for the costs of sale; or (B) the Principal Amount, plus Lost Earnings as described in section 5(b). This correction encompasses a sale of the illiquid asset to a party in interest by the plan even if the original purchase of the asset by the plan was not a prohibited transaction or imprudent. In this regard, the definition of Principal Amount is being modified to take into account the possibility that the transaction being corrected was neither a prohibited transaction nor a fiduciary Breach. Section 7.4(f)(2)(ii) will now define Principal Amount as either the amount that would have been available had the Breach not occurred, or the plan's original purchase price if the original purchase was not a prohibited transaction or imprudent. The amendments also clarify that in the case of an illiquid asset that is a parcel of real estate, no party in interest may own real estate that is contiguous to the plan's parcel of real estate on the Recovery Date.

(7) Definitions—Section 3

The definition of ''Under Investigation'' in section 3(b)(3)(i) is being modified to state that an investigation of a plan resulting from an EBSA staff review, which could include a review by an EBSA Benefits Advisor, is considered an investigation by EBSA that automatically makes an applicant, self-corrector or plan sponsor ineligible to participate in the Program in connection with the plan provided that, as is currently required, written or oral notice of an investigation, review or examination has been received by the plan, a Plan Official, or an authorized plan representative. However, section 3(b)(3) makes clear that a plan will not be considered to be ''Under Investigation'' merely because EBSA staff has contacted the plan, the applicant, the self-corrector, or the plan sponsor in connection with a participant complaint, unless the participant complaint concerns the transaction described in the application or identified in the SCC notice and the plan has not received the correction amount due under the Program as of the date EBSA staff contacted the plan, the applicant, the self-corrector, or the plan sponsor.

There is a new limited exception to the definition of ''Under Investigation'' for bulk applicants that is discussed more fully below. Moreover, the existing exception from the definition of ''Under Investigation'' in section 3(b)(3) for a work paper review of the accountant of a plan by EBSA's Office of the Chief Accountant remains unchanged.

(8) Eligibility Criteria—Section 4

Section 4 ''VFC Program Eligibility'' is being amended to add two new limited exceptions to the existing eligibility requirements to promote increased usage of the Program. Currently, in order to be eligible to participate in the VFC Program there are two requirements involving possible criminal activity. First, if ''any governmental agency is conducting a criminal investigation of the plan, or of the potential applicant, self-corrector or plan sponsor in connection with an act or transaction directly related to the plan,'' such plan is considered ''Under Investigation'' in accordance with section 3(b)(3)(iii) and is not eligible for relief under the Program. This requirement remains. However, in addition to the first requirement, a second eligibility requirement in section 4(b) requires that there can be ''no evidence of potential criminal violations as determined by EBSA.'' EBSA has received applications involving clear evidence of potential criminal violations such as when a bookkeeper allegedly embezzled money from the plan sponsor, including participant contributions. In some situations, the plan sponsor repaid the money to the plan, including Lost Earnings, and referred the embezzlement to the local authorities who subsequently prosecuted the alleged embezzler. In situations like this, EBSA does not believe an innocent applicant who applies under the Program in such situations should be ineligible for relief under the Program. Accordingly, an exception is being added in paragraph (b)(2) to the section 4 requirements for eligibility to allow participation in the Program by an innocent plan administrator, plan sponsor or applicant for cases involving delinquent participant contributions and loan repayments when (1) all funds have been repaid to the plan; (2) the appropriate law enforcement agency has been notified of the alleged criminal activity; and (3) the applicant submits a statement (covered by the Penalty of Perjury Statement) with the application providing contact information for the law enforcement agency, asserting that the applicant was not involved in the alleged criminal activity, and reporting whether a claim relating to the potential criminal violation has been made under an ERISA section 412 fidelity bond. In light of that change, section 4(b) is re-named and re-designated as section 4(b)(1), ''In general.'' EBSA always retains the right to reject any VFC Program application based on its review of the criminal activity involved.

With regard to the ERISA fidelity bond, although a copy was originally required to be included with an application, the 2002 Program was modified to instead permit applicants to include information concerning the plan's ERISA fidelity bond. This informational requirement was eliminated in the 2006 Program. Although the informational requirement is not being added back to the Program under the VFC Program 2022 Amendments, EBSA emphasizes that these modifications focused merely on streamlining the application process and should not be misconstrued as eliminating or modifying the ERISA section 412 bonding requirements that protect plans against loss by reason of acts of fraud or dishonesty.[12]

As noted above, a plan is automatically ineligible to participate in the Program if it is considered ''Under Investigation'' by EBSA as defined in section 3(b)(3) of the Program. Over the past several years, EBSA has received Program applications from service providers to correct Breaches involving multiple plans. Some of these applications have involved hundreds, or even thousands, of plans, some of which are Under Investigation by EBSA. Consequently under the 2006 Program, such plans could not be included in any resulting no action letter. EBSA would like to be able to issue a no action letter to the service provider that covers all plans named in the application in certain circumstances. Accordingly, an exception is being added in section 4(d) to permit the submission of bulk applications by a single service provider when certain conditions are met. To qualify: (1) the application must cover at

[12] *See* FAB 2008–04, (Nov. 25, 2008); 29 CFR 2550.412–1 (1975) and Part 2580 (1985).

least ten named plans and each plan must have participated in the transaction being corrected; (2) the applicant must be a service provider that is applying for relief only on its own behalf; (3) the applicant is currently or was providing services to each of the named plans at the time of the transaction being corrected; and (4) the service provider cannot be Under Investigation by EBSA and the corrective action cannot have been taken as a result of an EBSA investigation or review of any named plan. EBSA, of course, retains the right to determine whether the corrective action was taken as a result of any investigation, and to exclude any plan involved in the investigation from the no action letter. Also, section 6.1(d)(3) is being amended to permit a bulk applicant to provide for each named plan either the Annual Report Form 5500 filing information or the plan sponsor's nine-digit number (EIN). This procedural change will avoid undue delay while a service provider attempts to secure Annual Report Form 5500 filing information, which may not be directly related to the Breach. Section 6.1(g) is also being amended to permit a bulk applicant with knowledge of the transaction that is the subject of the application to sign and date the Penalty of Perjury Statement in which the applicant certifies that it is not Under Investigation by EBSA instead of requiring a signature from a plan fiduciary for each plan covered by the application.

(9) Miscellaneous Modifications

This document contains assorted other clarifying changes to update the Program, assist Program users and maintain consistency among provisions. For example, section 5(d) ''Distributions'' reflects the cessation of both the Internal Revenue Service (IRS) and Social Security Administration letter forwarding services for missing participants and now provides revised guidance on locating individuals who are owed supplemental distributions. Another example is sections 7.3(a)(3) and (b)(3). Those sections provide that only certain supporting documentation must be provided with the application. The words ''unless otherwise requested by EBSA'' have been added to confirm that EBSA may in individual cases request copies of other supporting documentation. Similarly, references to self-corrector, self-correction and the SCC notice have been added to various provisions where appropriate. Additionally, in sections 7.4(d) and (e) dealing with transactions at greater and less than fair market value respectively, the documentation requirement for the qualified, independent appraiser's report has been revised to correctly specify value rather than fair market value at the time of the transaction. In section 7.5 ''Benefits,'' concerning the distribution of overvalued plan assets in a defined contribution plan, the correction specifically requires the restoration to the plan of the amount that exceeded the paid distribution amount to which all affected participants were entitled under the terms of the plan, plus Lost Earnings as described in section 5(b) on the overpaid distributions.

C. Statement on Availability and Request for Comments

Although the Department is not required to seek public comments on an enforcement policy, the Department solicits comments from the public on the revisions to the VFC Program discussed in this document, including whether there are different ways in which the new transactions included in the Program could be corrected in accordance with the goals of the Program. Additionally, as the VFC Program includes information collections that are subject to the PRA, the Department seeks public comment below on the revisions to the information collections included in this amended and restated VFC Program. The Department will then seek approval of the revisions from OMB in accordance with procedures established by the PRA. A separate notice will be published in the **Federal Register** with a 30-day comment period when the Department submits the VFC Program to OMB seeking OMB's approval of the revised information collections. This amended and restated VFC Program, including the SC Component, will become available following OMB approval and the Department will announce the availability in a subsequent **Federal Register** Notice. Until such time, the existing VFC Program remains available.

The amendments to the associated class exemption, PTE 2002–51, are proposed so that its conditional relief also is not available until the amendments are published in final form; however, relief remains available under the conditions of the existing exemption. The Department expects that the availability of the amended and restated Program will encourage employers and fiduciaries, which otherwise might not do so, to correct Breaches and reimburse plan losses. Of course, implementation of this amended and restated Program does not foreclose resolution of fiduciary Breaches by other means, including entering into settlement agreements with the Department.

Comments may be submitted on any aspect of the VFC Program, including the amendments being announced in this document. The Department is particularly interested in comments on whether the Program should be further expanded in four respects.

First, EBSA has undertaken a nationwide compliance initiative to help retirement plans focus on practices to maintain complete and accurate census information, communicate with participants and beneficiaries about their eligibility for benefits, and implement effective policies and procedures to locate missing participants and beneficiaries. The Agency has a national enforcement project focused on these issues in defined benefit plans, has issued a compliance assistance release, and published a set of best practices that the fiduciaries of defined benefit and defined contribution plans, such as 401(k) plans, can follow to ensure that plan participants and beneficiaries receive promised benefits when they reach retirement age. The Department is interested in public comments on whether the VFC Program should include a transaction for correction of fiduciary breaches involved in such recordkeeping, communication, and benefit payment failures.

Second, the VFC Program contains a transaction for certain participant loans that fail to qualify for ERISA's statutory exemption for plan loan programs in ERISA section 408(b)(1). The covered transaction is for a loan the terms of which did not comply with plan provisions that incorporated requirements of section 72(p) of the Code. The VFC Program requires that the plan official voluntarily correct the loan with IRS approval under the Voluntary Correction Program of the IRS' Employee Plans Compliance Resolution System (EPCRS). The Department is interested in public comments on whether there are other circumstances in which the VFC Program could be integrated with corrections under EPCRS. For example, the IRS now allows participant loan transactions to be corrected under the Self-Correction Program component of EPCRS, but the VFC Program does not have a corollary self-correction component for participant loan transactions and requires that applicants correct participant loan transactions under the normal EPCRS procedures to be eligible for VFC Program correction under Title I of ERISA. Further, the latest updated version of EPCRS in Rev.

Proc. 2021–30 makes improvements to the program's rules for correcting benefit overpayments from defined benefit (DB) pension plans that give DB plan fiduciaries new options for correcting such overpayments and addressing inequities that may arise if the plan seeks to place a repayment burden on the participant. The Department has issued guidance that the hardship of a participant or beneficiary resulting from a recovery attempt, or the cost of collection efforts, may be such that it would be prudent for the plan not to seek recovery notwithstanding the fact that an overpayment of benefits to a participant or beneficiary may involve a fiduciary's failure to properly administer the plan in accordance with the terms of the plan's governing documents. See Advisory Opinions 77–07, 77–08, 77–32A, 77–33, 77–34. The Department is interested in comments on whether changes should be made to better integrate the VFC Program provisions on participant loan transactions with the IRS EPCRS and whether a transaction for correcting overpayments from DB pension plans should be added to the VFC Program that is integrated with correction of the overpayment under the IRS EPCRS.

Third, the Department is considering revising the program to either permit or require that VFC Program applications be submitted electronically. The Department is evaluating available alternative approaches to e-submission, *e.g.,* email versus an internet or web-based portal, but is particularly interested in comments on whether e-submission should be required and whether applicants or classes of applicants have issues or challenges with e-submission that the Department should consider ways to accommodate. The VFC Program application process is currently administered out of EBSA's Regional Offices. Some EBSA Regional Offices have email boxes that can be used for e-submission of VFC Program applications and supporting documents. As an interim step while EBSA considers a more uniform approach, text is being added to the VFC Program to encourage applicants to contact the relevant Regional Office about email submission options and format requirements, *e.g.,* penalty of perjury statements.

Fourth, on June 3, 2022, the IRS announced a pre-audit compliance pilot program for retirement plans. See Employee Plans News | Internal Revenue Service at *www.irs.gov/retirement-plans/employee-plans-news.* Under the program, the IRS will send a pre-audit letter to plan sponsors whose retirement plans have been selected for audit giving the plan sponsor a 90-day window to review the plan's documents and operations to determine if they meet current tax law requirements. If that review reveals mistakes, the plan sponsor may be able to self-correct or request a closing agreement, notify the IRS of correction actions taken and potentially avoid or limit the scope of the IRS examination. The goal is to reduce taxpayer burden and reduce the amount of time spent on retirement plan examinations. The IRS newsletter states that at the end of the pilot, the IRS intends to evaluate its effectiveness and determine if it should continue to be part of the IRS' overall compliance strategy. This is a change from the IRS' existing position that generally allows voluntary correction only until the IRS had identified the plan for audit. The VFC Program includes a similar principle under which persons are ineligible to use the VFC Program if they have received written or oral notice of an investigation, review, or examination by EBSA, IRS, and certain other governmental authorities. The Department is interested in comments on whether it should adopt a pre-audit program similar to the IRS pilot program, and if so, whether the ''under investigation'' provisions of the VFC Program should be revised to accommodate voluntary correction of covered transactions in connection with such a pre-audit program.

D. Regulatory Impact Analysis

The following is a discussion of the examination of the effects of this regulatory action as required by Executive Order 12866,[13] Executive Order 13563,[14] the Paperwork Reduction Act of 1995,[15] the Regulatory Flexibility Act,[16] section 202 of the Unfunded Mandates Reform Act of 1995,[17] Executive Order 13132,[18] and the Congressional Review Act.[19]

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing and streamlining rules, and of promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to the requirements of the executive order and review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. For this purpose, a ''rule'' includes ''an agency statement of general applicability and future effect . . . that is designed to implement, interpret, or prescribe . . . policy or to describe the procedure or practice requirements of an agency.''

OMB has determined that this action is significant under section 3(f)(4) because it raises novel legal or policy issues arising from the President's priorities. Accordingly, OMB has reviewed this action, and the Department has assessed the costs and benefits of its amended enforcement policy and related PTE proposal.

The VFC Program is designed to provide an efficient, cost-effective method for Plan Officials to correct a variety of ERISA fiduciary breaches and prohibited transactions and receive Departmental recognition of the correction. The Department expects that the amendments to the VFC Program will increase efficiency and accessibility for potential applicants and self-correctors. These changes, described further below, include in part, a new Self-Correction Component for delinquent participant contributions and loan repayments involving Lost Earnings less than or equal to $1,000, acceptance of bulk applications with modified requirements, and increased flexibility in the procedures for a variety of other transactions. These changes

[13] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[14] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

[15] 44 U.S.C. 3506(c)(2)(A) (1995).

[16] 5 U.S.C. 601 *et seq.* (1980).

[17] 2 U.S.C. 1501 *et seq.* (1995).

[18] Federalism, 64 FR 153 (Aug. 4, 1999).

[19] 5 U.S.C. 804(2) (1996).

also include proposed elimination from the exemption of a three-year limitation for VFC Program applicants that take advantage of the relief provided by the VFC Program and the exemption for a similar type of transaction.

All pension and welfare plans can utilize the VFC Program if they have a fiduciary breach for which there is an eligible transaction. Parties that are covered by section 4975 of the Code can rely on the related class exemption for excise tax relief for transactions identified in the exemption that are corrected under the VFC Program. In 2019 there were 686,809 defined contribution plans and 46,870 defined benefit plans that would be impacted by these changes.[20] In 2021 there were 2,468,363 health plans [21] and 673,000 other welfare benefit plans that would also be impacted by these changes.[22]

An average of 1,429 applicants per year used the VFC Program from 2018 to 2020. Since the Department does not have data on the Self-Correction Component, as it is new, the Department assumes that 74 percent of VFC Program applicants will move to the Self-Correction Component.[23] The Department projects that the changes to the VFC Program will result in two new Program users filing bulk applications, 367 Program users filing non-bulk applications,[24] 1,072 plans using the new Self-Correction Component,[25] for a total of 1,441 users of the program and PTE.[26]

The Department believes that the benefits of the amended VFC Program and related PTE justify its costs. Because participation is voluntary, the VFC Program imposes no costs unless Plan Officials choose to avail themselves of the opportunity to correct a potential fiduciary breach under the terms of the VFC Program. The Department expects that the revised VFC Program will be easier and more useful for potential applicants. The greater efficiency and accessibility that will result from the availability of a Self-Correction Component for delinquent participant contributions, and other expansions and clarifying modifications of the Program, are expected to make the Program easier to use, to lessen the cost of participation in many instances, and to increase efficiency for both applicants and reviewers.

The VFC Program has been very successful to date in encouraging and facilitating the correction of violations. The Department anticipates that the revised VFC Program will encourage Plan Officials, who otherwise might not do so, to correct violations and reimburse plan losses. The Department is unable to predict with certainty either the reduction in application costs that will arise from the revisions to the Program, or the potential increase in participation that will be associated with these revisions. However, these changes to the VFC Program will reduce associated costs by reducing the number of hours required to make corrections and file applications. Compared with the existing VFC Program, the Department expects the amended Program's per-user costs to be lower because the amendments could move 74 percent of VFC Program applications to the Self-Correction Component.[27] Moreover, implementing the Self-Correction Component will reduce the recordkeeping and reporting cost for Plan Officials with small amounts of delinquent participant contributions and loan repayments, because they no longer will have to submit an application to the Department with extensive supporting documentation, but merely submit a self-correction notice with minimal data to the Department and provide corroborating documentation to the plan administrator. This Self-Correction Component provides additional flexibility to Plan Officials. The Department is also providing additional flexibility by proposing to eliminate the three-year limitation in the PTE. The Department estimates that the total cost savings associated with the Self-Correction Component is $206,550.[28]

Plans or their service providers will need to familiarize themselves with the changes to the VFC Program and amendments to the PTE. Service providers can help multiple plans in a year or across years, so although it could take a service provider multiple hours to review the amended requirements the actual burden impact on an individual plan would be less. With an hourly rate for the in-house compensation and benefits manager of $124.75 per hour,[29] the Department estimates that the total cost burden for compensation and benefit managers to become familiar with the changes to the VFC Program and amended PTE will be $359,530.[30]

Overall, the Department estimates that the costs of the VFC Program and the associated class exemption, in their amended forms, would total approximately $1,359,006 ($1,289,305 in annual equivalent costs reflecting the monetized cost of the work performed by in-house personnel and outside service providers and $69,701 in annual cost burden reflecting the cost of materials and postage). These costs are quantified and discussed in more detail in the Paperwork Reduction Act section, below. This total represents a cost savings due to the new Self-Correction Component.

Benefits for Plan Officials who are granted relief under the VFC Program include elimination of risks arising from an otherwise uncorrected fiduciary breach, as well as savings of resources that otherwise might have been needed to defend against a civil action by the Department based on the breach. An additional and significant benefit of the VFC Program accrues to participants and beneficiaries through the correction of fiduciary breaches and the restoration to the plan of amounts representing losses or improperly generated profits arising from impermissible transactions, resulting in greater security of plan assets and future benefits. The changes to the VFC Program will allow Plan Officials to obtain the above benefits at a reduced cost. The Department hopes that this cost reduction may encourage other Plan Officials to correct previously undetected and unreported fiduciary breaches, which would enhance the retirement income security of participants and beneficiaries; however,

[20] Employee Benefits Security Administration. ''Private Pension Plan Bulletin: Abstract of 2019 Form 5500 Annual Reports.'' (September 2021).

[21] U.S. Department of Labor, EBSA calculations using the 2021 Medical Expenditure Panel Survey, Insurance Component (MEPS–IC), the Form 5500 and 2019 Census County Business Patterns.

[22] U.S. Department of Labor, EBSA calculations using non-health welfare plan Form 5500 filings and projecting non-filers using estimates based on the non-filing health universe.

[23] The Department estimates that the Self-Correction Component will streamline the process for the 74 percent of small and large VFC Program applicants involving lost earnings less than or equal to $1,000.

[24] 1,429 applicants × (100% minus 74.3%) = 367 non-bulk applicants.

[25] The estimate includes a one percent increase in the number of self-corrections, resulting from the removal of the three-year limitation provision for self-correctors. (1,429 applicants × 74.3% × 1.01 = 1,072.)

[26] 1,072 self-correctors + 2 bulk applicants + 367 non-bulk applicants = 1,441 Program Users.

[27] The Department estimates that the Self-Correction Component will streamline the process for 74 percent of small and large VFC cases involving lost earnings less than or equal to $1,000.

[28] The Department estimates that the quantified cost of the VFC Program before the addition of the Self-Correction Component would have been $794,724. The Department estimates that the quantified cost of the VFC Program with the Self-Correction Component is $588,174. Thus, the Department estimates that total cost savings associated with the Self-Correction Component is $206,550 ($794,724 − $588,174).

[29] Internal DOL calculation based on 2021 labor cost data. For a description of the Department's methodology for calculating labor rates, see: *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[30] 1,441 users × 2 hours × $124.75 = $359,530.

it has no data to reliably predict the extent of the increased usage. The Department will continue to actively monitor the use of the VFC Program in order to better evaluate its benefits and costs.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA)[31] imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act, or any other law, and are likely to have a significant economic impact on a substantial number of small entities.[32] Unless the head of an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to prepare and make available for public comment an initial regulatory flexibility analysis of the proposed rule.[33]

This document describes an enforcement policy of the Department that is not being issued as a general notice of proposed rulemaking. Therefore, the RFA does not apply. However, the Department is also issuing a proposed amendment to a class exemption (PTE 2002–51) to which the Regulatory Flexibility Act does apply. The Department certifies that the amendments to PTE 2002–51 will not have a significant economic impact on a substantial number of small entities. However, EBSA considered the potential costs and benefits of this action for small pension plans and the Plan Officials in developing the proposed amendment to the class exemption and believes that its greater simplicity and accessibility would make the Program more useful to small employers who wish to avail themselves of the relief offered under the exemption. Below is the factual basis for the certification.

As mentioned previously, all pension and welfare plans can utilize the VFC Program with the related PTE if they have a fiduciary breach for which there is an eligible transaction. In 2019 there were 600,165 small defined contribution plans and 39,586 small defined benefit plans and plan officials that would be impacted by these changes.[34] In 2021 there were 2,386,024 small health plans that would also be impacted by these changes.[35] Currently 1,429 plan fiduciaries make use of the VFC Program in a given year and the Department projects a small increase to 1,441 fiduciaries making use of the VFC Program in a given year. An estimated 1,072 plans will utilize the new Self-Correction Component in a given year.

The Department is proposing to amend the related PTE so that excise tax relief will be available for transactions that are corrected under the Self-Correction Component. The Department is also proposing to amend the PTE to eliminate the three-year limitation. Thus, all plans eligible to use the VFC Program would be eligible to use the PTE more than just once every three years. However, the Department estimates that, of the total number of pension and welfare plans significantly less than one percent will use the PTE in a given year.[36]

The proposed amended PTE would provide excise tax relief for self-correctors if they pay the amount of the excise tax owed to the plan. The Self-Correction Component can only be used in situations where the size of lost earnings is $1,000 or less. Section 4975(a) imposes an excise tax on each prohibited transaction equal to 15 percent of the amount involved with respect to the prohibited transaction for each year (or part thereof) in the taxable period. Therefore, the maximum excise tax owed for each year would generally not exceed $150.[37]

Plans or their service providers will need to familiarize themselves with the amendments to the PTE. Service providers can help multiple plans in a year or across years, so although it could take a service provider multiple hours to review the amended requirements the actual burden impact on an individual plan would be less. The Department estimates that all 1,072 self-correctors will use the new provisions of the amended class exemption.[38] The per-plan cost for rule familiarization would be $125.[39]

For plans with the maximum lost earnings of $1,000 and an excise tax of 15 percent the maximum excise tax in each year would generally not exceed $150. Including the cost of rule familiarization of $125, the total expense could be $275 in a year. Based on the foregoing, the Department hereby certifies that these proposed amendments will not have a significant economic impact on a substantial number of small entities. Therefore, the Department has not prepared an Initial Regulatory Flexibility Analysis.

Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The ICRs in the VFC Program and PTE 2002–51 are currently approved under OMB Control Number 1210–0118. A copy of the ICRs may be obtained by contacting the office listed in the Addresses section below.

The Department is seeking comment the revisions to the information collections in the enforcement policy and proposed amendments to PTE 2002–51. The Department is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

[31] 5 U.S.C. 601 *et seq.* (1980).

[32] 5 U.S.C. 551 *et seq.* (1946).

[33] 5 U.S.C. 604 (1980).

[34] Employee Benefits Security Administration. ''Private Pension Plan Bulletin: Abstract of 2019 Form 5500 Annual Reports.'' (September 2021).

[35] U.S. Department of Labor, EBSA calculations using the 2021 Medical Expenditure Panel Survey, Insurance Component (MEPS–IC), the Form 5500 and 2019 Census County Business Patterns.

[36] In 2019, there were 733,678 pension plans. (*Source:* Employee Benefits Security Administration. ''Private Pension Plan Bulletin: Abstract of 2019 Form 5500 Annual Reports.'' (September 2021).) In 2021, there were 673,000 welfare benefit plans. (*Source:* U.S. Department of Labor, EBSA calculations using non-health welfare plan Form 5500 filings and projecting non-filers using estimates based on the non-filing health universe.) Thus, 0.08% of all pension and welfare plans will use the PTE in a given year. (1,072 plans/(733,678 plans + 673,000 welfare benefit plans) = 0.08%.)

[37] Under Reorganization Plan No. 4 of 1978, supra n. 1, the Secretary of the Treasury retains interpretive authority over Code sections 4975(a) and (b).

[38] Internal DOL calculation based on 2021 labor cost data. For a description of the Department's methodology for calculating labor rates, see: *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[39] With an hourly rate for the in-house compensation and benefits manager of $124.75 per hour and one hour of burden allocated to a plan the burden be plan would be $125 (rounded).

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dates: Written comments must be submitted to the office shown in the Addresses section on or before January 20, 2023.

Addresses: Comments should be sent to James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210 or email: *ebsa.opr@dol.gov.*

The amended VFC Program, described above, includes a Self-Correction Component for delinquent participant contributions and loan repayments to pension plans involving Lost Earnings less than or equal to $1,000, streamlined requirements for bulk applications, and it expands and modifies transactions that are currently eligible for the VFC Program. The Self-Correction Component permits applicants to self-correct, and then provide EBSA with a notice of the self-correction through the online VFC Program web tool. Service providers are able to submit bulk applications to the VFC Program, under the existing terms and requirements of the Program, with some easing of the eligibility and information requirements. Under the new bulk applicant provisions, the bulk applicant will receive a no action letter providing relief only to the service provider correcting transactions involving each of the plans named in the application.

An average of 1,429 applicants per year used the VFC Program from 2018 to 2020. Since the Department does not have data on the Self-Correction Component, as it is new, the Department assumes that 74 percent of VFC Program applicants will move to the Self-Correction Component.[40] The Department projects that the changes to the VFC Program will result in two new Program users filing bulk applications, 367 Program users filing non-bulk applications,[41] 1,072 plans using the new Self-Correction Component,[42] for a total of 1,441 users of the program and PTE.[43]

In addition to the VFC Program, the Department is publishing a proposed amendment to the associated class exemption PTE 2002–51, which applies only to qualifying applicants and self-correctors participating in the VFC Program. The exemption is currently unavailable to VFC Program applicants that have, within the previous three years, taken advantage of the relief provided by the VFC Program and the exemption for a similar type of transaction. The Department is proposing to eliminate the three-year limitation. The three-year provision was initially included in the exemption to prevent parties from becoming lax in complying with fiduciary and other ERISA duties because of the availability of the exemption. Based on the Department's experience with the VFC Program and the exemption, the Department concluded that the risk of such behavior is low.

The overall paperwork burden for the amended VFC Program and the amended PTE 2002–51 is provided below.

VFC Program

For the VFC Program, the Department estimates that Plan Officials will devote 2.5 hours of clerical staff gathering paperwork, one hour of a compensation and benefits manager calculating Lost Earnings, and one hour of clerical staff engaging in recordkeeping activities for each non-bulk application or self-correction. The Department estimates that for each bulk application, Plan Officials will devote 25 hours of clerical staff gathering paperwork, 10 hours of a compensation and benefits manager calculating Lost Earnings, and 10 hours of clerical staff engaging in recordkeeping activities. Therefore, total burden hours for Plan Officials will equal approximately 6,566 hours.[44] With an hourly rate for the in-house compensation and benefits manager of $124.75 per hour[45] and an hourly rate for in-house clerical staff of $58.66 per hour,[46] this results in an equivalent cost of approximately $481,558.[47]

The Department estimates that external service providers will spend about 10 minutes completing and submitting the online Self-Correction Component notice, 20 hours completing and submitting bulk applications, and two hours completing and submitting all other applications.[48] Therefore, total hour burden for external service providers will be 952 hours.[49] With a rate of $108.04 per hour for an accounting professional,[50] the hour burden is equivalent to approximately $102,926.[51]

Factoring in mailing costs of $10 per application for all applications except those under the Self-Correction Component, the total cost burden for applicants will be approximately $3,690.[52]

The total hour burden associated with the VFC Program will be 7,518 hours with an equivalent cost of $584,484. The total cost burden associated with the VFC Program will be $3,690.

VFCP Class Exemption (PTE 2002–51)

The Department estimates that all 1,072 self-correctors and 286 of the VFC Program applicants will use the amended class exemption. The Department has determined that service

[40] The Department estimates that the Self-Correction Component will streamline the process for the 74 percent of small and large VFC Program applicants involving lost earnings less than or equal to $1,000.

[41] 1,429 applicants × (100% minus 74.3%) = 367 non-bulk applicants.

[42] The estimate includes a one percent increase in the number of self-corrections, resulting from the removal of the three-year limitation provision for self-correctors. (1,429 applicants × 74.3% × 1.01 = 1,072.)

[43] 1,072 self-correctors + 2 bulk applicants + 367 non-bulk applicants = 1,441 Program Users.

[44] [((1,072 self-correctors) + 367 non-bulk applicants) × (2.5 hours of gathering paperwork + 1 hour of calculating Lost Earnings + 1 hour of recordkeeping)] + [2 bulk applicants × (25 hours of gathering paperwork + 10 hours of calculating Lost Earnings + 10 hours of recordkeeping)] = 6,566 hours.

[45] Internal DOL calculation based on 2021 labor cost data. For a description of the Department's methodology for calculating labor rates, see: *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[46] *Ibid.*

[47] [((1,072 self-correctors) + 367 non-bulk applicants) × (2.5 hours of gathering paperwork × $58.66 + 1 hour of calculating Lost Earnings × $124.75 + 1 hour of recordkeeping × $58.66)] + [2 bulk applicants × (25 hours of gathering paperwork × $58.66 + 10 hours of calculating Lost Earnings × $124.75 + 10 hours of recordkeeping × $58.66)] = $481,558.

[48] It should be noted that the required checklist for applications filed with the Department under the Program appears twice within the Appendices to the Program. While it is required to be submitted only once, it is included as the separate Appendix B for applicants who do not choose to use the model application in Appendix E, and separately as the final item in the model application for ease of use for those who do choose to use the model application.

[49] (1,072 self-correctors 10 minutes) + (367 non-bulk application × 2 hours) + (2 bulk application × 20 hours) = 952 hours.

[50] Internal DOL calculation based on 2021 labor cost data. For a description of the Department's methodology for calculating labor rates, see: *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[51] (1,072 self-correctors × 10 minutes × $108.04) + (367 non-bulk application × 2 hours × $108.04) + (2 bulk application × 20 hours × $108.04) = $102,926.

[52] (367 non-bulk applications + 2 bulk applications) × $10 materials and postage per application = $3690.

providers will prepare the documentation required by the exemption at a cost of $108.04 per hour, which will require approximately one hour for completion and delivery. The hour burden associated with the exemption therefore is 1,358 hours with an equivalent cost of $146,718.[53]

Of the 286 VFC Program applicants using the exemption, 167 VFC Program applicants are required to send notices to their participants and beneficiaries.[54] Mailing notices to these 167 VFC Program applicants' estimated 242,956 participants and beneficiaries will result in a cost burden of $66,011 [55] and a hour burden of 3,385 hours [56] and an equivalent cost of $198,574.

The total hour burden associated with the VFCP exemption will be 4,743 hours with an equivalent cost of $345,292. The total cost burden associated with the VFCP exemption will be $66,011.

Summary

The total aggregate annual hour burden for the information collection arising from the VFC Program and the exemption is estimated at 12,261 hours with an equivalent cost of $929,776 (7,518 hours with an equivalent cost of $584,484 for the VFC Program, 4,743 hours with an equivalent cost of $345,292 for VFCP exemption).

The total aggregate annual cost burden for the information collection arising from the VFC Program and the exemption is estimated at $69,701 ($3,690 for the VFC Program and $66,011 for VFCP exemption).

In summary, the categories in the table below encompass the numbers for both the VFC Program and the amended class exemption:

Type of Review: Revision of currently approved collection of information.

Agency: Department of Labor, Employee Benefits Security Administration.

Title: Voluntary Fiduciary Correction Program.

OMB Number: 1210–0118.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 1,442.

Frequency of Response: On occasion.

Responses: 244,397.

Estimated Total Burden Hours: 12,261.

Total Annual Cost (Operating and Maintenance): $69,701.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record. The Department notes that persons are not required to respond to the revised information collection unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, this action does not include any Federal mandate that may result in expenditures by State, local, or tribal governments in the aggregate of more than $100 million, adjusted for inflation, or increase expenditures by the private sector of more than $100 million, adjusted for inflation.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials. This action does not have federalism implications because it has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The amendments of the VFC Program in this document do not alter the fundamental provisions of the statute with respect to employee benefit plans, and as such would have no implications for the States or the relationship or distribution of power between the national government and the States.

Authority: Secretary of Labor's Order 1–2011, 77 FR 1088 (January 9, 2012). 29 U.S.C. 1132(a)(2) and (a)(5), 1136(b).

Voluntary Fiduciary Correction Program

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(d) Loan at Below-Market Interest Rate Solely Due to a Delay in Perfecting the Plan's Security Interest
7.3 Participant Loans
(a) Loans Failing to Comply With Plan Provisions for Amount, Duration, or Level Amortization
(b) Default Loans
7.4 Purchases, Sales and Exchanges
(a) Purchase of an Asset (Including Real Property) by a Plan From a

[53] 1 hour × 1,358 users = 1,358 hours; 1 hour × 1,358 users × $108.04 per hour × = $146,718.

[54] The 1,072 self-correctors that meet the requirements of section IV D. of the exemption and 167 VFC Program applicants for whom a small amount of excise taxes otherwise would be imposed and that meet the requirement of section IV C. of the exemption are not required to provide the notice.

[55] For materials and postage for paper notices. 242,956 notices × 41.8% paper notices × ($0.65 per paper notice)] = $66,011. Electronic notices will be distributed at de minimis cost.

[56] For labor costs for paper notices. 242,956 notices × 41.8% paper notices × 2 minutes = 3,385; 242,956 notices × 41.8% paper notices × 2 minutes × $58.66 = $198,574. Electronic notices will be distributed at de minimis cost.

Party in Interest
(b) Sale of an Asset (Including Real Property) by a Plan to a Party in Interest
(c) Sale and Leaseback of Real Property to Employer
(d) Purchase of an Asset (Including Real Property) by a Plan From a Person Who is Not a Party in Interest With Respect to the Plan at a Price More Than Fair Market Value
(e) Sale of an Asset (Including Real Property) by a Plan to a Person Who is Not a Party in Interest With Respect to the Plan at a Price Less Than Fair Market Value
(f) Holding of an Illiquid Asset Previously Purchased by a Plan
7.5 Benefits
(a) Payment of Benefits Without Properly Valuing Plan Assets on Which Payment is Based
7.6 Plan Expenses
(a) Duplicative, Excessive, or Unnecessary Compensation Paid by a Plan
(b) Expenses Improperly Paid by a Plan
(c) Payment of Dual Compensation to a Plan Fiduciary
Appendix A. Sample VFC Program No Action Letter
Appendix B. VFC Program Application Checklist (Required)
Appendix C. List of EBSA Regional Offices
Appendix D. Lost Earnings Example
Appendix E. Model Application Form (Optional)
Appendix F. SCC Retention Record Checklist (Required)

Section 1. Purpose and Overview of the VFC Program

The purpose of the Voluntary Fiduciary Correction Program (VFC Program or Program), including its Self-Correction Component (SC Component or SCC), is to protect the financial security of workers by encouraging identification and correction of transactions that violate or may violate Part 4 of Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA). Part 4 of Title I of ERISA sets out the responsibilities of employee benefit plan fiduciaries. Section 409 of ERISA provides that a fiduciary who breaches any of these responsibilities shall be personally liable to make good to the plan any losses to the plan resulting from each breach and to restore to the plan any profits the fiduciary made through the use of the plan's assets. Section 405 of ERISA provides that a fiduciary may be liable, under certain circumstances, for a breach of fiduciary responsibility by a co-fiduciary. In addition, under certain circumstances, there may be liability for knowing participation in a fiduciary breach. In order to assist all affected persons in understanding the requirements of ERISA and meeting their legal responsibilities, the Employee Benefits Security Administration (EBSA) is providing guidance on what constitutes adequate correction under Title I of ERISA for the Breaches described in this Program.

Section 2. Effect of the VFC Program

(a)(1) *Effect of a no action letter.* EBSA generally will issue to the applicant a no action letter [57] with respect to a Breach identified in the Program application if the eligibility requirements of section 4 are satisfied and a Plan Official corrects a Breach, as defined in section 3, in accordance with the requirements of sections 5, 6 and 7. Pursuant to the no action letter it issues, EBSA will not initiate a civil investigation under Title I of ERISA regarding the applicant's responsibility for any transaction described in the no action letter, or assess civil penalties under either section 502(l) or 502(i) of ERISA on the correction amount paid to the plan or its participants.

(2) *Effect of correction under the SCC.* EBSA will not issue a no action letter to a self-corrector under the Self-Correction Component of the Program. A self-corrector will receive an acknowledgment and summary of the SCC notice submission by email. If the self-corrector satisfies the eligibility requirements of section 4 and corrects a Breach, as defined in section 3, in accordance with the requirements of sections 5, 6 and 7, EBSA will not initiate a civil investigation under Title I of ERISA regarding the self-corrector's responsibility for the Breach identified in the SCC notice or assess civil penalties under section 502(l) or 502(i) of ERISA on the correction amount paid to the plan or its participants.

(b) *Verification.* EBSA reserves the right to conduct an investigation at any time to determine (1) the truthfulness and completeness of the factual statements set forth in the Program application or the SCC notice and (2) that the corrective action was, in fact, taken.

(c) *Limits on the effect of a no action letter under the VFC Program.* (1) *In general.* Any no action letter issued under the VFC Program is limited to the Breach and applicants identified therein. Moreover, the method of calculating the correction amount described in this Program is only intended to correct the specific Breach described in the application. Methods of calculating losses other than, or in addition to, those set forth in the Program may be more appropriate, depending on the facts and circumstances, if the transaction violates provisions of ERISA other than those that can be corrected under the Program. If a transaction gave rise to Breaches not specifically described in the Program, the relief afforded by the Program would not extend to such additional Breaches.

(2) *No implied approval of other matters.* A no action letter does not imply Departmental approval of matters not included therein, including steps that the fiduciaries take to prevent recurrence of the Breach described in the application and to ensure the plan's future compliance with Title I of ERISA.

(3) *Material misrepresentation.* Any no action letter issued under the VFC Program is conditioned on the truthfulness, completeness and accuracy of the statements made in the application and of any subsequent oral and written statements or submissions. Any material misrepresentations or omissions will void the no action letter, retroactive to the date that the letter was issued by EBSA, with respect to the transaction that was materially misrepresented.

(4) *Applicant fails to satisfy terms of the VFC Program.* If an application fails to satisfy the terms of the VFC Program, as determined by EBSA, EBSA reserves the right to investigate and take any other action with respect to the transaction and/or plan that is the subject of the application, including issuing a rejection letter.

(5) *Criminal investigations not precluded.* Participation in the VFC Program will not preclude:

(i) EBSA or any other governmental agency from conducting a criminal investigation of the transaction identified in the application;

(ii) EBSA's assistance to such other agency; or

(iii) EBSA from making the appropriate referrals of criminal violations as required by section 506(b) of ERISA.[58]

(6) *Other actions not precluded.* Compliance with the terms of the VFC Program will not preclude EBSA from taking any of the following actions:

[57] *See* Appendix A.

[58] Section 506(b) provides that the Secretary of Labor shall have the responsibility and authority to detect and investigate and refer, where appropriate, civil and criminal violations related to the provisions of Title I of ERISA and other related Federal laws, including the detection, investigation, and appropriate referrals of related violations of Title 18 of the United States Code.

(i) Seeking removal from positions of responsibility with respect to a plan or other non-monetary injunctive relief against any person responsible for the transaction at issue;

(ii) Referring information regarding the transaction to the Internal Revenue Service as required by section 3003(c) of ERISA; [59] or

(iii) Imposing civil penalties under section 502(c)(2) of ERISA based on the failure or refusal to file a timely, complete and accurate Annual Report Form 5500. Applicants should be aware that amended annual report filings may be required if possible Breaches of ERISA have been identified, or if action is taken to correct possible Breaches in accordance with the VFC Program.

(7) *Not binding on others.* The issuance of a no action letter does not affect the ability of any other government agency, or any other person, to enforce any rights or carry out any authority they may have, with respect to matters described in the no action letter.

(8) *Example.* A plan fiduciary causes the plan to purchase real estate from the plan sponsor under circumstances to which no prohibited transaction exemption applies. In connection with this transaction, the purchase causes the plan assets to be no longer diversified, in violation of ERISA section 404(a)(1)(C). If the application reflects full compliance with the requirements of the Program, the Department's no action letter would apply to the violation of ERISA section 406(a)(1)(A) but would not apply to the violation of section 404(a)(1)(C).

(d) *Limits on the effect of self-correction under the SCC. (1) In general.* Any relief afforded by a self-correction under the SCC is limited to the Breaches described in section 7.1(b) of the Program and to the Plan Officials who complete the Penalty of Perjury Statement in accordance with section 6.2(e). If a transaction gives rise to Breaches not specifically described in section 7.1(b) of the Program, the relief afforded by the SCC will not extend to such additional Breaches.

(2) *Self-corrector fails to satisfy the terms of the SCC.* If a self-corrector fails to satisfy the terms of the SCC, as determined by EBSA, EBSA reserves the right to investigate and take any other action with respect to the transaction and/or plan that is the subject of the self-correction.

(3) *Criminal investigations not precluded.* Participation in the SCC will not preclude:

(i) EBSA or any other governmental agency from conducting a criminal investigation of the transactions identified in section 7.1(b) of the Program;

(ii) EBSA's assistance to such other agency; or

(iii) EBSA from making the appropriate referrals of criminal violations as required by section 506(b) of ERISA.[60]

(4) *Other actions not precluded.* Compliance with the terms of the SCC will not preclude EBSA from taking any of the following actions:

(i) Seeking removal from positions of responsibility with respect to a plan or other non-monetary injunctive relief against any person responsible for the transaction at issue; or

(ii) Imposing civil penalties under section 502(c)(2) of ERISA based on the failure or refusal to file a timely, complete and accurate Annual Report Form 5500. Self-correctors should be aware that amended annual report filings may be required if action is taken to correct a Breach in accordance with submitting an SCC notice.

(5) *Not binding on others.* Compliance with the SCC does not affect the ability of any other government agency, or any other person, to enforce any rights or carry out any authority they may have regarding the Breach corrected under the SCC.

Example. The plan sponsor withheld monies from employees' paychecks, which were to be contributed, in part, to both a 401(k) plan and an insured health benefit plan. The plan sponsor did not remit the funds to either plan until four months after the Date of Withholding or Receipt. The plan sponsor corrects both Breaches and pays the appropriate Lost Earnings amount to each of the plans. The plan sponsor properly completes and submits an SCC notice to EBSA identifying the transaction involving the 401(k) plan. Assuming all conditions of the SCC have been met, relief under the Program is provided to the plan sponsor as the self-corrector for the delinquent participant contributions to the 401(k) plan, but not for the delinquent participant contributions to the insured health benefit plan. However, the plan sponsor may submit an application to correct the Breach involving the insured health benefit plan contributions under section 7.1(c) of the Program.

(e) *Correction.* The correction criteria listed in the VFC Program represent EBSA enforcement policy with respect to both applications under the Program and use of the SC Component, and are provided for informational purposes to the public, but are not intended to confer enforceable rights on any person who purports to correct a Breach. Applicants and self-correctors are advised that the term ''correction'' as used in the VFC Program is not necessarily the same as ''correction'' pursuant to section 4975 of the Internal Revenue Code (Code).[61] Correction may not be achieved under the Program by engaging in a prohibited transaction that is not subject to a prohibited transaction administrative exemption.

(f) *EBSA's authority to investigate.* EBSA reserves the right to conduct an investigation and take any other enforcement action relating to the transaction identified in a VFC Program application or SCC notice in certain circumstances, such as prejudice to the Department that may be caused by the expiration of the statute of limitations period, material misrepresentations or omissions, other abuses of the VFC Program, or significant harm to the plan or its participants that is not cured by the correction provided under the VFC Program. EBSA may also conduct a civil investigation and take any other enforcement action relating to matters not covered by the VFC Program application or SCC notice, or relating to other plans sponsored by the same plan sponsor, while a VFC Program application involving the plan or the plan sponsor is pending.

(g) *Confidentiality.* EBSA will maintain the confidentiality of any documents submitted under the VFC Program, to the extent permitted by law. However, as noted in paragraphs (c)(5) and (6) and (d)(3) and (4) of this section, EBSA has an obligation to make referrals to the IRS and to refer to other agencies evidence of criminality and other information for law enforcement purposes.

[59] Section 3003(c) provides that, whenever the Secretary of Labor obtains information indicating that a party in interest or disqualified person is violating section 406 of ERISA, the Secretary shall transmit such information to the Secretary of the Treasury.

[60] *See supra* note 58.

[61] *See* section 4975(f)(5) of the Code; section 141.4975–13 of the temporary Treasury Regulations and section 53.4941(e)–1(c) of the Treasury Regulations. The federal tax treatment of a violation and correction under the VFC Program (including the federal income and employment tax consequences to participants, beneficiaries, and plan sponsors) are determined under the Code. The IRS has indicated that, unless and until the Department of the Treasury and the IRS issue further guidance, except in those instances where the fiduciary breach or its correction involve a tax abuse, a correction under the VFC Program for a breach that constitutes a prohibited transaction under section 4975 of the Code generally will be treated as correction for purposes of section 4975. Also, a correction under the VFC Program for a breach that also constitutes an operational plan qualification failure generally will be treated as correction for purposes of the IRS' EPCRS.

Section 3. Definitions

(a) The terms used in this document have the same meaning as provided in section 3 of ERISA, 29 U.S.C. 1002, unless separately defined herein.

(b) The following definitions apply for purposes of the VFC Program:

(1) *Breach.* The term ''Breach'' means any transaction that is or may be a violation of the fiduciary responsibility provisions contained in Part 4 of Title I of ERISA.

(2) *Plan Official.* The term ''Plan Official'' means a plan fiduciary, plan sponsor, party in interest with respect to a plan, or other person who is in a position to correct a Breach by filing an application or submitting a self-correction notice in accordance with the VFC Program's requirements.

(3) *Under Investigation.* For purposes of section 4(a), a plan, potential applicant or self-corrector shall be considered to be ''Under Investigation'' if any investigation, review or examination described in (i), (ii), (iii), (iv) or (v) of this section 3 exists, and the plan, a Plan Official, or any authorized plan representative has received a written or oral notice of the investigation, review or examination.

(i) EBSA is conducting an investigation or review of the plan;

(ii) EBSA is conducting an investigation of the potential applicant, self-corrector or plan sponsor in connection with an act or transaction directly related to the plan;

(iii) any governmental agency is conducting a criminal investigation of the plan, or of the potential applicant, self-corrector or plan sponsor in connection with an act or transaction directly related to the plan;

(iv) the IRS is conducting an Employee Plans examination of the plan; or

(v) Other than investigations identified in sections 3(b)(3)(i), (ii), (iii), or (iv), the Pension Benefit Guaranty Corporation (PBGC), any state attorney general, any federal governmental agency, or any state insurance commissioner is conducting an investigation or examination of the plan, or of the applicant, self-corrector or plan sponsor in connection with an act or transaction directly related to the plan, unless in the case of a VFC Program application, the applicant notifies EBSA, in writing, of such an investigation or examination at the time of the application.

An applicant notifying EBSA of an investigation or examination under section 3(b)(3)(v) must submit the name of the examining agency and a contact person at such agency. Upon receipt of an application including such information, EBSA will promptly notify the investigating agency in writing of the VFC Program application. EBSA's notice will afford the examining agency an opportunity to provide EBSA with information relevant to the investigation or examination. In response to the information received from the investigating agency, EBSA, in its sole discretion, may decline to issue a no action letter to the applicant. For purposes of section 4(a), a plan shall not be considered to be ''Under Investigation'' merely because EBSA staff has contacted the plan, the applicant, the self-corrector or the plan sponsor in connection with a participant complaint, unless the participant complaint concerns the transaction described in the application or identified in the SCC notice and the plan has not received the correction amount due under the Program as of the date EBSA staff contacted the plan, the applicant, the self-corrector or the plan sponsor. A plan also is not considered to be ''Under Investigation'' if the accountant of the plan is undergoing a work paper review based on such accountant's audit of the plan by EBSA's Office of the Chief Accountant under the authority of ERISA section 504(a).

Example 1. On March 1, the plan sponsor of a multiple employer welfare arrangement (MEWA) received written notification from an agent of the state insurance commissioner's office that the MEWA has been scheduled for examination. The applicant does not notify EBSA of the examination. As of March 1, the plan is ineligible for participation in the VFC Program because the plan sponsor has received a notice from the state insurance commissioner's office concerning its intent to examine the plan, and the applicant did not provide EBSA written notice of the examination with the application.

Example 2. Assume the same facts as in Example 1, except that the applicant chooses to notify EBSA in writing of the examination. The plan's eligibility to apply under the VFC Program would not be affected because the applicant provides written notice of the examination to EBSA with the application. EBSA will promptly notify the state insurance commissioner of the pending VFC Program application so that the state insurance commissioner's office has an opportunity to provide information about its examination to EBSA. EBSA will include the information received from the state insurance commissioner's office in its review of the VFC Program application.

Section 4. VFC Program Eligibility

Eligibility for the VFC Program is conditioned on the following:

(a) The plan, the applicant, or the self-corrector is not Under Investigation.

(b)(1) *In general.* The Program application contains no evidence of potential criminal violations as determined by EBSA.

(2) *Exception for VFC Program applications correcting transactions described in Section 7.1(a).* Participation in the VFC Program to correct delinquent participant contributions and loan repayments is permitted in cases where there is evidence of potential criminal violation by parties other than the plan administrator, the plan sponsor or the applicant provided:

(i) all funds have been repaid to the plan;

(ii) the appropriate law enforcement agency has been notified of the potential criminal violation; and

(iii) the applicant submits to the appropriate EBSA office a statement (A) providing contact information for the law enforcement agency that has been notified of the alleged criminal activity; (B) asserting that the applicant was not involved in the potential criminal violation; and (C) stating whether a claim relating to the criminal activity has been made under an ERISA section 412 fidelity bond.

Example. The bookkeeper of the plan sponsor of a 401(k) plan allegedly embezzled funds from the plan sponsor, including amounts which had been withheld from employees' paychecks but not yet forwarded to the plan. As a result of the embezzlement, participant contributions were remitted to the plan two months later than the plan sponsor's usual practice. The owner of the company sponsoring the plan was not involved in the embezzlement and notified local law enforcement of the embezzlement. This owner is eligible to submit an application for relief under the VFC Program despite the potential criminal violation if the requirements under section 4(b)(2) are met. Note that the owner is not eligible for relief under the SCC because the exception under section 4(b)(2) is only available to applicants under the VFC Program and not the SC Component.

(c) EBSA has not conducted an investigation which resulted in written notice to a plan fiduciary that the transaction, for which the potential applicant or self-corrector could otherwise have sought relief under the Program, has been referred to the IRS. This condition applies only to those transactions specifically identified in

EBSA's written notice of referral to the IRS.

(d) *Exception for Bulk VFC Program Applicants.* An applicant is eligible to submit a bulk application under the VFC Program, even if one or more of the plans named in the application (''named plans'') is Under Investigation, and to receive a no action letter covering each of the named plans provided: (1) the applicant is a service provider that is seeking the relief afforded by the Program only on its own behalf; (2) the applicant was providing services to each of the named plans at the time of the transaction being corrected; (3) the application includes at least ten named plans; (4) all named plans participated in the transaction being corrected; and (5) the corrective action was not taken as a result of an investigation of any named plan. A determination by EBSA that the corrective action was taken as a result of an investigation of any named plan results in the no action letter specifically excluding such plan.

Example. A bank provides investment management services to pension plans. As part of these services, it bought bonds on behalf of its plan clients directly from a broker dealer's inventory. The bank independently discovered that the broker dealer is an affiliate of the bank and consequently, a party in interest to the plans (PII). No available class exemption permitted these purchases. The bank's review showed it had bought bonds for thirty-three (33) of its plan clients from the PII broker dealer. The bank, as a service provider to the plans, may submit a bulk application correcting the transaction in compliance with section 7.4(a) of the Program provided the application names all 33 plans that participated in the transaction and the bank is seeking relief only on its own behalf under the Program. Assuming the applicant has complied with the terms of the VFC Program, EBSA will issue a no action letter to the service provider, which includes the name of each of the participating plans.

Section 5. General Rules for Acceptable Corrections

(a) *Fair Market Determinations.* Many corrections require that the current or fair market value (FMV) of an asset be determined as of a particular date, usually either the date the plan originally acquired the asset or the date of the correction, or both. In order to be acceptable as part of a VFC Program correction, the valuation must meet the conditions in (1) through (4) below. Other corrections require that a fair market interest rate be determined as of a particular date, usually the date the loan was made. In order to be acceptable as part of a VFC Program correction, this determination must be made by an independent commercial lender, which meets the conditions in (5) below:

(1) If there is a generally recognized market for the property (*e.g.,* the New York Stock Exchange), the FMV of the asset is the average value of the asset on such market on the applicable date, unless the plan document specifies another objectively determined value (*e.g.,* the closing price).

(2) If there is no generally recognized market for the asset, the FMV of that asset must be determined in accordance with generally accepted appraisal standards by a qualified, independent appraiser and reflected in a written appraisal report signed by the appraiser.

(3) An appraiser is ''qualified'' if the appraiser has met the education, experience, and licensing requirements that are generally recognized for appraisal of the type of asset being appraised.

(4) An appraiser is ''independent'' if the appraiser is not one of the following, does not own or control any of the following, and is not owned or controlled by, or affiliated with, any of the following:

(i) The prior owner of the asset, if the asset was purchased by the plan;

(ii) The purchaser of the asset, if the asset was, or is now being, sold by the plan;

(iii) Any other owner of the asset, if the plan is not the sole owner;

(iv) a fiduciary of the plan (except to the extent the appraiser becomes a fiduciary when retained to perform this appraisal for the plan);

(v) a party in interest with respect to the plan (except to the extent the appraiser becomes a party in interest when retained to perform this appraisal for the plan); or

(vi) the VFC Program applicant.

(5) a commercial lender is ''independent'' if it is not one of the following, does not own or control any of the following, and is not owned or controlled by, or affiliated with any of the following:

(i) a person or entity who was involved in securing or maintaining the loan, or in determining or modifying the terms of the loan at any time during the life of the loan;

(ii) a fiduciary of the plan (except to the extent the commercial lender becomes a fiduciary when retained to provide this service for the plan);

(iii) a party in interest with respect to the plan (except to the extent the commercial lender becomes a party in interest when retained to provide this service for the plan); or

(iv) the VFC Program applicant.

(b) *Correction Amount.* (1) *In general.* For purposes of the VFC Program, the correction amount is the amount that must be paid to the plan as a result of the Breach in order to make the plan whole. In most instances, the correction amount will be a combination of the Principal Amount involved in the transaction (*see* paragraph (b)(2) of this section), the Lost Earnings amount, which is earnings that would have been earned on the Principal Amount for the period of the transaction (*see* paragraph (b)(6) of this section, and *also see* paragraph (b)(3) of this section for a special rule for Loss Date under the SCC), and any interest on Lost Earnings. However, in circumstances when the Restoration of Profits amount (*see* paragraph (b)(7) of this section) exceeds the Lost Earnings amount and any interest on Lost Earnings, the correction amount will be a combination of the Principal Amount and the Restoration of Profits amount. The responsible fiduciary, plan sponsor or other Plan Official, must pay the correction amount and any costs of correction. No part of the correction amount or costs of correction can be paid from plan assets, including charges against participant accounts or plan forfeiture accounts.

(2) *Principal Amount.* ''Principal Amount'' is the amount that would have been available to the plan for investment or distribution on the date of the Breach, had the Breach not occurred. The Principal Amount, when applicable, must be determined for each transaction by reference to section 7 of the VFC Program. Generally, the Principal Amount is the base amount on which Lost Earnings and, if applicable, Restoration of Profits is calculated. The Principal Amount shall include any transaction costs associated with entering into the transaction that constitutes the Breach, which were paid by the plan.

(3) *Loss Date. (i) In general* ''Loss Date'' is the date that the plan lost the use of the Principal Amount.

(ii) Special rule under the SCC. ''Loss Date'' is the Date of Withholding or Receipt.

(4) *Date of Withholding or Receipt.* ''Date of Withholding or Receipt'' is the date the amount would otherwise have been payable to the participant in cash in the case of amounts withheld by an employer from a participant's wages, or the day on which the participant contribution or loan payment is received by the employer in the case of amounts that a participant or beneficiary pays to an employer. Date of Withholding or Receipt is not the same date as the date on which contributions

or loan repayments could reasonably have been segregated from the employer general assets.

Example 1. An employer pays its employees' wages on the 1st and the 15th of each month. Participant contributions to a pension plan are withheld from employees' wages on these dates. The employer determined that it could reasonably take two business days to segregate these withholdings from its general assets for transmittal to the plan. The ''Date of Withholding or Receipt'' is the 1st and 15th of each month. For purposes of a Program application to correct delinquent participant contributions, without taking into account any non-business days, the ''Loss Date'' would be the 3rd and 17th of each month.

Example 2. Assuming the same facts as Example 1, except the delinquent participant contributions are being corrected using the SC Component. The ''Date of Withholding or Receipt'' is the 1st and 15th of each month. For purposes of using the SCC to correct delinquent participant contributions, the ''Loss Date'' would be the 1st and 15th of each month.

(5) *Recovery Date.* ''Recovery Date'' is the date that the Principal Amount is restored to the plan.

(6) *Lost Earnings.* (i) *General.* ''Lost Earnings'' is intended to approximate the amount that would have been earned by the plan on the Principal Amount, but for the Breach. For purposes of this Program, Lost Earnings shall be calculated in accordance with this paragraph.

(ii) *Initial Calculation.* Lost Earnings shall be calculated by: (A) determining the applicable corporate underpayment rate(s) established under section 6621(a)(2) of the Code [62] for each quarter (or portion thereof) for the period beginning with the Loss Date and ending with the Recovery Date; (B) determining, by reference to IRS Revenue Procedure 95–17,[63] the applicable factor(s) for such quarterly underpayment rate(s) for each quarter (or portion thereof) of the period beginning with the Loss Date and ending with the Recovery Date; and (C) multiplying the Principal Amount by the first applicable factor to determine the amount of earnings for the first quarter (or portion thereof). If the Loss Date and Recovery Date are within the same quarter, the initial calculation is complete. If the Recovery Date is not in the same quarter as the Loss Date, the applicable factor for each subsequent quarter (or portion thereof) must be applied to the sum of the Principal Amount and all earnings as of the end of the immediately preceding quarter (or portion thereof), until Lost Earnings have been calculated for the entire period, ending with the Recovery Date.

(iii) *Payment of Lost Earnings after Recovery Date.* If Lost Earnings are not paid to the plan on the Recovery Date along with the Principal Amount, payment of Lost Earnings shall include interest on the amount of Lost Earnings. Such interest shall be calculated in the same manner as Lost Earnings described in paragraph (b)(6)(ii) above, for the period beginning on the Recovery Date and ending on the date the Lost Earnings are paid to the plan.

(iv) *Special Rule for Transactions Causing Large Losses.* If the amount of Lost Earnings (determined in accordance with paragraph (b)(6)(ii) above) and any interest added to such Lost Earnings (determined in accordance with paragraph (b)(6)(iii) above), exceed $100,000, the amount of Lost Earnings and interest, if any, to be paid to the plan shall be determined in accordance with paragraphs (b)(6)(ii) and (iii) above, substituting the applicable underpayment rates under section 6621(c)(1) of the Code [64] in lieu of the rates under section 6621(a)(2).

(v) *Method of Calculation for VFC Program Applications.* For purposes of calculating Lost Earnings and interest, if any, a Plan Official may either (A) use the Online Calculator described in paragraph (b)(8) below, or (B) perform a manual calculation in accordance with subparagraphs (i) through (iv) of this paragraph (b)(6). A Plan Official using the Online Calculator or performing a manual calculation shall include as part of the VFC Program application sufficient information to verify the correctness of the amounts to be paid to the plan.

(vi) *Method of Calculation under the SCC.* For purposes of calculating Lost Earnings and interest, if any, the self-corrector must use the Online Calculator described in paragraph (b)(8) below.

(7) *Restoration of Profits.* (i) *General.* If the Principal Amount was used for a specific purpose such that a profit on the use of the Principal Amount is determinable, the Plan Official must calculate the Restoration of Profits amount and compare it to the Lost Earnings amount to determine the correction amount (*see* paragraph (b)(1) of this section). If the Restoration of Profits amount exceeds Lost Earnings and interest, if any, the Restoration of Profits amount must be paid to the plan instead of Lost Earnings. ''Restoration of Profits'' is a combination of two amounts: (A) the amount of profit made on the use of the Principal Amount by the fiduciary or party in interest who engaged in the Breach, or by a person who knowingly participated in the Breach, and (B) if the profit is returned to the plan on a date later than the date on which the profit was realized (*i.e.,* received or determined), the amount of interest earned on such profit from the date the profit was realized to the date on which the profit is paid to the plan. The amount of such interest shall be determined in accordance with paragraph (b)(7)(ii) below. There is no requirement to calculate a Restoration of Profits amount for corrections of delinquent participant contributions including loan repayments, if any, under section 7.1 of the Program.

(ii) *Calculation of Interest.* Interest shall be calculated by: (A) determining the applicable corporate underpayment rate(s) established under section 6621(a)(2) of the Code for each quarter (or portion thereof) for the period beginning with the date the profit was realized (*i.e.,* received or determined) and ending with the date on which the profit is paid to the plan; (B) determining, by reference to IRS Revenue Procedure 95–17, the applicable factor(s) for such quarterly underpayment rate(s) for each quarter (or portion thereof) of the period beginning with the date the profit was realized and ending with the date on which the profit is paid to the plan; and (C) multiplying the first applicable factor by the profit on the Principal Amount, referred to in paragraph (b)(7)(i)(A) above, to determine the amount of interest for the first quarter (or portion thereof). If the date the profit was realized and the date the profit is paid to the plan are within the same quarter, the initial calculation is complete. If the date the profit was realized is not in the same quarter as the date the profit was paid to the plan, the applicable factor for each subsequent quarter (or portion thereof) must be applied to the sum of the profit on the Principal Amount, referred to in paragraph (b)(7)(i)(A) above, and all interest as of the end of the immediately preceding quarter (or portion thereof), until interest has been calculated for the entire period, ending with the date the profit is paid to the plan.

[62] These underpayment rates are displayed on EBSA's website and will be updated when necessary.

[63] Rev. Proc. 95–17, 1995–1 C.B. 556 (Feb. 8, 1995). These factors, which are displayed on EBSA's website in a tabular format, incorporate daily compounding of an interest rate over a set period of time.

[64] These underpayment rates are displayed on EBSA's website and will be updated when necessary.

(iii) *Special Rule for Transactions Resulting in Large Restorations.* If the amount of Restoration of Profits (determined in accordance with paragraph (b)(7)(i) above) exceeds $100,000, the amount of any interest on the Restoration of Profits to be paid to the plan shall be determined in accordance with paragraph (b)(7)(ii), above, substituting the applicable underpayment rates under section 6621(c)(1) of the Code in lieu of the rates under section 6621(a)(2).

(iv) *Method of Calculation for VFC Program Applications.* For purposes of calculating the interest amount for Restoration of Profits, pursuant to paragraphs (b)(7)(ii) and (iii) above, a Plan Official may either (A) use the Online Calculator described in paragraph (b)(8) below, or (B) perform a manual calculation in accordance with subparagraphs (ii) and (iii) of this paragraph (b)(7). A Plan Official using the Online Calculator or performing a manual calculation shall include as part of the VFC Program application sufficient information to verify the correctness of the amounts to be paid to the plan.

(8) *Online Calculator.* ''Online Calculator'' is an internet based compliance assistance tool provided on EBSA's website that permits applicants and self-correctors to calculate the amount of Lost Earnings, any interest on Lost Earnings, and the interest amount for Restoration of Profits, if applicable, for certain transactions. The Online Calculator will be updated as necessary.

(i) *Lost Earnings and Interest.* To calculate Lost Earnings, applicants or self-correctors must input the (A) Principal Amount, (B) Loss Date, (C) Recovery Date, and, if the final payment will occur after the Recovery Date, (D) the date of such final payment. The Online Calculator selects the applicable factors under Revenue Procedure 95–17 after referencing the underpayment rates over the relevant time period. The Online Calculator then automatically applies the factors to provide applicants and self-correctors with the amount of Lost Earnings and interest, if any, that must be paid to the plan.

(ii) *Interest Amount for Restoration of Profits.* To calculate the interest amount on the profit, applicants must input (A) the amount of profit, (B) the date the amount of profit was realized (*i.e.* received or determined), and (C) the date of payment of the Restoration of Profits amount. The Online Calculator selects the applicable factors under Revenue Procedure 95–17 after referencing the underpayment rates over the relevant time period. The Online Calculator then automatically applies the factors to provide applicants with the interest amount on the profit that must be paid to the plan.

(9) The principles of paragraph (b) of this section are illustrated by example in Appendix D.

(c) *Costs of Correction.* (1) The fiduciary, plan sponsor or other Plan Official, must pay the costs of correction. The costs of correction cannot be paid from plan assets, including charges against participant accounts or plan forfeiture accounts.

(2) The costs of correction include, where appropriate, such expenses as closing costs, prepayment penalties, or sale or purchase costs associated with correcting the transaction.

(3) The principle of paragraph (c)(1) of this section is illustrated in the following example and in paragraph (d) below:

Example. The plan fiduciaries did not obtain a required independent appraisal in connection with a transaction described in section 7. In connection with correcting the transaction, the plan fiduciaries now propose to have the appraisal performed as of the date of purchase. The plan document permits the plan to pay reasonable and necessary expenses; the fiduciaries have objectively determined that the cost of the proposed appraisal is reasonable and is not more expensive than the cost of an appraisal contemporaneous with the purchase. The plan may therefore pay for this appraisal. However, the plan may not pay any costs associated with recalculating participant account balances to take into account the new valuation. There would be no need for these additional calculations or any increased appraisal cost if the plan's assets had been valued properly at the time of the purchase. Therefore, the cost of recalculating the plan participants' account balances is not a reasonable plan expense but is part of the costs of correction.

(d) *Distributions.* Plans will have to make supplemental distributions to former employees, beneficiaries receiving benefits, or alternate payees, if the original distributions were too low because of the Breach. In these situations, the Plan Official or plan administrator must determine who received distributions from the plan during the time period affected by the Breach, recalculate the account balances, and determine the amount of the underpayment to each affected individual. The applicant must demonstrate proof of payment to participants and beneficiaries whose current location is known to the plan and/or applicant. For individuals whose location is unknown, applicants must demonstrate that they have segregated adequate funds to pay the missing individuals and that the applicant has commenced the process of locating the missing individuals using methods involving nominal expense such as certified mail and electronic search technologies as well as checking related plan records and with any designated plan beneficiary. If these methods are unsuccessful, the applicant should consider the use of commercial locator services, credit reporting agencies, information brokers and investigation databases as well as analogous computer services depending on the amount of underpayment in relation to the cost of the services. The costs of such efforts are part of the costs of correction. See Missing Participants—Best Practices for Pension Plans for more information on fiduciary best practices that, based on EBSA's experience working with plans have proven effective at minimizing and mitigating the problem of missing or nonresponsive participants (available at *www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/retirement/missing-participants-guidance*).

(e) *De Minimis Exception.* Where correction under the Program requires distributions in amounts less than $35 to former employees, their beneficiaries and alternate payees, who neither have account balances with, nor have a right to future benefits from the plan, and the applicant demonstrates in its submission that the cost of making the distribution to each such individual exceeds the amount of the payment to which such individual is entitled in connection with the correction of the transaction that is the subject of the application, the applicant need not make distributions to such individuals who would receive less than $35 each as part of the correction. However, the applicant must pay to the plan as a whole the total of such de minimis amounts not distributed to such individuals.

Example. Employer X sponsors Plan Y. Employer X submits an application under the VFC Program to correct a failure to timely forward participant contributions to Plan Y. Employer X had paid the delinquent contributions six months late but had not paid Lost Earnings on the delinquency. The correction under the VFC Program, therefore, required only payment of Lost Earnings for the six-month delinquency. During the six-month period 25 employees separated from service and rolled over their plan accounts to individual retirement accounts. The amount of Lost Earnings due to 20 of those former employees is less than $35,

and Employer X demonstrates that the cost of making the distribution to those former employees is $42 per individual. Employer X need not make distributions to those 20 former employees. However, the total amount of distributions that would have been due to those former employees must be paid to Plan Y. The payment to Plan Y may be used for any purpose that payments or credits, which are not allocated directly to participant accounts, are used.[65] Employer X must make distributions to the five former employees who are entitled to receive distributions of more than $35.

Section 6. VFC Program Application and Self-Correction Component Procedures

6.1 VFC Program Application Procedures

(a) *In general.* Each application must adhere to the requirements set forth below. Failure to do so may render the application invalid.

(b) *Applicant.* The application must be prepared by a Plan Official or an authorized representative (*e.g.,* attorney, accountant, or other service provider). If a representative of the Plan Official is submitting the application, the application must include a statement signed by the Plan Official that the representative is authorized to represent the Plan Official. Any fees paid to such representative for services relating to the preparation and submission of the application may not be paid from plan assets, including charges to participants accounts or plan forfeiture accounts.

(c) *Contact person.* Each application must include the name, address (street and email) and telephone number of a contact person. The contact person must be familiar with the contents of the application and have authority to respond to inquiries from EBSA.

(d) *Detailed narrative.* The applicant must provide to EBSA a detailed narrative describing the Breach and the corrective action. The narrative must include:

(1) a list of all persons materially involved in the Breach and its correction (*e.g.,* fiduciaries, service providers, borrowers);

(2) the plan sponsor's nine-digit number (EIN), plan number, and address of the plan sponsor and administrator;

(3) the date the plan's most recent Form 5500 was filed; or, in the case of a bulk VFC Program application, for each plan named in the application, either the date the most recent Form 5500 was filed or the plan sponsor's nine-digit number (EIN);

(4) an explanation of the Breach, including the date it occurred;

(5) an explanation of how the Breach was corrected, by whom and when; and

(6)(i) if the applicant performs a manual calculation in accordance with paragraphs (b)(6)(i) through (iv) of section 5 or paragraphs (b)(7)(i) through (iii), specific calculations demonstrating how Principal Amount and Lost Earnings or, if applicable, Restoration of Profits were computed;

(ii) if the applicant uses the Online Calculator in accordance with paragraph (b)(8) of section 5, the data elements required to be input into the Online Calculator under paragraphs (b)(8)(i) and/or (ii) of section 5, as applicable (to satisfy this requirement, applicants may submit a copy of the page(s) that results from the ''*View Printable Results*'' function used after inputting data elements and completing use of the Online Calculator); and

(iii) an explanation of why payment of Lost Earnings or Restoration of Profits was chosen to correct the Breach.

(e) *Supporting documentation.* The applicant must also include:

(1) copies of the relevant portions of the plan document and any other pertinent documents (such as the adoption agreement, trust agreement, or insurance contract);[66]

(2) documentation that supports the narrative description of the transaction and its correction;

(3) documentation establishing the Lost Earnings amount;

(4) documentation establishing the amount of Restoration of Profits, if applicable;

(5) all documents described in section 7 with respect to the transaction involved; and

(6) proof of payment of Principal Amount and Lost Earnings or Restoration of Profits.

Applicants using the Online Calculator may satisfy the requirements of paragraph (e)(3) above, with respect to Lost Earnings, and paragraph (e)(4) above, as to the amount of interest, if any, payable with respect to the profit amount, by complying with the requirements of paragraph (d)(6)(ii) of this section. Except for proof of payment, as described in paragraph (e)(6) above, applicants correcting participant loan transactions in section 7.3 are not required to submit the other documentation described above unless requested by EBSA.

(f) *Examples of supporting documentation.* (1) Examples of documentation supporting the description of the transaction and correction are leases, appraisals, notes and loan documents, service provider contracts, invoices, settlement documents, deeds, perfected security interests, and amended annual reports.

(2) Examples of acceptable proof of payment include copies of canceled checks, executed wire transfers, a signed, dated receipt from the recipient of funds transferred to the plan (such as a financial institution), and bank statements for the plan's account.

(g) *Penalty of Perjury Statement.* Each application must include the following statement: ''Under penalties of perjury I certify that I am not Under Investigation (as defined in section 3(b)(3) of the VFC Program) and that I have reviewed this application, including all supporting documentation, and to the best of my knowledge and belief the contents are true, correct, and complete.''

(1) Applicants in general. The Penalty of Perjury Statement must be signed and dated by a plan fiduciary with knowledge of the transaction that is the subject of the application and the authorized representative of the applicant, if any. In addition, each Plan Official applying under the VFC Program must sign and date the Penalty of Perjury Statement. The statement must accompany the application and any subsequent additions to the application. Use of the Penalty of Perjury Statement included with the Model Application Form in Appendix E will satisfy the requirements of paragraph (g) of this section.

(2) Bulk Applicants. The Penalty of Perjury Statement must be signed and dated by the bulk applicant with knowledge of the transaction that is the subject of the application and the authorized representative of the bulk applicant, if any. The statement must accompany the application and any subsequent additions to the application. Use of the Penalty of Perjury Statement included with the Model Application Form in Appendix E will satisfy the requirements of paragraph (g) of this section.

(h) *Checklist.* The checklist in Appendix B must be completed, signed,

[65] For example, the Department has taken the position that where a plan document is silent as to the payment of reasonable administrative expenses, the plan may pay reasonable administrative expenses. Where a plan document provides that the employer will pay any such expenses, and if the employer has reserved the right to amend the plan document, ERISA would not prevent the employer from amending the plan to require, prospectively, that the relevant expenses be paid by the plan. The Department does not believe that ERISA would permit a fiduciary to implement a plan amendment that attempted to retroactively relieve the employer of an obligation to pay plan expenses.

[66] Applicants must supply complete copies of the plan documents and other pertinent documents if requested by EBSA during its review of the application.

dated and submitted with the application. Use of the checklist included with the Model Application Form in Appendix E also will satisfy the requirements of paragraph (h) of this section.

(i) *Where to apply.* The application shall be submitted to the appropriate EBSA Regional Office listed in Appendix C. Applicants should check with the relevant EBSA Regional Office whether the office accepts email submissions of applications and supporting documentation.

(j) *Submission of Additional Documentation.* If EBSA determines that required information is missing from the application or that additional documentation is needed to complete EBSA's review, EBSA will request such documentation in writing from the applicant or authorized representative. If EBSA does not receive the requested documentation within a time period specified in writing by the EBSA reviewer, EBSA may suspend its review of the application and consider appropriate action. EBSA will notify the applicant or authorized representative in writing regarding such suspension. If EBSA does not receive the requested documentation within a reasonable time after providing notice of the suspension, EBSA will issue a rejection letter.

(k) *Recordkeeping.* The applicant must maintain copies of the application and any subsequent correspondence with EBSA for the period required by section 107 of ERISA.

6.2 VFC Program Self-Correction Component Procedures

(a) In general. Each self-corrector must adhere to the requirements set forth below. Failure to do so may render the self-correction invalid.

(b) Self-corrector. The SCC notice must be submitted by the self-corrector who is a Plan Official or an authorized representative (*e.g.,* attorney, accountant, or other service provider). If a representative of the Plan Official is submitting the SCC notice, the plan administrator must retain a statement signed by the Plan Official that the representative is authorized to represent the Plan Official. Use of the model authorization included in the SCC Retention Record Checklist in Appendix F will satisfy this requirement. Any fees paid to such representative for services relating to the correction under the SCC may not be paid from plan assets.

(c) Submission of SCC notice. The self-corrector must notify EBSA of participation in the SC Component by submitting the SCC notice through the online VFC Program web tool in accordance with paragraph 7.1(b)(2)(iii).[67] EBSA will acknowledge receipt of a properly completed and submitted SCC notice in an email addressed to the self-corrector.

(d) SCC Retention Record Checklist. The self-corrector must complete the SCC Retention Record Checklist in Appendix F, prepare or collect the documents listed in this Appendix, and provide copies of the completed checklist and required documentation to the plan administrator.

(e) Penalty of Perjury Statement. The plan administrator must retain the following statement: ''Under penalties of perjury I certify that I am not Under Investigation (as defined in section 3(b)(3) of the VFC Program) and that I have reviewed the SCC notice acknowledgment and summary, the checklist, and all the required documentation, and to the best of my knowledge and belief the contents are true, correct, and complete.'' The statement must be signed and dated by a plan fiduciary with knowledge of the transaction that is the subject of the self-correction and the authorized representative of the plan sponsor, if any. In addition, each Plan Official who is seeking the relief afforded under the Program must sign and date the Penalty of Perjury Statement. Use of the Penalty of Perjury Statement included in Appendix F will satisfy the requirements of paragraph (e) of this section.

(f) Recordkeeping. The plan administrator must retain a copy of the SCC Retention Record Checklist in Appendix F along with copies of the required documentation, the authorization form, if any, and a signed Penalty of Perjury Statement, for the period required by section 107 of ERISA.

Section 7. Description of Eligible Transactions and Corrections Under the VFC Program

EBSA has identified certain Breaches and methods of correction that are suitable for the VFC Program. Any Plan Official may correct a Breach listed in this section in accordance with section 5 and the applicable correction method. The correction methods set forth are strictly construed and are the only acceptable correction methods under the VFC Program and the SC Component for the identified transactions described in this section.

[67] The online VFC Program web tool will be located on EBSA's website.

7.1 Delinquent Remittance of Funds

(a) Delinquent Participant Contributions and Loan Repayments to Pension Plans under VFC Program Applications

(1) *Description of Transaction.* An employer receives directly from participants, or withholds from employees' paychecks, certain amounts for either participants' contribution to a pension plan or for repayment of participants' plan loans. Instead of forwarding such contributions or loan repayments to the plan for investment in accordance with the provisions of the plan and by reference to the principles of the Department's regulation at 29 CFR 2510.3–102, the employer retains such amounts for a longer period of time.

(2) *Correction of Transaction.* (i) *Unpaid Participant Contributions or Loan Repayments.* Pay to the plan the Principal Amount plus Lost Earnings on the Principal Amount as described in section 5(b). The Loss Date for such contributions or repayments is the date on which each contribution reasonably could have been segregated from the employer's general assets. In no event shall the Loss Date for such contributions or repayments be later than the applicable maximum time period described in 29 CFR 2510.3–102.[68] Any penalties, late fees or other charges shall be paid by the employer and not from such contributions or loan repayments.

(ii) *Late Participant Contributions or Loan Repayments.* If participant contributions or loan repayments were remitted to the plan outside of the time periods described above, the only correction required is to pay to the plan Lost Earnings as described in section 5(b). Any penalties, late fees or other charges shall be paid by the employer and not from participant contributions or loan repayments.

(iii) For this transaction, the Principal Amount is the amount of delinquent participant contributions or loan repayments retained by the employer.

(iv) *Example.* The principles of paragraph (a)(2) of this section are illustrated by example in Appendix D.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A statement from a Plan Official identifying the earliest date on which the participant contributions and/or repayments reasonably could have been

[68] The Department amended paragraph (a)(1) of 29 CFR 2510.3–102 to extend the application of the regulation to amounts paid by a participant or beneficiary or withheld by an employer from a participant's wages for purposes of repaying a participant's loan (regardless of plan size). 75 FR 2068 (2010).

segregated from the employer's general assets, along with the supporting documentation on which the Plan Official relied in reaching this conclusion;

(ii) If restored participant contributions and/or repayments (exclusive of Lost Earnings) either total $50,000 or less, or exceed $50,000 and were remitted to the plan within 180 calendar days from the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) A narrative describing the applicant's contribution and/or repayment remittance practices before and after the period of unpaid or late contributions and/or repayments including any steps taken to prevent future delinquencies, and

(B) Summary documents demonstrating the amount of unpaid or late contributions and/or repayments; and

(iii) If restored participant contributions and/or repayments (exclusive of Lost Earnings) exceed $50,000 and were remitted to the plan more than 180 calendar days after the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) A narrative describing the applicant's contribution and/or repayment remittance practices before and after the period of unpaid or late contributions and/or repayments including any steps taken to prevent future delinquencies;

(B) For participant contributions and/or repayments received from participants, a copy of the accounting records which identify the date and amount of each contribution received; and

(C) For participant contributions and/or repayments withheld from employees' paychecks, a copy of the payroll documents showing the date and amount of each withholding.

(b) Delinquent Participant Contributions and Loan Repayments to Pension Plans under the Self-Correction Component

(1) *Description of Transaction.* (i) An employer receives directly from participants, or withholds from employees' paychecks, certain amounts for either participants' contribution to a pension plan or for repayment of participants' plan loans. Instead of forwarding such contributions or loan repayments to the plan for investment in accordance with the provisions of the plan and by reference to the principles of the Department's regulation at 29 CFR 2510.3–102, the employer retains such amounts for a longer period of time. [69]

(ii) For this transaction: (A) the amount of Lost Earnings resulting from the correction of the delinquent participant contributions or loan repayments is less than or equal to $1,000, excluding any excise tax amounts paid to the plan under the related class exemption PTE 2002–51; and

(B) the delinquent participant contributions or loan repayments were remitted to the plan within 180 calendar days from the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks).

(2) *Correction of Transaction.* (i) *Unpaid Participant Contributions or Loan Repayments.* Pay to the plan the Principal Amount plus Lost Earnings on the Principal Amount as described in section (5)(b). The Loss Date for such contributions or repayments is the Date of Withholding or Receipt in accordance with section 5(b)(3)(ii). All calculations must be made using the Online Calculator in accordance with section 5(b)(6)(vi). Any penalties, late fees or other charges shall be paid by the employer and not from participant contributions or loan repayments.

(ii) *Principal Amount.* For this transaction, the Principal Amount is the amount of delinquent participant contributions or loan repayments retained by the employer.

(iii) *SCC Notice.* The self-corrector must input the required information in the fields provided in the SCC notice and submit the notice to EBSA through the online VFC Program web tool.[70] The required information includes certain data elements listed below:

(A) name and email address of the self-corrector;

(B) plan name;

(C) plan sponsor's nine-digit number (EIN) and the plan's three-digit number (PN);

(D) Principal Amount;

(E) amount of Lost Earnings and the date paid to the plan;

(F) Loss Date (Date(s) of Withholding or Receipt); and

(G) number of participants affected by the correction.

(3) *Documentation.* The self-corrector must complete the SCC Retention Record Checklist in Appendix F, prepare or collect the documents listed in this Appendix, and provide copies of the completed checklist and required documentation to the plan administrator.

(c) Delinquent Participant Contributions to Insured Welfare Plans

(1) *Description of Transaction.* Benefits are provided exclusively through insurance contracts issued by an insurance company or similar organization licensed to do business in any state or through a health maintenance organization (HMO) defined in section 1310(c) of the Public Health Service Act, 42 U.S.C. 300e–9(c). An employer receives directly from participants or withholds from employees' paychecks certain amounts that the employer forwards to an insurance provider for the purpose of providing group health or other welfare benefits. The employer fails to forward such amounts in accordance with the terms of the plan (including the provisions of any insurance contract) or the requirements of the Department's regulation at 29 CFR 2510.3–102. There are no instances in which claims have been denied under the plan, nor has there been any lapse in coverage, due to the failure to transmit participant contributions on a timely basis.

(2) *Correction of Transaction.* (i) Pay to the insurance provider or HMO the Principal Amount, as well as any penalties, late fees, or other charges necessary to prevent a lapse in coverage due to such failure. Any penalties, late fees or other such charges shall be paid by the employer and not from participant contributions.

(ii) For this transaction, the Principal Amount is the amount of delinquent participant contributions retained by the employer.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A statement from a Plan Official: (A) identifying the earliest date on which the participant contributions reasonably could have been segregated from the employer's general assets, along with the supporting documentation on which the Plan Official relied in reaching this conclusion; (B) attesting that there are no instances in which claims have been denied under the plan for nonpayment, nor has there been any lapse in coverage; and (C) attesting that any penalties, late fees or other such charges have been paid by the employer and not from participant contributions;

[69] *See* 29 CFR 2510.3–102(a)(2), 75 FR 2068 (2010).

[70] The online VFC Program web tool will be located on EBSA's website.

(ii) Copies of the insurance contract or contracts for the group health or other welfare benefits for the plan;

(iii) If restored participant contributions either total $50,000 or less, or exceed $50,000 and were remitted to the insurance provider within 180 calendar days from the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) a narrative describing the applicant's contribution practices before and after the period of unpaid or late contributions, and

(B) summary documents demonstrating the amount of unpaid or late contributions; and

(iv) If restored participant contributions exceed $50,000 and were remitted to the insurance provider more than 180 calendar days after the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) a narrative describing the applicant's contribution remittance practices before and after the period of unpaid or late contributions including any steps taken to prevent future delinquencies,

(B) for participant contributions received directly from participants, a copy of the accounting records which identify the date and amount of each contribution received, and

(C) for participant contributions withheld from employees' paychecks, a copy of the payroll documents showing the date and amount of each withholding.

(d) Delinquent Participant Contributions to Welfare Plan Trusts

(1) *Description of Transaction.* An employer receives directly from participants or withholds from employees' paychecks certain amounts that the employer forwards to a trust maintained to provide, through insurance or otherwise, group health or other welfare benefits. The employer fails to forward such amounts in accordance with the terms of the plan or the requirements of the Department's regulation at 29 CFR 2510.3–102. There are no instances in which claims have been denied under the plan, nor has there been any lapse in coverage, due to the failure to transmit participant contributions on a timely basis.

(2) *Correction of Transaction.* (i) *Unpaid Contributions.* Pay to the trust (A) the Principal Amount, and, where applicable, any penalties, late fees, or other charges necessary to prevent a lapse in coverage due to the failure to make timely payments, and (B) Lost Earnings on the Principal Amount as described in section 5(b). The Loss Date for such contributions is the date on which each contribution would become plan assets under 29 CFR 2510.3–102. Any penalties, late fees or other charges shall be paid by the employer and not from participant contributions.

(ii) *Late Contributions.* If participant contributions were remitted to the trust outside of the time period required by the regulation, the only correction required is to pay to the trust the Lost Earnings as described in section 5(b). Any penalties, late fees or other such charges shall be paid by the employer and not from participant contributions.

(iii) For this transaction, the Principal Amount is the amount of delinquent participant contributions retained by the employer.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A statement from a Plan Official: (A) identifying the earliest date on which the participant contributions reasonably could have been segregated from the employer's general assets, along with the supporting documentation on which the Plan Official relied in reaching this conclusion, and (B) attesting that there are no instances in which claims have been denied under the plan for nonpayment, nor has there been any lapse in coverage;

(ii) If restored participant contributions (exclusive of Lost Earnings) either total $50,000 or less, or exceed $50,000 and were remitted to the trust within 180 calendar days from the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) a narrative describing the applicant's contribution practices before and after the period of unpaid or late contributions including any steps taken to prevent future delinquencies, and

(B) summary documents demonstrating the amount of unpaid or late contributions; and

(iii) If restored participant contributions (exclusive of Lost Earnings) exceed $50,000 and were remitted to the trust more than 180 calendar days after the date such amounts were received by the employer, or the date such amounts otherwise would have been payable to the participants in cash (regarding amounts withheld by an employer from employees' paychecks), submit:

(A) a narrative describing the applicant's contribution remittance practices before and after the period of unpaid or late contributions,

(B) for participant contributions received directly from participants, a copy of the accounting records which identify the date and amount of each contribution received, and

(C) for participant contributions withheld from employees' paychecks, a copy of the payroll documents showing the date and amount of each withholding.

7.2 Loans

(a) Loan at Fair Market Interest Rate to a Party in Interest With Respect to the Plan

(1) *Description of Transaction.* A plan made a loan to a party in interest at an interest rate no less than that for loans with similar terms (for example, the amount of the loan, amount and type of security, repayment schedule, and duration of loan) to a borrower of similar creditworthiness. The loan was not exempt from the prohibited transaction provisions of Title I of ERISA.

(2) *Correction of Transaction.* Pay off the loan in full, including any prepayment penalties. An independent commercial lender must also confirm in writing that the loan was made at a fair market interest rate for a loan with similar terms to a borrower of similar creditworthiness.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit a narrative describing the process used to determine the fair market interest rate at the time the loan was made, validated in writing by an independent commercial lender.

(b) Loan at Below-Market Interest Rate to a Party in Interest With Respect to the Plan

(1) *Description of Transaction.* A plan made a loan to a party in interest with respect to the plan at an interest rate that, at the time the loan was made, was less than the fair market interest rate for loans with similar terms (for example, the amount of loan, amount and type of security, repayment schedule, and duration of the loan) to a borrower of similar creditworthiness. The loan was not exempt from the prohibited transaction provisions of Title I of ERISA.

(2) *Correction of Transaction.* (i) Pay off the loan in full, including any prepayment penalties. Pay to the plan the Principal Amount, plus the greater of (A) the Lost Earnings as described in

section 5(b), or (B) the Restoration of Profits, if any, as described in section 5(b).

(ii) For purposes of this transaction, each loan payment has a Principal Amount equal to the excess of the loan payment that would have been received if the loan had been made at the fair market interest rate (from the beginning of the loan until the Recovery Date) over the loan payment actually received under the loan terms during such period. Under the VFC Program, the fair market interest rate must be determined by an independent commercial lender.

Example. The plan made to a party in interest a $150,000 mortgage loan, secured by a first Deed of Trust, at a fixed interest rate of 4% per annum. The loan was to be fully amortized over 30 years. The fair market interest rate for comparable loans, at the time this loan was made, was 7% per annum. The party in interest or Plan Official must repay the loan in full plus any applicable prepayment penalties. The party in interest or Plan Official also must pay the difference between what the plan would have received through the Recovery Date had the loan been made at 7% and what, in fact, the plan did receive from the commencement of the loan to the Recovery Date, plus Lost Earnings on that amount as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A narrative describing the process used to determine the interest rate at the time the loan was made;

(ii) A copy of the independent commercial lender's fair market interest rate determination(s); and

(iii) A copy of the independent fiduciary's dated, written approval of the fair market interest rate determination(s), except for below-market interest rate loans of $10,000 or less.

(c) Loan at Below-Market Interest Rate to a Person Who Is Not a Party in Interest With Respect to the Plan

(1) *Description of Transaction.* A plan made a loan to a person who is not a party in interest with respect to the plan at an interest rate which, at the time the loan was made, was less than the fair market interest rate for loans with similar terms (for example, the amount of loan, amount and type of security, repayment schedule, and duration of the loan) to a borrower of similar creditworthiness.

(2) *Correction of Transaction.* (i) Pay to the plan the Principal Amounts from the inception of the loan until the Recovery Date, plus Lost Earnings on the series of Principal Amounts through the Recovery Date, as described in section 5(b).

(ii) In addition, the applicant or other party must pay to the plan the present value of the Principal Amounts from the Recovery Date to the maturity date of the loan, as determined by an independent commercial lender. The borrower must continue to pay to the plan the outstanding loan balance according to the repayment schedule for the duration of the loan. Alternatively, instead of the applicant or other party paying the present value of the Principal Amounts, the borrower may pay to the plan the outstanding loan balance amortized over the remaining payment schedule for the duration of the loan at the interest rate that would have been applicable if the loan had been made at the fair market interest rate.

(iii) For purposes of this transaction, each loan payment has a Principal Amount equal to the excess of the loan payment that would have been received if the loan had been made at the fair market interest rate (from the inception of the loan until the Recovery Date) over the loan payment actually received under the loan terms during such period. Under the VFC Program, the fair market interest rate must be determined by an independent commercial lender.

(iv) The principles of paragraph (c)(2) of this section are illustrated in the following example:

Example. The plan made a $150,000 mortgage loan, secured by a first Deed of Trust, at a fixed interest rate of 4% per annum. The loan was to be fully amortized over 30 years. The fair market interest rate for comparable loans, at the time this loan was made, was 7% per annum. The applicant or other person must pay the excess of what the plan would have received through the Recovery Date had the loan been made at 7% over what, in fact, the plan did receive from the commencement of the loan to the Recovery Date (the Principal Amounts from the loan's inception until the Recovery Date), plus Lost Earnings on that amount as described in section 5(b). The applicant must also pay on the Recovery Date the present value of the difference of what the plan would have received between the 7% and the 4% interest rate for the remaining payments on the loan for the duration of the time the plan is owed repayments on the loan (the Principal Amounts from the Recovery Date until the loan's maturity date). The borrower must continue to repay the outstanding loan balance based on the loan's repayment schedule.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A narrative describing the process used to determine the interest rate at the time the loan was made;

(ii) A copy of the independent commercial lender's fair market interest rate determination(s); and

(iii) If applicable, a copy of the loan repayment schedule for the re-amortized loan repayments.

(d) Loan at Below-Market Interest Rate Solely Due to a Delay in Perfecting the Plan's Security Interest

(1) *Description of Transaction.* For purposes of the VFC Program, if a plan made a purportedly secured loan to a person who is not a party in interest with respect to the plan, but there was a delay in recording or otherwise perfecting the plan's interest in the loan collateral, the loan will be treated as an unsecured loan until the plan's security interest is perfected.

(2) *Correction of Transaction.* (i) Pay to the plan the Principal Amounts through the date the loan became fully secured, plus Lost Earnings on the series of Principal Amounts, as described in section 5(b).

(ii) Record or perfect the plan's interest in the loan collateral.

(iii) In addition, if the delay in perfecting the loan's security caused a permanent change in the risk characteristics of the loan, the fair market interest rate for the remaining term of the loan must be determined by an independent commercial lender. In that case, the correction amount includes an additional payment to the plan. The applicant must pay to the plan the present value of the Principal Amounts from the date the loan is fully secured to the maturity date of the loan, as determined by an independent commercial lender. The borrower must continue to pay to the plan the outstanding loan balance according to the repayment schedule for the duration of the loan. Alternatively, instead of the applicant paying the present value of the Principal Amounts, the borrower may pay to the plan the outstanding loan balance amortized over the remaining payment schedule for the duration of the loan at the interest rate that would have been applicable if the loan had been made at the fair market interest rate that would have been applicable for a loan with the changed risk characteristics.

(iv) For purposes of this transaction, each loan payment has a Principal Amount equal to the excess of the loan payment that would have been received if the loan had been made at the fair market interest rate for an unsecured loan (from the inception of the loan until the Recovery Date) over the loan payment actually received under the

loan terms during such period. Under the VFC Program, the fair market interest rate must be determined by an independent commercial lender.

(v) The principles of paragraph (d)(2) of this section are illustrated in the following examples:

Example 1. The plan made a mortgage loan, which was supposed to be secured by a Deed of Trust. The plan's Deed was not recorded for six months, but, when it was recorded, the Deed was in first position. The interest rate on the loan was the fair market interest rate for a mortgage loan secured by a first-position Deed of Trust. The loan is treated as an unsecured, below-market loan for the six months prior to the recording of the Deed of Trust.

Example 2. Assume the same facts as in Example 1, except that, as a result of the delay in recording the Deed, the plan ended up in second position behind another lender. The risk to the plan is higher and the interest rate on the note is no longer commensurate with that risk. The loan is treated as a below-market loan (based on the lack of security) for the six months prior to the recording of the Deed of Trust and as a below-market loan (based on secondary status security) from the time the Deed is recorded until the end of the loan.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A narrative describing the process used to determine the fair market interest rate for the period that the loan was unsecured and, if applicable, for the remaining term of the loan;

(ii) A copy of the independent commercial lender's fair market interest rate determination(s); and

(iii) If applicable, a copy of the loan repayment schedule for the re-amortized loan repayments.

7.3 Participant Loans

(a) Loans Failing to Comply With Plan Provisions for Amount, Duration or Level Amortization

(1) *Description of Transaction.* A plan extended a loan to a plan participant who is a party in interest with respect to the plan based solely on their status as an employee of any employer whose employees are covered by the plan, as defined in section 3(14)(H) of ERISA. The loan was a prohibited transaction that failed to qualify for ERISA's statutory exemption for plan loan programs because the loan terms did not comply with applicable plan provisions, which incorporated the requirements of section 72(p) of the Code concerning:

(i) the amount of the loan,

(ii) the duration of the loan, or

(iii) the level amortization of the loan repayment.

(2) *Correction of Transaction.* Plan Officials must make a voluntary correction of the loan with IRS approval under the Voluntary Correction Program of the IRS' Employee Plans Compliance Resolution System (EPCRS).

(3) *Documentation.* The applicant is not required to submit any of the supporting documentation listed in section 6.1(e) unless otherwise requested by EBSA, except that the applicant must provide (i) proof of payment, as described in paragraph (e)(6) of section 6.1, and (ii) a copy of the IRS compliance statement.

(b) Default Loans

(1) *Description of Transaction.* A plan extended a loan to a plan participant who is a party in interest with respect to the plan based solely on their status as an employee of any employer whose employees are covered by the plan, as defined in section 3(14)(H) of ERISA. At origination, the loan qualified for ERISA's statutory exemption for plan loan programs because the loan complied with applicable plan provisions, which incorporated the requirements of section 72(p) of the Code. During the loan repayment period, the Plan Official responsible for loan administration failed to properly withhold a number of loan repayments from the participant's wages and included the amount of such repayments in the participant's wages based on administrative or systems processing errors. The failure to withhold is a Breach causing the loan to become non-compliant with applicable plan provisions, which incorporated the requirements of section 72(p) of the Code.

(2) *Correction of Transaction.* Plan Officials must make a voluntary correction of the loan with IRS approval under the Voluntary Correction Program of the IRS' EPCRS.

(3) *Documentation.* The applicant is not required to submit any of the supporting documentation listed in section 6.1(e) unless otherwise requested by EBSA, except that the applicant must provide (i) proof of payment, as described in paragraph (e)(6) of section 6.1, and (ii) a copy of the IRS compliance statement.

7.4 Purchases, Sales and Exchanges

(a) Purchase of an Asset (Including Real Property) by a Plan from a Party in Interest

(1) *Description of Transaction.* A plan purchased an asset with cash from a party in interest with respect to the plan, in a transaction to which no prohibited transaction exemption applies.

(2) *Correction of Transaction.* (i) The plan may sell the asset back to the party in interest who originally sold the asset to the plan [71] or to a person who is not a party in interest. Whether the asset is sold to a person who is not a party in interest with respect to the plan or is sold back to the original seller, the plan must receive the higher of (A) the FMV of the asset at the time of resale, without a reduction for the costs of sale, plus restoration to the plan of the party in interest's investment return from the proceeds of the sale, to the extent they exceed the plan's net profits from owning the property; or (B) the Principal Amount, plus the greater of (*1*) Lost Earnings on the Principal Amount as described in section 5(b), or (*2*) the Restoration of Profits, if any, as described in section 5(b).

(ii) As an alternative to the correction described in paragraph (a)(2)(i) above, the plan may retain the asset and receive (A) the greater of (*1*) Lost Earnings less any earnings received on the asset up to the Recovery Date or (*2*) the Restoration of Profits, if any, as described in section 5(b), on the Principal Amount, but only to the extent that such Lost Earnings or Restoration of Profits exceeds the difference between the FMV of the asset as of the Recovery Date and the original purchase price; and (B) the amount by which the Principal Amount exceeded the FMV of the asset (at the time of the original purchase), plus the greater of (*1*) Lost Earnings or (*2*) Restoration of Profits, if any, as described in section 5(b), on such excess; provided an independent fiduciary determines that the plan will realize a greater benefit from this correction than it would from the resale of the asset described in paragraph (a)(2)(i) above.

(iii) As a cash settlement alternative, when the plan no longer owns the asset and the transaction cannot be reversed or the asset cannot be retained as described respectively in paragraphs (a)(2)(i) and (ii) above, the plan may accept in cash the amounts specified in (A) plus (B) where (A) is—the greater of (*1*) Lost Earnings less any earnings received on the asset up to the Recovery Date or (*2*) the Restoration of Profits, if any, as described in section 5(b), on the Principal Amount, and (3) with the resulting amount from (1) or (2) reduced by any profit if the asset were resold or matured at a gain, or increased by any

[71] The resale of the same property to the party in interest from whom the asset was purchased is a reversal of the original prohibited transaction. The resale is not a new prohibited transaction and therefore does not require an exemption.

loss including Lost Earnings on such loss if either the asset was resold at a loss or the plan otherwise ceased to own the asset (*e.g.,* maturity; destruction); and (B) is—the amount by which the Principal Amount exceeded the FMV of the asset (at the time of the original purchase), plus the greater of (*1*) Lost Earnings or (*2*) Restoration of Profits, if any, as described in section 5(b), on such excess. If the plan sold the asset, the asset must have been sold upon the advice of an independent fiduciary and not in anticipation of applying under the VFC Program.

(iv) For this transaction, the Principal Amount is the plan's original purchase price.

(v) The principles of paragraph (a)(2) of this section are illustrated in the following examples:

Example 1. A plan purchased a parcel of real property from the plan sponsor. The plan does not lease the property to any person. Instead, the plan uses the property as an office. The plan paid $120,000 for the property and $5,000 in transaction costs. As part of the correction, the Plan Official obtains two appraisals from a qualified, independent appraiser in order to determine the FMV of the property at the time of the purchase and at the time of the correction (the ''Recovery Date''). The FMV of the property at the time of purchase was $100,000 ($20,000 less than the plan paid for the property). As of the Recovery Date, the appraiser values the property at $110,000. To correct the transaction, the plan sponsor repurchases the property for $120,000 with no reduction for the costs of sale and reimburses the plan for the $5,000 in initial costs of sale. The plan sponsor also must pay the plan the greater of the plan's Lost Earnings or the sponsor's investment return on these amounts. The determination of an independent fiduciary is not required because the applicant is correcting the transaction by selling the asset back to the party in interest pursuant to paragraph (a)(2)(i) of this section.

Example 2. On February 1, 2002, a plan purchased from a party in interest a parcel of commercial real estate for $120,000 and incurred $5,000 in costs of sale. The plan initially uses the property as an office. At the same time, it is discovered that the original purchase was a prohibited transaction, the plan enters into a lucrative lease with an unrelated party for use of the property to begin January 1 of the following year. Due to commercial developments in adjacent properties, the Plan Official believes that the property will increase in value and that the plan would be able to obtain substantially increasing rental payments for the use of the property. As part of the correction, the Plan Official obtains two appraisals from a qualified, independent appraiser in order to determine the FMV of the asset at the time of the purchase and at the time of the correction (the ''Recovery Date''). The FMV of the property at the time of purchase was $120,000 (the same as the original purchase price). As of the Recovery Date, the property is valued at $150,000. Lost Earnings are calculated through September 30, 2005, the anticipated Recovery Date. The Online Calculator determined that Lost Earnings is $26,098.23 on the Principal Amount of $125,000 (purchase price plus transaction costs). There were no determinable profits. The increase in the FMV, $30,000, is greater than Lost Earnings or Restoration of Profits. Because the property is rapidly appreciating in value, and because the Plan Official expects to realize significant rental income from the property, the Plan Official would like to correct by retaining the property pursuant to paragraph (a)(2)(ii) of this section rather than selling the asset back to the party in interest pursuant to paragraph (a)(2)(i) of this section. The Plan Official must obtain a determination by an independent fiduciary that the plan will realize a greater benefit by retaining the asset than by selling the asset back to the party in interest. Because the original purchase price was the same as the FMV, and the increase in the FMV is greater than any earnings or investment return on the original purchase price, the only cash payment to the plan involved in this correction is the $5,000 in costs of sale, plus Lost Earnings.

Example 3: The plan purchased bonds from a party in interest on November 30, 2011 (the ''Loss Date'') at a face value of $100,000 with a yield of 2% interest annually. The purchase was at FMV and the bonds' maturity date was November 30, 2012. The plan received $102,000 on November 30, 2012 (the ''Recovery Date''). In January 2013, the plan trustee realized that the original purchase was a prohibited transaction because the seller is a party in interest. There were no determinable profits. Under these facts, because the plan no longer owns the asset, the transaction cannot be reversed under paragraph (a)(2)(i) above. Similarly, the plan cannot use the correction under paragraph (a)(2)(ii) above. A Plan Official may correct the transaction under paragraph (a)(2)(iii) by paying to the plan on January 7, 2013 (the ''Final Payment Date'') an amount of cash equal to the Lost Earnings as calculated using the Online Calculator less the interest paid on the bonds ($3,055.55 − $2,000).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's purchase of the asset, including the date of the purchase, the plan's purchase price, and the identity of the seller;

(ii) A narrative describing the relationship between the original seller of the asset and the plan;

(iii) The qualified, independent appraiser's report addressing the FMV of the asset purchased by the plan, both at the time of the original purchase and at the recovery date;

(iv) If applicable, a report of the independent fiduciary's determination that the plan will realize a greater benefit by receiving the correction amount described in paragraph (a)(2)(ii) of this section than by reselling the asset pursuant to paragraph (a)(2)(i) of this section; and

(v) In a transaction involving a cash settlement correction under section 7.4(a)(2)(iii) where the plan sold the asset, a statement by a Plan Official that the asset was sold upon the advice of an independent fiduciary and not in anticipation of applying under the VFC Program.

(b) Sale of an Asset (Including Real Property) by a Plan to a Party in Interest

(1) *Description of Transaction.* A plan sold an asset for cash to a party in interest with respect to the plan, in a transaction to which no prohibited transaction exemption applies.

(2) *Correction of Transaction.* (i) The plan may repurchase the asset from the party in interest [72] at the lower of (A) the price for which it originally sold the property or (B) the FMV of the property as of the Recovery Date plus restoration to the plan of the party in interest's net profits from owning the property, to the extent they exceed the plan's investment return from the proceeds of the sale.

(ii) As an alternative to the correction described in paragraph (b)(2)(i) above, the plan may receive the Principal Amount plus the greater of (A) Lost Earnings as described in section 5(b) or (B) the Restoration of Profits, if any, as described in section 5(b), provided an independent fiduciary determines that the plan will realize a greater benefit from this correction than it would from the repurchase of the asset described in paragraph (b)(2)(i), or provided a Plan

[72] The repurchase of the same property from the party in interest to whom the asset was sold is a reversal of the original prohibited transaction. The repurchase is not a new prohibited transaction and therefore does not require an individual prohibited transaction exemption.

Official determines that the asset cannot be repurchased (e. g., maturity, destruction).

(iii) For this transaction, the Principal Amount is the amount by which the FMV of the asset (at the time of the original sale) exceeds the original sale price.

(iv) The principles of paragraph (b)(2) of this section are illustrated in the following examples:

Example 1. A plan sold a parcel of unimproved real property to the plan sponsor. The sponsor did not make any profit on the use of the property. As part of the correction, the Plan Official obtains an appraisal of the property reflecting the FMV of the property as of the date of sale from a qualified, independent appraiser. The appraiser values the property at $130,000, although the plan sold the property to the plan sponsor for $120,000. The plan did not incur any transaction costs during the original sale. As of the Recovery Date, the appraiser values the property at $140,000. The plan corrects the transaction by repurchasing the property at the original sale price of $120,000, with the party in interest assuming the costs of the reversal of the sale transaction. The determination of an independent fiduciary is not required because the applicant is correcting the transaction by repurchasing the property from the party in interest pursuant to paragraph (b)(2)(i) of this section.

Example 2. Assume the same facts as in Example 1, except that the appraiser values the property as of the Recovery Date at $100,000, and the plan fiduciaries believe that the property will continue to decrease in value based on environmental studies conducted in adjacent areas. Based on the determination of an independent fiduciary that the plan will realize a greater benefit by receiving the Principal Amount (FMV of the asset at the time of the original sale less the original sales price equals $10,000) plus the greater of Lost Earnings or Restoration of Profits, as described in section 5(b), the transaction is corrected by cash settlement pursuant to paragraph (b)(2)(ii) of this section, rather than by repurchasing the asset.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's sale of the asset, including the date of the sale, the sales price, and the identity of the original purchaser;

(ii) A narrative describing the relationship of the purchaser to the asset and the relationship of the purchaser to the plan;

(iii) The qualified, independent appraiser's report addressing the FMV of the property at the time of the sale from the plan and as of the Recovery Date; and

(iv) If applicable, a report of the independent fiduciary's determination that the plan will realize a greater benefit by receiving the correction amount described in paragraph (b)(2)(ii) of this section than by repurchasing the asset pursuant to paragraph (b)(2)(i) of this section, or if the asset cannot be repurchased, a written explanation of such circumstance from the Plan Official making this determination.

(c) Sale and Leaseback of Real Property to Employer

(1) *Description of Transaction.* The plan sponsor, or an affiliate of the plan sponsor, sold a parcel of real property to the plan, which then was leased back to the sponsor or affiliate, in a transaction that is not otherwise exempt.

(2) *Correction of Transaction.* (i) The transaction must be corrected by the sale of the parcel of real property back to the plan sponsor or affiliate of the plan sponsor, or to a person who is not a party in interest with respect to the plan.[73] The plan must receive the higher of (A) FMV of the asset at the time of resale, without a reduction for the costs of sale; or (B) the Principal Amount, plus the greater of (*1*) Lost Earnings on the Principal Amount as described in section 5(b), or (*2*) the Restoration of Profits, if any, as described in section 5(b).

(ii) For purposes of this transaction, the Principal Amount is the plan's original purchase price.

(iii) If the plan has not been receiving rent at FMV, as determined by a qualified, independent appraisal, the sale price of the real property should not be based on the historic below-market rent that was paid to the plan.

(iv) In addition to the correction amount in subparagraph (1), if the plan was not receiving rent at FMV, as determined by a qualified, independent appraiser, the Principal Amount also includes the difference between the rent actually paid and the rent that should have been paid at FMV. The plan sponsor or an affiliate of the plan sponsor must pay to the plan this additional Principal Amount, plus the greater of (A) Lost Earnings or (B) Restoration of Profits resulting from the plan sponsor's or affiliate's use of the Principal Amount, as described in section 5(b).

(v) The principles of paragraph (c)(2) of this section are illustrated in the following example:

Example. The plan purchased at FMV from the plan sponsor an office building that served as the sponsor's primary business site. Simultaneously, the plan sponsor leased the building from the plan at below the market rental rate. The Plan Official obtains from a qualified, independent appraiser an appraisal of the property reflecting the FMV of the property and rent. To correct the transaction, the plan sponsor purchases the property from the plan at the higher of the appraised value at the time of the resale or the original sales price and also pays the Lost Earnings. Because the rent paid to the plan was below the market rate, the sponsor must also make up the difference between the rent paid under the terms of the lease and the amount that should have been paid, plus Lost Earnings on this amount, as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's purchase of the real property, including the date of the purchase, the plan's purchase price, and the identity of the original seller;

(ii) Documentation of the plan's sale of the asset, including the date of sale, the sales price, and the identity of the purchaser;

(iii) A narrative describing the relationship of the original seller to the plan and the relationship of the purchaser to the plan;

(iv) A copy of the lease;

(v) Documentation of the date and amount of each lease payment received by the plan; and

(vi) The qualified, independent appraiser's report addressing both the FMV of the property at the time of the original sale and at the Recovery Date, and the FMV of the lease payments.

(d) Purchase of an Asset (Including Real Property) by a Plan From a Person Who Is Not a Party in Interest With Respect to the Plan at a Price More Than Fair Market Value

(1) *Description of Transaction.* A plan acquired an asset from a person who is not a party in interest with respect to the plan, without determining the asset's FMV. As a result, the plan paid more than it should have for the asset.

[73] If the plan purchased the property from the plan sponsor or an affiliate of the plan sponsor, the sale of the same property back to the plan sponsor or affiliate is a reversal of the prohibited transaction. The sale is not a new prohibited transaction and therefore does not require an individual prohibited transaction exemption, as long as the plan did not make improvements while it owned the property.

(2) *Correction of Transaction.* The Principal Amount is the difference between the actual purchase price and the asset's FMV at the time of purchase. The plan must receive the Principal Amount plus the Lost Earnings, as described in section 5(b).

(i) The principles of paragraph (d)(2) of this section are illustrated in the following example:

Example. A plan bought unimproved land without obtaining a qualified, independent appraisal. Upon discovering that the purchase price was $10,000 more than the appraised FMV, the Plan Official pays the plan the Principal Amount of $10,000, plus Lost Earnings as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's original purchase of the asset, including the date of the purchase, the purchase price, and the identity of the seller;

(ii) A narrative describing the relationship of the seller to the plan; and

(iii) A copy of the qualified, independent appraiser's report addressing the value at the time of the plan's purchase.

(e) Sale of an Asset (Including Real Property) By a Plan to a Person Who Is Not a Party in Interest With Respect to the Plan at a Price Less Than Fair Market Value

(1) *Description of Transaction.* A plan sold an asset to a person who is not a party in interest with respect to the plan, without determining the asset's FMV. As a result, the plan received less than it should have from the sale.

(2) *Correction of Transaction.* The Principal Amount is the amount by which the FMV of the asset as of the Recovery Date exceeds the price at which the plan sold the property. The plan must receive the Principal Amount plus Lost Earnings as described in section 5(b).

(i) The principles of paragraph (e)(2) of this section are illustrated in the following example:

Example. A plan sold unimproved land without taking steps to ensure that the plan received FMV. Upon discovering that the sale price was $10,000 less than the FMV, the Plan Official pays the plan the Principal Amount of $10,000 plus Lost Earnings as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's original sale of the asset, including the date of the sale, the sale price, and the identity of the buyer;

(ii) A narrative describing the relationship of the buyer to the plan; and

(iii) A copy of the qualified, independent appraiser's report addressing the value at the time of the plan's sale.

(f) Holding of an Illiquid Asset Previously Purchased by a Plan

(1) *Description of Transaction.* A plan is holding an asset previously purchased from (i) a party in interest with respect to the plan in an acquisition for which relief was available under a statutory or administrative prohibited transaction exemption, (ii) a party in interest with respect to the plan at no greater than FMV at that time in an acquisition to which no prohibited transaction exemption applied, (iii) a person who was not a party in interest with respect to the plan in an acquisition in which a plan fiduciary failed to appropriately discharge their fiduciary duties, or (iv) a person who was not a party in interest with respect to the plan in an acquisition in which a plan fiduciary appropriately discharged their fiduciary duties. Currently, a plan fiduciary determines that such asset is an illiquid asset because: (A) the asset failed to appreciate, failed to provide a reasonable rate of return, or caused a loss to the plan; (B) the sale of the asset is in the best interest of the plan; and (C) following reasonable efforts to sell the asset to a person who is not a party in interest with respect to the plan, the asset cannot immediately be sold for its original purchase price, or its current FMV, if greater. Examples of assets that may meet this definition include, but are not limited to, restricted and thinly traded stock, limited partnership interests, real estate and collectibles. In the case of an illiquid asset that is a parcel of real estate, no party in interest may own real estate that is contiguous to the plan's parcel of real estate on the Recovery Date.

(2) *Correction of Transaction.* (i) The transaction may be corrected by the sale of the asset to a party in interest, provided the plan receives the higher of (A) the FMV of the asset at the time of resale, without a reduction for the costs of sale; or (B) the Principal Amount, plus Lost Earnings as described in section 5(b). The Plan Official may cause the plan to sell the asset to a party in interest. This correction provides relief for both the original purchase of the asset, if required, and the sale of the illiquid asset by the plan to a party in interest; relief from the prohibited transaction excise tax also is provided if the Plan Official satisfies the applicable conditions of the VFC Program class exemption.

(ii) For this transaction, the Principal Amount is (A) the amount that would have been available had the Breach not occurred, or (B) the plan's original purchase price if the original purchase was not a prohibited transaction or imprudent.

(iii) The principles of paragraph (f)(2) of this section are illustrated in the following examples:

Example 1. A plan purchases undeveloped real property from a party in interest with respect to the plan for $60,000 in June 1999. In April 2004, Plan Officials determine that the property is an illiquid asset. A qualified, independent appraiser appraises the property at a current FMV of $20,000. The plan sponsor pays the plan the Principal Amount of $60,000 plus Lost Earnings as described in section 5(b), and Plan Officials transfer the property from the plan to the plan sponsor. The Plan Officials also comply with the applicable terms of the related exemption.

Example 2. A plan purchases a limited partnership interest for $60,000 in June 1999 from an unrelated party after plan fiduciaries properly fulfill their fiduciary duties with respect to the purchase. In April 2004, Plan Officials determine that the interest is an illiquid asset because the interest has failed to generate a reasonable rate of return. A qualified, independent appraiser appraises the interest at a current FMV of $80,000. The plan sponsor pays the plan the FMV of $80,000 without a reduction for the costs of the sale, which is greater than the Principal Amount plus Lost Earnings, and Plan Officials transfer the interest from the plan to the plan sponsor. The Plan Officials also comply with the applicable terms of the related exemption.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) Documentation of the plan's original purchase of the asset, including the date of the purchase, the plan's purchase price, the identity of the original seller, and a description of the relationship, if any, between the original seller and the plan;

(ii) The qualified, independent appraiser's report addressing the FMV of the asset purchased by the plan at the recovery date;

(iii) A narrative describing the plan's efforts to sell the asset to persons who are not parties in interest with respect to the plan and any documentation of such efforts to sell the asset;

(iv) A statement from a Plan Official attesting that: (A) the asset failed to appreciate, failed to provide a reasonable rate of return, or caused a loss to the plan; (B) the sale of the asset is in the best interest of the plan; (C) the asset is an illiquid asset; and (D) the plan made reasonable efforts to sell the asset to persons who are not parties in interest with respect to the plan without success; and

(v) In the case of an illiquid asset that is a parcel of real estate, a statement from a Plan Official attesting that no party in interest owns real estate that is contiguous to the plan's parcel of real estate on the Recovery Date.

7.5 Benefits

(a) Payment of Benefits Without Properly Valuing Plan Assets on Which Payment is Based

(1) *Description of Transaction.* A defined contribution pension plan pays benefits based on the value of the plan's assets. If one or more of the plan's assets are not valued at current value, the benefit payments are not correct. If the plan's assets are overvalued, the current benefit payments will be too high. If the plan's assets are undervalued, the current benefit payments will be too low.

(2) *Correction of Transaction.* (i) Establish the correct value of the improperly valued asset for each plan year, starting with the first plan year in which the asset was improperly valued. In the case of undervalued plan assets, restore to the plan for distribution to the affected plan participants, or restore directly to the plan participants, the amount by which all affected participants were underpaid distributions to which they were entitled under the terms of the plan, plus Lost Earnings as described in section 5(b) on the underpaid distributions. In the case of overvalued plan assets, restore to the plan the amount which exceeded the paid distribution amount to which all affected participants were entitled under the terms of the plan, plus Lost Earnings as described in section 5(b) on the overpaid distributions. File amended Annual Report Forms 5500, as detailed below.

(ii) To correct the valuation defect, a Plan Official must determine the FMV of the improperly valued asset per section 5(a) for each year in which the asset was valued improperly.

(iii) Once the FMV has been determined, the participant account balances for each year must be adjusted accordingly.

(iv) The Annual Report Forms 5500 must be amended and refiled for (A) the last three plan years or (B) all plan years in which the value of the asset was reported improperly, whichever is less.

(v) The Plan Official or plan administrator must determine who received distributions from the plan during the time the asset was valued improperly. For distributions that were too low, the amount of the underpayment is treated as a Principal Amount for each individual who received a distribution. The Principal Amount and Lost Earnings must be paid to the affected individuals. For distributions that were too high, the total of the overpayments constitutes the Principal Amount for the plan. The Principal Amount plus the Lost Earnings, as described in section 5(b), must be restored to the plan or to any participants who received distributions that were too low.

(vi) The principles of paragraph (a)(2) of this section are illustrated in the following examples:

Example 1. On December 31, 1995, a profit sharing plan purchased a 20-acre parcel of real property for $500,000, which represented a portion of the plan's assets. The plan has carried the property on its books at cost, rather than at FMV. One participant left the company on January 1, 1997, and received a distribution, which included the participant's portion of the value of the property. The separated participant's account balance represented 2% of the plan's assets. As part of the correction for the VFC Program, a qualified, independent appraiser has determined the FMV of the property for 1996, 1997, and 1998. The FMV as of December 31, 1996, was $400,000. Therefore, this participant was overpaid by $2,000 (($500,000 − $400,000) multiplied by 2%). The Plan Officials corrected the transaction by paying to the plan the $2,000 Principal Amount plus Lost Earnings as described in section 5(b).

The plan administrator also filed an amended Form 5500 for plan years 1996 and 1997, to reflect the proper values. The plan administrator will include the correct asset valuation in the 1998 Form 5500 when that form is filed.

Example 2. Assume the same facts as in Example 1, except that the property had appreciated in value to $600,000 as of December 31, 1996. The separated participant would have been underpaid by $2,000. The correction consists of locating the participant and distributing to the participant the $2,000 Principal Amount plus Lost Earnings as described in section 5(b), as well as filing the amended Forms 5500.

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) A copy of the qualified, independent appraiser's report for each plan year in which the asset was revalued;

(ii) A written statement confirming the date that amended Annual Report Forms 5500 with correct valuation data were filed;

(iii) If losses are restored to the plan, proof of payment to the plan and copies of the adjusted participant account balances; and

(iv) If supplemental distributions are made, proof of payment to the individuals entitled to receive the supplemental distributions or to the plan if paid pursuant to the de minimis exception in section 5(e).

7.6 Plan Expenses

(a) Duplicative, Excessive, or Unnecessary Compensation Paid by a Plan

(1) *Description of Transaction.* A plan used plan assets to pay compensation, including commissions or fees, to a service provider (such as an attorney, accountant, recordkeeper, actuary, financial adviser, or insurance agent), and the compensation was:

(i) excessive in amount for the services provided to the plan;

(ii) duplicative, in that a plan paid two or more providers for the same service; or

(iii) unnecessary for the operation of the plan, in that the services were not helpful and appropriate in carrying out the purposes for which the plan is maintained.

(2) *Correction of Transaction.* (i) Restore to the plan the Principal Amount, plus the greater of (A) Lost Earnings or (B) Restoration of Profits resulting from the use of the Principal Amount, as described in section 5(b).

(ii) (A) For the transactions described in paragraph (a)(1)(i) above, the Principal Amount is the difference between (*1*) the amount of compensation paid by the plan to the service provider and (*2*) the reasonable market value of such services.

(B) For the transactions described in paragraph (a)(1)(ii) above, the Principal Amount is the difference between (*1*) the total amount of compensation paid to the service providers and (*2*) the least amount of compensation paid to one of the service providers for the duplicative services.

(C) For the transactions described in paragraph (a)(1)(iii) above, the Principal Amount is the amount of compensation paid by the plan to the service provider for the unnecessary services.

(iii) The principles of paragraph (a)(2) of this section are illustrated in the following examples:

Example 1. Excessive compensation. A plan hired an investment adviser who advised the plan's trustees about how to invest the plan's entire portfolio. In accordance with the plan document, the trustees instructed the adviser to limit the plan's investments to equities and bonds. In exchange for the services, the plan paid the investment adviser 3% of the value of the portfolio's assets. If the trustees had inquired, they would have learned that comparable investment advisers charged 1% of the value of the assets for the type of portfolio that the plan maintained. To correct the transaction, the plan must be paid the Principal Amount of 2% of the value of the plan's assets, plus the higher Lost Earnings or Restoration of Profits, as described in section 5(b).

Example 2. Unnecessary Compensation. A plan paid a travel agent to arrange a fishing trip for the plan's investment adviser as a way of rewarding the adviser because the plan's investment return for the year exceeded the plan's investment goals by 10%. An internal auditor discovered the charge on the plan's record books. To correct the transaction, the plan must be paid the Principal Amount, which is the total amount paid to the travel agent, plus the higher of Lost Earnings or Restoration of Profits as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit the following documents:

(i) For the transactions described in paragraph (a)(1)(i) above, a written estimate of the reasonable market value of the services and the estimator's qualifications; and

(ii) The cost of the services at issue during the period that such services were provided to the plan.

(b) Expenses Improperly Paid by a Plan

(1) *Description of Transaction.* A plan used plan assets to pay expenses, including commissions or fees, which should have been paid by the plan sponsor, to a service provider (such as an attorney, accountant, recordkeeper, actuary, financial adviser, or insurance agent) for:

(i) services provided in connection with the administration and maintenance of the plan (''plan expenses'' [74]) in circumstances where a plan provision requires that such plan expenses be paid by the plan sponsor, or

(ii) services provided in connection with the establishment, design, or termination of the plan (''settlor expenses'' [75]), which relate to the activities of the plan sponsor in its capacity as settlor.

(2) *Correction of Transaction.* (i) Restore to the plan the Principal Amount, plus the greater of (A) Lost Earnings or (B) Restoration of Profits resulting from the use of the Principal Amount, as described in section 5(b).

(ii) The Principal Amount is the entire amount improperly paid by the plan to the service provider for expenses that should have been paid by the plan sponsor.

(iii) The principles of paragraph (b)(2) of this section are illustrated in the following example:

Example. Employer X, the plan sponsor of Plan Y, is considering amending its defined contribution plan to add a 5% matching contribution. Employer X operates in a competitive industry, and a human resources consultant has recommended, among other improvements, that Employer X provide a competitive matching contribution to help attract and retain a highly qualified workforce. Employer X hired an actuary to estimate the cost of providing this matching contribution over the next ten years. In exchange for these services, the plan paid the actuary $10,000. Several months after the actuary's bill has been paid, a Plan Official realizes that one of Employer X's employees erroneously paid the bill from the defined contribution plan's assets. The bill should have been paid by Employer X because the bill related to settlor expenses incurred by Employer X in analyzing whether to add a matching contribution to the plan. To correct the transaction, the plan must be paid the Principal Amount ($10,000), plus Lost Earnings or Restoration of Profits, as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit copies of the plan's accounting records which show the date and amount of expenses paid by the plan to the service provider.

(c) Payment of Dual Compensation to a Plan Fiduciary

(1) *Description of Transaction.* A plan used plan assets to pay compensation to a fiduciary for services rendered to the plan when the fiduciary already receives full-time pay from an employer or an association of employers, whose employees are participants in the plan, or from an employee organization whose members are participants in the plan. The plan's payments to the plan fiduciary are not reimbursements of expenses properly and actually incurred by the fiduciary in the performance of their fiduciary duties.

(2) *Correction of Transaction.* (i) Restore to the plan the Principal Amount, plus the greater of (A) Lost Earnings or (B) Restoration of Profits resulting from the fiduciary's use of the Principal Amount, as described in section 5(b).

(ii) The Principal Amount is the amount of compensation paid to the fiduciary by the plan.

(iii) The principles of paragraph (c)(2) of this section are illustrated in the following example:

Example. A union sponsored a health plan funded through contributions by employers. The union president receives $50,000 per year from the union in compensation for services as union president. The president is appointed as a trustee of the health plan while retaining the position as union president. In exchange for acting as plan trustee, the union president is paid a salary of $200 per week by the plan while still receiving the $50,000 salary from the union. Since $50,000 is full-time pay, the plan's weekly salary payments are improper. To correct the transaction, the plan must be paid the Principal Amount, which is the $200 weekly salary amount for each week that the salary was paid, plus the higher of Lost Earnings or Restoration of Profits, as described in section 5(b).

(3) *Documentation.* In addition to the documentation required by section 6.1, submit copies of the plan's accounting records which show the date and amount of compensation paid by the plan to the identified fiduciary.

Appendix A—Sample VFC Program No Action Letter

Applicant (Plan Official)
Address

Re: VFC Program Application No. xx–xxxxxx

The Department of Labor, Employee Benefits Security Administration (EBSA), administers and enforces Title I of the Employee Retirement Income Security Act of 1974 (ERISA). EBSA established a Voluntary Fiduciary Correction (VFC) Program to encourage the voluntary correction of breaches of fiduciary responsibility and the restoration of losses to the plan participants and beneficiaries.

You submitted a VFC Program application identifying the following transactions as breaches, or potential breaches, of the fiduciary duty provisions in Part 4 of Title I of ERISA. You also submitted documentation to EBSA under the VFC Program on the corrective action you have taken. Your application was assigned the application number indicated above.

[74] *See* Advisory Opinion 2001–01A (Jan. 18, 2001).

[75] *See id.*

[Briefly recap the transaction and correction. *Example:* Failure to deposit participant contributions to the XYZ Corp. 401(k) plan within the time frames required by ERISA from (date) to (date). All participant contributions were deposited by (date) and lost earnings on the delinquent contributions were deposited and allocated to participants' plan accounts on (date).]

Based on your representations and the corrective actions taken, in accordance with the terms and limitations set forth in the VFC Program, EBSA will not recommend that the Solicitor of Labor initiate legal action against you, and EBSA will not seek to impose civil penalties under section 502(l) or section 502(i) of ERISA with respect to the transactions described above.

EBSA's decision is conditioned on the representations in your VFC Program application being complete and accurate. The decision does not preclude EBSA from conducting an investigation of any potential violations of criminal law in connection with the transaction identified in the application or seeking appropriate relief from any other person. EBSA's decision is binding on EBSA only, and does not bar other governmental agencies, plan fiduciaries, participants or beneficiaries, and other interested persons from seeking separate or additional remedies.

[If the transaction is a prohibited transaction for which no exemptive relief is available, add the following language: The Secretary of Labor is required by section 3003(c) of ERISA, 29 U.S.C. 1203(c), to transmit to the Secretary of the Treasury information indicating that a prohibited transaction has occurred. Accordingly, this matter will be referred to the Internal Revenue Service.]

If you have any questions about this letter, you may contact the Regional VFC Program Coordinator at (insert *applicable address and telephone number).*

Appendix B—VFC Program Application Checklist (Required)

Use this checklist to make sure you are submitting a complete application. Indicate ''Yes'', ''No'' or ''N/A'' next to each item. A ''No'' answer or the failure to include a completed checklist will delay review of the application until all required items are received. The applicant must sign and date the checklist and include it with the application. Check with the relevant Regional Office whether it accepts email submissions of VFC Program applications.

____1. Have you reviewed the eligibility, definitions, transaction and correction, and documentation sections of the VFC Program?

____2. Have you included the name, address (street or email) and telephone number of a contact person familiar with the contents of the application?

____3. Have you provided the EIN, Plan Number, and address (street and email) of the plan sponsor and plan administrator?

____4. Have you provided the date that the most recent Form 5500 was filed by the plan (or for a bulk application as described in section 4(d), the nine-digit employer identification number for each plan sponsor of a named plan)?

____5. Have you enclosed a signed and dated certification under penalty of perjury for the plan fiduciary with knowledge of the transactions and for each applicant and the applicant's representative, if any? In the case of a bulk application, have you enclosed a signed and dated certification under penalty of perjury for the bulk applicant based on knowledge of the transactions and for the bulk applicant's representative, if any?

_____6. Have you enclosed relevant portions of the plan document and any other pertinent documents (such as the adoption agreement, trust agreement, or insurance contract) with the relevant sections identified?

____7. If applicable, have you provided written notification to EBSA of any current investigation or examination of the plan, or of the applicant or plan sponsor in connection with an act or transaction directly related to the plan by the PBGC, any state attorney general, or any state insurance commissioner?

____8. If applicable (under section 4(b)(2) of the Program), have you included the following items?

____a. Contact information for the law enforcement agency notified of the criminal activity;

____b. A statement from the applicant asserting no involvement in the potential criminal activity; and

____c. A statement as to whether a claim relating to the criminal activity has been made under an ERISA section 412 fidelity bond.

____9. Where applicable, have you enclosed a copy of an appraiser's report?

____10. Where applicable, have you enclosed a copy of an independent fiduciary's approval?

____11. Have you enclosed supporting documentation, including:

____a. A detailed narrative of the Breach, including the date it occurred;

____b. Documentation that supports the narrative description of the transaction;

____c. An explanation of how the Breach was corrected, by whom and when, with supporting documentation;

____d. A list of all persons materially involved in the Breach and its correction (*e.g.,* fiduciaries, service providers, borrowers, lenders);

____e. Specific calculations demonstrating how Principal Amount and Lost Earnings or Restoration of Profits were computed, or, if the Online Calculator was used, a copy of the ''Print Viewable Results'' page(s) after completing use of the Online Calculator;

____f. Proof of payment of principal amount;

____g. Proof of payment of lost earnings or restoration of profits to the plan; and

Caution: The correction amount and the costs of correction cannot be paid from plan assets, including by charges against participant accounts or plan forfeiture accounts.

____h. If application concerns delinquent participant contributions or loan repayments, a statement from a Plan Official identifying the earliest date on which participant contributions/loan repayments reasonably could have been segregated from the employer's general assets and supporting documentation on which the Plan Official relied?

____12. If you are an eligible applicant and wish to avail yourself of excise tax relief under the VFC Program Class Exemption:

____a. Have you made proper arrangements to provide within 60 calendar days after submission of this application a copy of the VFC Program Class Exemption notice to all interested persons and to the EBSA Regional Office to which the application is filed; or

____b. If you are relying on the exception to the notice requirement in section IV.C. of the VFC Program Class Exemption because the amount of the excise tax otherwise due would be less than or equal to $100.00, have you provided to the appropriate EBSA Regional Office a copy of a completed IRS Form 5330 or other written documentation containing the information required by IRS Form 5330 and proof of payment?

____13. In calculating Lost Earnings, have you elected to use:

____a. The Online Calculator; or

____b. A manual calculation performed in accordance with section 5(b) of the VFC Program?

____14. If the application involves payments to participants and beneficiaries:

____a. Have you enclosed a description demonstrating proof of payment to participants and beneficiaries whose current location is known to the plan and/or applicant in accordance with section 5(d) of the VFC Program?

____b. For individuals who need to be located, have you demonstrated how adequate funds have been segregated to pay missing individuals and included a description of the process that you commenced to locate missing individuals in accordance with section 5(d)?

____15. For purposes of the three transactions involving participant contributions covered under section 7.1, has the plan implemented measures to ensure that such transactions do not recur?

Signature of Applicant and Date Signed:

_____

Name of Applicant:

_____

Title/Relationship to the Plan:

_____

Name of Plan, EIN and Plan Number:

_____

Contact information: Phone; email

_____

Paperwork Reduction Act Notice

The information identified on this form is required for a valid application for the Voluntary Fiduciary Correction Program of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA). You must complete this form and submit it as part of the application in order to receive the relief offered under the Program with respect to a breach of fiduciary responsibility under Part 4 of Title I of ERISA. EBSA will use this information to determine that you have satisfied the requirements of the Program. EBSA estimates that completing and submitting this form will require an average of 2 to 4 minutes. This collection of information is currently approved under OMB Control Number 1210–0118. You are not required to respond to a collection of information unless it displays a currently valid OMB Control Number.

Appendix C—EBSA Regional Offices

Submit your VFC Program application to the appropriate EBSA Regional Office. Verify current telephone numbers and addresses on EBSA's website, *www.dol.gov/ebsa/* before you submit your application. Check with the relevant Regional Office whether it accepts email submissions of VFC Program applications.

Atlanta Regional Office, 61 Forsyth Street SW, Suite 7B54, Atlanta, GA 30303, telephone (404) 302–3900, fax (404) 302–3975; jurisdiction: Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico.

Boston Regional Office, J.F.K. Federal Building, 15 New Sudbury Street, Room 575, Boston, MA 02203, telephone (617) 565–9600, fax: (617) 565–9666; jurisdiction: Connecticut, Maine, Massachusetts, New Hampshire, central and western New York, Rhode Island, Vermont.

Chicago Regional Office, John C. Kluczynski Federal Building, 230 South Dearborn Street, Suite 2160, Chicago, IL 60604, telephone (312) 353–0900, fax (312) 353–1023; jurisdiction: northern Illinois, northern Indiana, Wisconsin.

Cincinnati Regional Office, 1885 Dixie Highway, Suite 210, Ft. Wright, KY 41011–2664, telephone (859) 578–4680, fax (859) 578–4688; jurisdiction: southern Indiana, Kentucky, Michigan, Ohio.

Dallas Regional Office, 525 South Griffin Street, Rm. 900, Dallas, TX 75202–5025, telephone (972) 850–4500, fax (214) 767–1055; jurisdiction: Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Kansas City Regional Office, 2300 Main Street, Suite 1100, Kansas City, MO 64108, telephone (816) 285–1800, fax (816) 285–1888; jurisdiction: Colorado, southern Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, South Dakota, Wyoming.

Los Angeles Regional Office, 35 N. Lake Ave., Suite 300, Pasadena, CA 91101, telephone (626) 229–1000, fax (626) 229–1098; jurisdiction: 10 southern counties of California, Arizona, Hawaii, American Samoa, Guam, Wake Island.

New York Regional Office, 201 Varick Street, Room 746, New York, NY 10014, telephone (212) 607–8600, fax (212) 607–8611; jurisdiction: southeastern New York, northern New Jersey.

Philadelphia Regional Office, 1835 Market Street, 21st Floor, Mailstop EBSA/21, Philadelphia, PA 19103, telephone (215) 861–5300, fax (215) 861–5347; jurisdiction: Delaware, Maryland, southern New Jersey, Pennsylvania, Virginia, Washington, DC, West Virginia.

San Francisco Regional Office, 90 7th Street, Suite 11–300, San Francisco, CA 94103, telephone (415) 625–2481, fax (415) 625–2450; jurisdiction: Alaska, 48 northern counties of California, Idaho, Nevada, Oregon, Utah, Washington.

Appendix D —Lost Earnings Example (Manual Calculation)

Delinquent Participant Contributions

Company A pays its employees every other Friday. Each pay date, participant contributions total $10,000, which reasonably can be segregated from Company A's general assets by ten business days following each pay date. Company A should have remitted participant contributions for the pay date ending March 2, 2001 to the plan by March 16, 2001, the Loss Date, but actually remitted them on April 13, 2001, the Recovery Date. In early 2004, a Plan Official discovers that participant contributions for this pay period were not remitted on a timely basis. To comply with the Program, the Plan Official decided to repay all Lost Earnings on January 30, 2004.

Based on the above facts:

- Principal Amount is $10,000
- Loss Date is March 16, 2001
- Recovery Date is April 13, 2001
- Number of Days Late is 28 (Recovery Date less Loss Date)

The basic formula for computing earnings using the applicable factors under IRS Revenue Procedure 95–17 is: Dollar Amount * IRS factor

Step 1. The Plan Official must calculate Lost Earnings, based on the Principal Amount, that should have been paid on the Recovery Date.

The first period of time is from March 16, 2001 to March 31, 2001 (15 days). The Code underpayment rate is 9%. Using Revenue Procedure 95–17, the factor for 15 days at 9% is 0.003705021 from table 23.

$10,000 * 0.003705021 = $37.05

The plan is due $10,037.05 as of March 31, 2001. The second period of time is April 1, 2001 through April 13, 2001 (13 days). The Code underpayment rate is 8%. Using Revenue Procedure 95–17, the factor for 13 days at 8% is 0.002853065 from table 21.

$10,037.05 * 0.002853065 = $28.64

Therefore, Lost Earnings of $65.69 ($37.05 plus $28.64) must be paid to the plan.

Step 2. If Lost Earnings are paid to the plan after the Recovery Date, the Plan Official must calculate the amount of interest on the Lost Earnings (determined in Step 1) that must also be paid to the plan. This calculation is shown by the following chart: (The ''Interest'' column is the previous time period's ''Amnt. Due'' multiplied by the Factor. ''Amnt. Due'' is the previous ''Amnt. Due'' plus ''Interest''. The calculation in the first row is based on the $65.69 Lost Earnings.)

1st Day	To	Days	Underpmnt. rate (percent)	Rev. Proc. table	Factor	Interest	Amnt. due
4/14/01	6/30/01	78	8	21	.017240956	1.132558	66.82256
7/1/01	9/30/01	92	7	19	.017798686	1.189354	68.01191
10/1/01	12/31/01	92	7	19	.017798686	1.210523	69.22243
1/1/02	3/31/02	90	6	17	.014903267	1.031640	70.25408
4/1/02	6/30/02	91	6	17	.015070101	1.058736	71.31281
7/1/02	9/30/02	92	6	17	.015236961	1.086591	72.39940
10/1/02	12/31/02	92	6	17	.015236961	1.103147	73.50255
1/1/03	3/31/02	90	5	15	.012404225	0.911742	74.41429
4/1/03	6/30/03	91	5	15	.012542910	0.933372	75.34766
7/1/03	9/30/03	92	5	15	.012681615	0.955530	76.30319
10/1/03	12/31/03	92	4	13	.010132630	0.773152	77.07634
1/1/04	1/30/04	30	4	61	.003283890	0.253110	77.32945
Total Interest:						11.64	

Note that the last factor comes from the Revenue Procedure 95–17 tables for leap years.

The plan is also owed $11.64. This is the amount of interest on $65.69 (Lost Earnings on the Principal Amount) accrued between April 13, 2001, the Recovery Date, when the Principal Amount $10,000 was paid to the plan, and January 30, 2004, the date chosen to repay Lost Earnings.

Therefore, the Plan Official must pay $77.33 to the plan on January 30, 2004, as Lost Earnings ($65.69) plus interest on Lost Earnings ($11.64) for the pay period ending March 2, 2001, in addition to the Principal Amount ($10,000) that was paid on April 13, 2001. This total corresponds with the final Total Due in the above chart (emphasized).

Appendix E—Model Application Form (Optional)

Voluntary Fiduciary Correction Program Application Form

This application form provides a recommended format for your VFC Program application. Please make sure you have attached all documents identified on the VFC Program Checklist (for example, proof of

payment). If you choose to use a different format to submit the required information for your VFC Program Application, your application must still include a completed copy of the VFC Program Checklist. Submit your application to the appropriate EBSA Regional Office. Check with the relevant Regional Office whether it accepts email submissions of VFC Program applications. For full application procedures, consult *www.dol.gov/ebsa/*.

Applicant Name(s) and Address(es) (street and email)

List separately: _____

_____

_____

List Transaction(s) Corrected

Check which transaction(s) listed in the VFC Program you have corrected:

____Delinquent Participant Contributions and Loan Repayments to Pension Plans
____Delinquent Participant Contributions to Insured Welfare Plans
____Delinquent Participant Contributions to Welfare Plan Trusts
____Loan at Fair Market Interest Rate to a Party in Interest
____Loan at Below-Market Interest Rate to a Party in Interest
____Loan at Below-Market Interest Rate to a Non-Party in Interest
____Loan at Below-Market Interest Rate Due to Delay in Perfecting Plan's Security Interest
____Loans Failing to Comply with Plan Provisions for Amount, Duration or Level Amortization
____Default Loans
____Purchase of an Asset by a Plan from a Party in Interest
____Sale of an Asset by a Plan to a Party in Interest
____Sale and Leaseback of Real Property to Employer
____Purchase of Asset by a Plan from a Non-Party in Interest at More Than Fair Market Value
Sale of an Asset by a Plan to a Non-Party in Interest at Less Than Fair Market Value
____Holding of an Illiquid Asset Previously Purchased by a Plan
____Payment of Benefits Without Properly Valuing Plan Assets on Which Payment is Based
____Duplicative, Excessive, or Unnecessary Compensation Paid by a Plan
____Expenses Improperly Paid by a Plan
____Payment of Dual Compensation to a Plan Fiduciary

Correction Amount

*Principal Amount: $*_____
Date Paid __/__/__
*Lost Earnings/Restoration of Profit: $*_____
Date Paid __/__/__

Narrative and Calculations

List:

(1) All persons materially involved in the Breach and its correction (*e.g.,* fiduciaries, service providers):

_____

_____

_____

(2) An explanation of the Breach, including the date(s) it occurred (attach separate sheets if necessary):

_____

_____

_____

(3) An explanation of how the Breach was corrected, by whom, and when (attach separate sheets if necessary):

_____

_____

_____

(4) For a correction of Delinquent Participant Contributions or Loan Repayments, provide a statement from a Plan Official identifying the earliest date on which participant contributions/loan repayments reasonably could have been segregated from the employer's general assets (attach supporting documentation on which Plan Official relied).

Number of days used to determine the date on which participant contributions/loan repayments withheld from employees' pay could reasonably have been segregated from the employer's general assets:

_____

_____

Description of how this date was determined, including the applicant's current contribution and/or repayment remittance practices:

_____

_____

_____

(5) For a correction of Delinquent Participant Contributions or Loan Repayments, provide a narrative describing any changes to the applicant's contribution and/or repayment remittance practices after the period of unpaid or late contributions and/or repayments, including any steps taken to prevent future delinquencies: (attach separate sheets if necessary)

_____

_____

_____

(6) Specific calculations demonstrating how Principal Amount and Lost Earnings or Restoration of Profits were calculated (attach separate sheets if necessary): If the Online Calculator was used, you only need to indicate this and attach a copy of the ''View Printable Results'' page.

____Online Calculator—''View Printable Results'' page attached.
____Manual calculation—see attached calculations, which must follow the method used in subparagraphs (i) through (iv) of section 5(b)(6). See Appendix D for a sample.

Supplemental Information

(1) Plan Sponsor Name:

_____

EIN: _____
Address: _____

(2)(a) Plan Name: _____

_____

Plan Number: _____

(2)(b) For Bulk Applicants (attach additional sheets identifying this information for each Plan named in the application involved in the transaction):

Plan Name: _____
Plan Sponsor EIN or date the most recent Form 5500 was filed: _____

(3) Plan Administrator Name:

_____

EIN: _____
Address: _____

(4) Name of Authorized Representative: (Submit written authorization signed by the Plan Official.)
Address: _____
Telephone: _____

(5) Name of Contact Person:

_____

Address: _____
Telephone: _____
Email: _____

(6) Date of Most Recent Annual Report Form 5500 Filing, if applicable: __/__/__ for Plan Year Ending: __/__/__

(7) Is Applicant Seeking Relief From Excise Tax Under PTE 2002–51?

____Yes—Either:
  ____Submit a copy of the notice to interested parties within 60 calendar days of this application and indicate date of the notice if not on the notice itself; or
  ____If you are relying on the exception to the notice requirement contained in section IV.C. of PTE 2002–51, provide a copy of a completed IRS Form 5330 or other written documentation and proof of payment.
____No.

(8) Proof of Payment:

____Canceled check
____Executed wire transfer
____Signed, dated receipt from the recipient of funds transferred to the plan (such as a financial institution)
____Bank statements for the plan's account
____Other: _____

Caution: The correction amount and the costs of correction cannot be paid from plan assets, including by charges against participant accounts or plan forfeiture accounts.

(9) Disclosure of a current investigation or examination of the plan by an agency, to comply with section 3(b)(3)(v):

____PBGC
____Any state attorney general
State: _____
____Any state insurance commissioner
State: _____
____Other federal governmental agency: ____
____Contact person for the agency identified:

(10) Be sure to include the required VFC Program Application Checklist and all other documentation identified as being enclosed. The checklist is available at *http://www.dol.gov/ebsa/calculator/2006vfcpchecklist.html.*

(11) In order to help us improve our service, please indicate how you learned about the VFC Program: _____

Authorization of Representative

I have authorized (insert name of authorized representative) to represent me concerning this VFC Program application.

Name of Plan Official

_____

Signature of Plan Official

_____
Date _____

Penalty of Perjury Statement

The following statement must be signed and dated by a plan fiduciary, or bulk applicant, with knowledge of the transaction that is the subject of the application and by the authorized representative, if any. Each Plan Official applying under the VFC Program must also sign and date the statement, which must accompany any subsequent additions to the application.

''Under penalties of perjury I certify that I am not Under Investigation (as defined in section 3(b)(3) of the VFC Program) and that I have reviewed this application, including all supporting documentation, and to the best of my knowledge and belief the contents are true, correct, and complete.''

_____
Name and Title
Signature _____
Date _____

_____
Name and Title
Signature _____
Date _____

Paperwork Reduction Act Notice

The information identified on this form is required for a valid application for the Voluntary Fiduciary Correction Program of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA). You are not required to use this form; however, you must supply the information identified in order to receive the relief offered under the Program with respect to a breach of fiduciary responsibility under Part 4 of Title I of ERISA. EBSA will use this information to determine whether you have satisfied the requirements of the Program. EBSA estimates that assembling and submitting this information will require an average of 7 hours. This collection of information is currently approved under OMB Control Number 1210–0118. You are not required to respond to a collection of information unless it displays a currently valid OMB Control Number.

VFC Program Application Checklist (Required)

Use this checklist to make sure you are submitting a complete application. Indicate ''Yes'', ''No'' or ''N/A'' next to each item. A ''No'' answer or the failure to include a completed checklist will delay review of the application until all required items are received. The applicant must sign and date the checklist and include it with the application. Check with the relevant Regional Office whether it accepts email submissions of VFCP applications.

____1. Have you reviewed the eligibility, definitions, transaction and correction, and documentation sections of the VFC Program?
____2. Have you included the name, address (street or email) and telephone number of a contact person familiar with the contents of the application?
____3. Have you provided the EIN, Plan Number, and address (street and email) of the plan sponsor and plan administrator?
____4. Have you provided the date that the most recent Form 5500 was filed by the plan (or for a bulk application as described in section 4(d), the nine-digit employer identification number for each plan sponsor of a named plan)?
____5. Have you enclosed a signed and dated certification under penalty of perjury for the plan fiduciary with knowledge of the transactions and for each applicant and the applicant's representative, if any? In the case of a bulk application, have you enclosed a signed and dated certification under penalty of perjury for the bulk applicant based on knowledge of the transactions and for the bulk applicant's representative, if any?
____6. Have you enclosed relevant portions of the plan document and any other pertinent documents (such as the adoption agreement, trust agreement, or insurance contract) with the relevant sections identified?
____7. If applicable, have you provided written notification to EBSA of any current investigation or examination of the plan, or of the applicant or plan sponsor in connection with an act or transaction directly related to the plan by the PBGC, any state attorney general, or any state insurance commissioner?
____8. If applicable (under section 4(b)(2) of the Program), have you included the following items?
____a. Contact information for the law enforcement agency notified of the criminal activity;
____b. A statement from the applicant asserting no involvement in the potential criminal activity; and
____c. A statement as to whether a claim relating to the criminal activity has been made under an ERISA section 412 fidelity bond.
____9. Where applicable, have you enclosed a copy of an appraiser's report?
____10. Where applicable, have you enclosed a copy of an independent fiduciary's approval?
____11. Have you enclosed supporting documentation, including:
____a. A detailed narrative of the Breach, including the date it occurred;
____b. Documentation that supports the narrative description of the transaction;
____c. An explanation of how the Breach was corrected, by whom and when, with supporting documentation;
____d. A list of all persons materially involved in the Breach and its correction (*e.g.,* fiduciaries, service providers, borrowers, lenders);
____e. Specific calculations demonstrating how Principal Amount and Lost Earnings or Restoration of Profits were computed, or, if the Online Calculator was used, a copy of the ''Print Viewable Results'' page(s) after completing use of the Online Calculator;
____f. Proof of payment of principal amount;
____g. Proof of payment of lost earnings or restoration of profits to the plan; and
____Caution: The correction amount and the costs of correction cannot be paid from plan assets, including by charges against participant accounts or plan forfeiture accounts.
____h. If application concerns delinquent participant contributions or loan repayments, a statement from a Plan Official identifying the earliest date on which participant contributions/loan repayments reasonably could have been segregated from the employer's general assets and supporting documentation on which the Plan Official relied?
____12. If you are an eligible applicant and wish to avail yourself of excise tax relief under the VFC Program Class Exemption:
____a. Have you made proper arrangements to provide within 60 calendar days after submission of this application a copy of the VFC Program Class Exemption notice to all interested persons and to the EBSA Regional Office to which the application is filed; or
____b. If you are relying on the exception to the notice requirement in section IV.C. of the VFC Program Class Exemption because the amount of the excise tax otherwise due would be less than or equal to $100.00, have you provided to the appropriate EBSA Regional Office a copy of a completed IRS Form 5330 or other written documentation containing the information required by IRS Form 5330 and proof of payment?
____13. In calculating Lost Earnings, have you elected to use:
____a. The Online Calculator; or
____b. A manual calculation performed in accordance with section 5(b) of the VFC Program?
____14. If the application involves payments to participants and beneficiaries:
____a. Have you enclosed a description demonstrating proof of payment to participants and beneficiaries whose current location is known to the plan and/or applicant in accordance with section 5(d) of the VFC Program?
____b. For individuals who need to be located, have you demonstrated how adequate funds have been segregated to pay missing individuals and included a description of the process that you commenced to locate missing individuals in accordance with section 5(d)?
____15. For purposes of the three transactions involving participant contributions covered under section 7.1, has the plan implemented measures to ensure that such transactions do not recur?

Signature of Applicant and Date Signed:

_____
Name of Applicant: _____
Title/Relationship to the Plan: _____
Name of Plan, EIN and Plan Number: _____
Contact information: Phone; email _____

Paperwork Reduction Act Notice

The information identified on this form is required for a valid application for the Voluntary Fiduciary Correction Program of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA). You must complete this form and submit it as part of the application in order to receive the relief offered under the Program with respect to a breach of fiduciary responsibility under Part 4 of Title I of ERISA. EBSA will use this information to determine that you have satisfied the requirements of the Program. EBSA estimates that completing and submitting this form will require an average of 2 to 4 minutes. This collection of information is currently approved under OMB Control Number 1210–0118. You are not required to respond to a collection of

information unless it displays a currently valid OMB Control Number.

Appendix F: SCC Retention Record Checklist

Delinquent Participant Contributions or Loan Repayments

A self-corrector must complete this checklist, prepare or collect the listed documents and provide a copy of the completed checklist and the required documentation to the plan administrator (generally the plan sponsor/employer) to obtain relief under the SCC.

____Did you attach a brief statement explaining why the employer retained the participant contributions or loan repayments instead of timely forwarding such amounts to the plan (the Breach).

____Did you attach proof of payment, such as canceled checks, executed wire transfers, bank statements for the plan's account, or other documents showing the actual date the plan received the corrective payment(s)? If you paid the total amount of delinquent contributions and loan repayments (Principal Amount) separately from the total amount of earnings (Lost Earnings) that would have been earned on the Principal Amount but for the delinquency, make sure to attach proof of payment of both amounts. (Caution—Plan Assets, including charges to participant accounts or plan forfeiture accounts, cannot be used to pay the correction amount or the costs of correction);

____Did you attach other documents (if any) to support proof of payment, such as offsetting overpayments or annotations that provide a clear record of the correction?

____Did you attach a copy of the page(s) that results from the ''View Printable Results'' function of the Online Calculator? Self-correctors must use the Online Calculator to determine Lost Earnings and print a copy of the ''View Printable Results'' page.

____Did you attach a statement describing policies and procedures (if any) that the employer put into place to prevent future delinquencies of participant contributions or loan repayments?

____Did you attach a copy of the SCC Notice Acknowledgement and Summary page that you received from EBSA after submission of the SCC notice?

____Did a plan fiduciary and each plan official seeking relief complete the following Penalty of Perjury Statement and provide the signed statement to the plan administrator?

Penalty of Perjury Statement—The following statement must be signed and dated by a plan fiduciary with knowledge of the transaction that is the subject of the SCC notice and by the authorized representative, if any. Each plan official who is seeking the relief afforded under the SCC must also sign and date the statement, which must be retained by the plan administrator.

Under penalties of perjury I certify that I am not Under Investigation (as defined in VFC Program section 3(b)(3)) and that I have reviewed the SCC notice acknowledgement and summary, the checklist and all the required documentation, and to the best of my knowledge and belief the contents are true, correct, and complete.

Name and Title _____
Signature _____
Date _____
Name and Title _____
Signature _____
Date _____

____Did a plan official complete the following authorization, if an authorized preparer was used to submit the SCC notice?

Authorization of Plan Official

I have authorized _____ to submit the VFCP SCC notice.

Name of Plan Official _____
Signature _____
Date _____

Paperwork Reduction Act Notice

The information identified on this form is required for a valid use of the Self-Correction Component for Delinquent Participant Contributions or Loan Repayments of the Voluntary Fiduciary Correction Program of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA). You must complete this form and provide a copy of the completed checklist and the required documentation to the plan administrator to receive the relief under the Self-Correction Component of the Program with respect to the breach of fiduciary responsibility under Part 4 of Title I of ERISA associated with the delinquent participant contributions or loan repayments. EBSA may request a copy of this information to determine that you have satisfied the requirements of the Self-Correction Component of the Program. EBSA estimates assembling this information will require an average of 4 hours and completing this form will require an average of 2 to 4 minutes. This collection of information is currently approved under OMB Control Number 1210–0118. You are not required to respond to a collection of information unless it displays a currently valid OMB Control Number.

Signed at Washington, DC, this 7th day of November, 2022.

Lisa M. Gomez

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2022–24703 Filed 11–18–22; 8:45 am]

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FEDERAL REGISTER

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No. 223 November 21, 2022

Part V

The President

Memorandum of November 10, 2022—Delegation of Authority Under Section 506(a)(1) of the Foreign Assistance Act of 1961

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Presidential Documents

Title 3—

The President

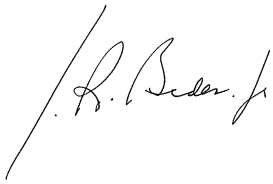
Memorandum of November 10, 2022

Delegation of Authority Under Section 506(a)(1) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(1) of the FAA to direct the drawdown of up to $400 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Ukraine and to make the determinations required under such section to direct such a drawdown.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, November 10, 2022

[FR Doc. 2022–25522
Filed 11–18–22; 11:15 am]
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