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.

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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.

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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*).
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10. * FDA Memorandum, ''Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223),'' September 2022.
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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*).
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15. * FDA Memorandum, ''Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing,'' October 2022.
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2022 Edition),'' June 2022 (*https://www.fda.gov/media/80637/download*).
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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.

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