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OFFICE OF MANAGEMENT AND BUDGET

2 CFR Part 200

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Office of Management and Budget.

ACTION: Guidance.

SUMMARY: This document announces the availability of the first of two 2021 Compliance Supplement Addenda (2021 Addendum 1) for the Office of Management and Budget's uniform administrative requirements, cost principles, and audit requirements regulations. This document also offers interested parties an opportunity to comment on the 2021 Addendum 1.

DATES: The 2021 Addendum 1 serves as a complement to the 2021 Compliance Supplement published on August 13, 2021 (FR Doc. 2021–17363) and applies to fiscal year audits beginning after June 30, 2020. All comments to the 2021 Addendum 1 must be in writing and received by January 3, 2022. Late comments will be considered to the extent practicable.

ADDRESSES: Comments will be reviewed and addressed, when appropriate, in the 2022 Compliance Supplement. Electronic mail comments may be submitted to: *http://www.regulations.gov.* Please include ''2 CFR part 200 Subpart F—Audit Requirements, Appendix XI—Compliance Supplement Addendum—2021 1'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be sent to: *GrantsTeam@omb.eop.gov.*

Please note that all public comments received are subject to the Freedom of Information Act and will be posted in their entirety, including any personal and/or business confidential information provided. Do not include any information you would not like to be made publically available.

The 2021 Addendum 1 with Part 4 of the two American Rescue Plan Act (ARP) programs is available online on the CFO homepage at *https://www.cfo.gov/policies-and-guidance/.*

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. The Federal agency contacts are listed in appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies should contact Gil Tran at *Hai_M._Tran@omb.eop.gov* or (202) 395–3052 or the OMB Grants team at *GrantsTeam@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The 2021 Addendum 1 (2 CFR part 200, subpart F, appendix XI) adds audit guidance for two new ARP programs to Part 4 of the 2021 Compliance Supplement. The programs are: (1) Treasury's Coronavirus State and Local Fiscal Recovery Funds (assistance listing number 21.027), and (2) Education's Education Stabilization Fund (assistance listing number 84.425). Other Parts of the 2021 Compliance Supplement remain unchanged.

As Federal awarding agencies are implementing additional ARP programs, OMB will continue to work with them to identify the new ARP programs that have special compliance and reporting requirements. When completed by the agencies and reviewed by OMB, these audit guides will be published as on the *CFO.gov* website as Addendum 2 to the 2021 Compliance Supplement.

Agencies have identified the following potential programs for Addendum 2.

USDA 10.542—Pandemic EBT—Food Benefits
USDA 10.649—Pandemic EBT—Admin Costs
HHS 93.575—Child Care and Development Block Grant
HHS 93.499—Low Income Household Water Assistance Program
HHS 93.558—TANF
HUD 14.871—Section 8 Housing Choice Vouchers
DOT 20.315—National Railroad Passenger Corporation Grants

Deidre A. Harrison,
Acting Controller.

[FR Doc. 2021–26238 Filed 12–2–21; 8:45 am]
BILLING CODE 3110–01–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 2

[Docket No. APHIS–2020–0101]

RIN 0579–AC69

Handling of Animals; Contingency Plans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Animal and Plant Health Inspection Service issued a final rule on December 31, 2012, to establish regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers must meet certain requirements for contingency planning and training of personnel. Implementation of the final rule was stayed on July 31, 2013, so that the agency could conduct additional review to further consider the impact of contingency plan requirements on regulated entities. Since that time, we have conducted such a review, and the 2021 Congressional Appropriations Act has required us to propose to lift the stay. We are therefore lifting the stay and making minor revisions to the requirements in order to update compliance dates and clarify intent. The lifting of the stay and proposed revisions will better ensure that entities responsible for animals regulated under the Animal Welfare Act are prepared to safeguard the health and welfare of such animals in the event of possible emergencies or disasters.

DATES: Effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Theodorson, DVM, MPH, Assistant Deputy Administrator, Animal Care, APHIS, 4700 River Road, Unit 86, Riverdale, MD 20737; (970) 494–7473.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Welfare Act (AWA) (7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary has delegated authority for administering the AWA to the Administrator of the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for APHIS' Animal Care program (AC). Regulations and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations).

Following the events experienced during the 2005 hurricane season, AC concluded that entities responsible for animals covered by the AWA could better safeguard the health and welfare of their animals by developing contingency plans for possible emergencies or disasters. Consequently, on December 31, 2012, APHIS published in the **Federal Register** (77 FR 76815–76824, Docket No. APHIS–2006–0159) a final rule [1] establishing regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers of animals regulated under the AWA must meet certain requirements for developing contingency plans and training personnel in their role and responsibilities related to the contingency plan.

After learning that a number of small entities considered the requirements of these regulations excessive for their specific cases, and determining there to be validity to such a claim, on July 31, 2013, we published in the **Federal Register** (78 FR 46255, Docket No. APHIS–2006–0159) a stay [2] of the regulations to reexamine any unique circumstances and costs that may vary by the type and size of businesses affected by the final rule.

Since that time, APHIS has issued *de minimis* exemptions to animal licensure that we believe address the concerns that led to the stay. Additionally, on December 27, 2020, the 2021 Congressional Appropriations Act (Pub. L. 116–260) required APHIS to propose to lift the stay on the final rule establishing contingency plan requirements within 180 days of issuance of that Act.

On June 25, 2021, we published in the **Federal Register** (86 FR 33567–33570, Docket No. APHIS–2020–0101) a proposal [3] to lift the stay and make minor changes to the contingency plan regulations. These changes included updating the compliance dates by which regulated entities must create their contingency plans to 180 days after the effective date of this final rule; modifying the dates regarding when regulated entities must provide training to personnel to 60 days after the contingency plan being put in place; removing an extraneous reference to additional requirements for marine mammals to minimize confusion; removing the requirement that facilities as well as dealers, exhibitors, intermediate handlers, and carriers document their personnel's participation in requisite trainings; and adding a reference to a new optional form that entities may use to develop and document a contingency plan.

We solicited comments concerning our proposal for 60 days ending August 24, 2021. We received 140 submissions representing 35,654 comments by that date (one of the submissions had 35,000-plus form comments in support of the rule attached). They were from non-profit organizations; businesses; an association of research centers; national and state associations for biomedical research; associations of zoos, aquariums, and marine parks; veterinary associations; animal welfare organizations; and members of the public.

Of the 140 submissions, 138 supported the rule, and most exhorted us to finalize it without change to the rule or supporting documents. The comments that we received are discussed below by topic.

Contingency Plans

One commenter claimed that creating a contingency plan would be impossible for them because they had too many animals spread over too much acreage to shelter them in one location in the event of an emergency. The commenter noted that their animals used scattered shelters in extreme weather and that their geographical location was not at risk of flooding.

The regulations require entities to identify potential emergencies or disasters they are likely to experience and outline specific tasks to take (such as evacuation or shelter-in-place instructions) in the event that these situations occur.

The use of scattered shelters in extreme weather is an example of what could be an appropriate response to a potential emergency or disaster depending on an entity's circumstances. As such, the regulations authorize their use, if a regulated entity considers them appropriate based on the entity's unique circumstances. The regulations also do not require an entity to plan a response to flooding if flooding could not reasonably be anticipated.

Another commenter suggested that, instead of requiring entities to create contingency plans, USDA should provide yearly educational coaching on best practices for facility management and animal care.

While USDA inspectors will provide advice on facility management and animal care during inspections, such advice is not a sufficient replacement for this rule. The adverse events due to lack of planning detailed in the proposed rule and its supporting economic analysis outline the need for regulatory action. Accordingly, APHIS maintains that regulations are necessary to ensure the safety and well-being of animals under the care of regulated entities in compliance with the AWA.

Four commenters suggested APHIS provide additional resources for entities creating contingency plans, such as training materials, webinars, or links for further reading.

APHIS AC will conduct internal and external webinars regarding contingency planning and provide outreach materials on the APHIS website such as Frequently Asked Questions, aids, resources for further reading, and contact information in case entities have further questions.

Another commenter suggested that USDA develop sample templates, provide training for USDA inspectors who will help entities develop contingency plans, and obtain funding for this training.

As stated in the proposed rule, APHIS has provided an optional form that regulated entities may use as a template. This template was published alongside the proposed rule and will be available on the APHIS website. The APHIS website will also include various outreach materials to assist with contingency planning. AC's Center for Animal Welfare has developed a plan to implement the contingency planning regulations and has trained its personnel accordingly. This training is possible without additional funding

[1] To view the final rule, go to *https://www.regulations.gov/document/APHIS-2006-0159-0209*.

[2] To view the stay of the regulations, go to *https://www.regulations.gov/document/APHIS-2006-0159-0214*.

[3] To view the proposed rule, the comments we received, and supporting documents go to *www.regulations.gov* and type APHIS–2020–0101 into the Search field.

apart from that appropriated by Congress for AC's ongoing operations.

Another commenter asked for the contingency requirements to be more prescriptive. Specifically, the commenter wanted APHIS to require entities to create contingency plans for the potential death of an owner and heat waves.

The regulations require a regulated entity to identify emergencies or disasters that could reasonably be anticipated and that would be detrimental to the well-being of their animals. We expect that, for most entities, it would be difficult to reasonably anticipate death.

If an entity determines that they are located in an area prone to heat waves that could be reasonably anticipated to be harmful to their animals, they would need to address heat waves in their contingency plans. However, an entity located in an extremely temperate climate may assess climatic conditions and determine a heat wave to be unlikely. APHIS believes that regulated entities themselves are best suited to make such determinations, and therefore will not provide a one-size-fits-all list of emergencies or disasters that all entities must plan for.

Another commenter requested explicit acknowledgement that plans developed for compliance with The Guide for the Care and Use of Laboratory Animals (The Guide) comply with this rule's contingency plan regulations.

Contingency plans developed using The Guide are acceptable so long as they fulfill the requirements laid out in the regulations.

The commenter also requested assurance that APHIS will not view deviations from contingency plans in emergency situations as violations, but as on-the-ground efforts to tailor the plan to specific events and opportunities to improve the contingency plan.

APHIS agrees with the commenter that the actual response may vary from the written contingency plan in an emergency situation, and that these variations can serve as a basis for updating and improving a contingency plan. If an entity varies its response from its written contingency plan in order to better meet the needs of an unfolding emergency situation, this would not necessarily be viewed as a violation. In such situations, APHIS would determine whether or not a violation has occurred on a case-by-case basis, based on whether the deviation furthers the purpose of the regulation, which is to safeguard the health and welfare of animals in the event of possible emergencies or disasters.

One commenter suggested requiring regulated entities to submit their contingency plans to USDA for review.

We are making no changes in response to the commenter. Submitting a plan to APHIS is not the sole means to demonstrate that a plan has been developed and satisfies the requirements of the regulations, and would impose a significant resource constraint on AC to receive and compile the plans and ensure their confidentiality. Rather, AC will ensure compliance with this rule through reviewing the entity's plan during announced and unannounced inspections. We believe that this method of enforcing the requirements provides sufficient assurance that the contingency planning requirements are being met while minimizing regulatory burden on entities and more efficiently allocating agency resources.

One commenter urged APHIS to take further action to ensure that an entity's contingency plans are kept confidential.

APHIS will not maintain the plans. Therefore, this rule does not raise confidentiality concerns.

Training

A commenter wrote that the regulatory text should overtly state that it is up to the regulated entity to determine who needs to be trained and how.

The entity is responsible for including all personnel encompassed by the plan in the training and is responsible for the content and delivery of the training. We do not believe it is necessary to add this statement into the regulatory text, as the regulations do not state or imply otherwise.

The commenter also asked that the regulatory text clarify that only substantive changes to a contingency plan would necessitate updated training.

We agree with the commenter that non-substantive changes, which could include revisions as minor as reordering of instructions or grammatical corrections, do not necessitate updated training, and have made this change in §§ 2.38(l)(3) and 2.134(c). Our intent was that only substantive changes, that is, changes that materially alter the plan, would require updated training.

The commenter also asked that the 60- or 30-day training deadlines that we proposed be extended to 90 days for both initial and subsequent training of personnel.

We are making no changes in response to this comment. Training required by the regulations entails familiarizing personnel with their roles and responsibilities as outlined in the contingency plan. APHIS believes the deadlines in the proposed rule (60 days for initial training and 30 days for new employees and updates to the contingency plan) are sufficient time to provide this basic training, and the commenter did not provide information suggesting this basic training could not be accomplished within that time period.

As noted above, we proposed to remove a requirement from the stayed final rule that facilities as well as dealers, exhibitors, intermediate handlers, and carriers document their personnel's participation in requisite trainings. Seven commenters disagreed with our proposed removal and asked for it to be reinstated.

APHIS does not believe that requiring entities to keep training records would significantly increase compliance with the training requirements, but it would increase burden on regulated entities.

Rather than require documentation, we will evaluate compliance with the training requirement through discussions with the licensee or registrant during announced and unannounced inspections. APHIS AC successfully enforces other training requirements in this manner, and is confident that this model will work for the regulations promulgated in this rule as well. Therefore, we are making no change in response to the commenters.

Economic Analysis

Two commenters stated that our estimates for the time it will take entities to create contingency plans and train personnel are too low.

Our estimates are averages based on the varying sizes of the entities and the optional fillable template the agency is providing. Some entities may require less time, and some will require more. Additionally, based on the comments received, it appears that most entities will not be formulating their plans de novo. Several commenters who were regulated entities themselves opined that it would be difficult for a regulated entity to remain operational without at least some contingency planning, and a few commenters stated that the regulated entities they represented already have contingency plans in place that meet the requirements of the rule. Indeed, one of the commenters who stated that our estimates were too low also stated that the entities that it represents already have plans in place and should not incur new costs as a result of the rule.

Based on the comments received, we believe that the 1-to-2-hours for plan

creation and 1 hour for training estimates, relative to the current plans maintained and training conducted by the entity, are reasonable.

One commenter stated that costs are unlikely to drop to zero after the first year.

We are not assuming that there will be no reoccurring annual costs after the first year of the implementation of the rule. We believe that the costs after the first year of developing and implementing contingency plans will decrease for existing entities as they would have already incurred the initial development and implementation costs.

The commenter also stated that, while they agree that capital costs will vary between entities, these costs will not be minimal.

The proposed rule did not prescribe any capital investments that entities must make. The entities vary by size and type and will have different requirements in terms of equipment. While some entities may incur costs to purchase equipment, others may already have equipment as a part of their business operations. We also note that the same commenter stated that the entities it represents had already assumed those costs apart from this rule as a cost of doing business.

Environmental Analysis

One commenter questioned why an environmental analysis was prepared, since they expected contingency plans to have only a positive impact on the environment.

APHIS conducted an environmental assessment based on the Council on Environmental Quality's (CEQ's) newly revised implementing procedures. The National Environmental Policy Act (NEPA) reviews all potential impacts, not just those with negative implications (40 CFR 1508.1(g)(1)).

Other Comments

A commenter asked that contingency plan regulations for marine mammals in 9 CFR 3.101(b) be eliminated.

This is outside of this rule's scope.

A commenter stated that there was a lack of a clear definition for the term ''breeding female'' as used in AWA regulations.

This is also outside of this rule's scope.

Miscellaneous

Finally, in reviewing the proposed rule with an eye toward implementation, we noticed that the explanations of training deadlines in §§ 2.38(l)(3) and 2.134(c) were ambiguous and did not clearly reflect APHIS' intent in drafting the proposed rule. We intended to state that if an employee was hired before or up to 30 days after a facility has its plan in place, that employee would have to be trained within 60 days of the plan being in place, whereas, if an employee was hired after that date, the facility would have 30 days to train the employee. However, the proposed rule could be read to suggest that employees hired at least 30 days before the plan is put in place must be trained by the time the plan is put in place, which would require training in the provisions of the plan before the plan itself was finalized. Requiring training in a plan that is not yet finalized and in place could be logistically problematic for regulated entities and, again, was not APHIS' intent. We have revised the paragraphs accordingly to make our intent clearer.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 3 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are amending the AWA regulations to implement contingency plans for the handling of animals during emergencies. In December 2012, the USDA's APHIS published a final rule requiring all dealers, exhibitors, intermediate handlers, carriers, research facilities, and other entities regulated under the AWA to take steps to be better prepared for potential emergencies and disasters (situations which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in the regulated entity's possession). In July 2013, USDA issued a stay of the Contingency Plan Regulation in order to undertake a review of its requirements. In June of 2021, we published a proposed rule to lift the stay on the December 2012 rulemaking along with other minor administrative changes. This final rule will codify the provisions of the proposed rule and lift the stay on the 2012 final rule.

While it is difficult to quantify the benefits of contingency planning, they are numerous. First, contingency planning can prevent loss of animal life and any resulting undisposed carcasses that pose a threat to public health. Second, loss of valuable research resources and income can be mitigated with contingency planning. Third, having a contingency plan can reduce the time of recovery from disasters and thus provide cost savings to the affected businesses and organizations and allow for business continuity. Finally, required contingency planning will reassure the general public that facilities have measures in place to ensure the welfare of the animals in times of catastrophic and common emergencies.

APHIS' AC program will be providing a fillable form that can be used to develop and document the contingency plan; however, entities that have contingency plans in place may use those. For example, we believe that U.S. Public Health Service-funded research facilities and AZA zoos and aquariums have already developed contingency plans; they will not need to adopt the template. The template is intended to aid entities currently without a written contingency plan, and we estimate it will take on average 1–2 hours per entity to complete the plan, which includes the time to collect and document the required information. We anticipate that the use of this form will improve compliance and expedite the time for annual review by regulated entities of the plan. APHIS also estimates it will take, on average, 1 hour to train employees on the operations of the plan, which consists of familiarizing employees with their roles and responsibilities as outlined in the plan.

We estimated lower and upper range estimates of costs for licensees and registrants to develop contingency plans in the first year. As noted above, we assume an average of 1 to 2 hours is required to prepare and implement a contingency plan using the form and 1 hour for employee training in the first year. We multiplied this time by the average industry-specific wage rate of the entities. Our estimate of the total one-time cost to develop the contingency plans across all affected entity categories ranges from about $185,000 to about $370,000 and $185,000 for employee training, as well as possible capital costs, which will differ from entity to entity and which we accordingly are not able to estimate in aggregate. These estimates may be high, given our inclusion of entities that may currently have comparable

contingency plans and already provide employee training, but for which we lack verifying information.

The 1 to 2 hours that we assume would be required to develop a contingency plan includes the time needed to identify resources for the plan's preparation and documentation. The 1-hour training estimate for all current and new employees considers the time it would take an employee to become familiar with their roles and responsibilities as outlined in the plan. The costs included in this analysis reflect training for the first year only. Contingency planning also requires record keeping, ensuring that the contingency plans are kept current, and employee training. The type of training and type of contingency plan required may differ depending on the type of organization or business, as well as its location and the location's climate history.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the creation of contingency plans will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the CEQ for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the *Regulations.gov* website.[4] Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, Room 1620, South Building, 14th Street and Independence Avenue SW, Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

In accordance with Section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule have been submitted to the Office of Management and Budget (OMB) for approval under control number 0579–0479. When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483.

List of Subjects in 9 CFR Part 2

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we are amending 9 CFR part 2 as follows:

PART 2—REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

■ 2. Amend § 2.38:
■ a. By lifting the stay on paragraph (l) published at July 31, 2013 (78 FR 46255);
■ b. In paragraph (l)(2):
■ i. In the first sentence by removing the date ''July 29, 2013'' and adding ''July 5, 2022'' in its place;
■ ii. In the fifth sentence by removing the words ''and training records''; and
■ iii. By revising the last sentence; and
■ c. By revising paragraph (l)(3); and
■ d. By adding an OMB citation at the end of the section.

The revisions and addition read as follows:

§ 2.38 Miscellaneous.

* * * * *

(l) * * *

(2) * * * The APHIS Contingency Plan form may be used to keep and maintain the information required by paragraph (l)(1) and (2) of this section.

(3) The facility must provide training for its personnel regarding their roles and responsibilities as outlined in the plan. For current registrants, training of facility personnel must be completed within 60 days of the research facility putting their plan in place; for research facilities registered after July 5, 2022, training of facility personnel must be completed within 60 days of the facility putting its contingency plan in place. This deadline applies to employees hired before and up to 30 days after the facility puts its contingency plan in place. For employees hired more than 30 days after the facility puts its contingency plan in place, training must be conducted within 30 days of their start date. Any substantive changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

(Approved by the Office of Management and Budget under control number 0579–0479)

■ 3. Amend § 2.134:
■ a. By lifting the stay on the section published July 31, 2013 (78 FR 46255);
■ b. In paragraph (b):
■ i. In the first sentence by removing the date ''July 29, 2013'' and adding ''July 5, 2022'' in its place;
■ ii. In the fifth sentence by removing the words ''and training records''; and
■ iii. By revising the last sentence; and
■ c. By revising paragraph (c); and
■ d. By adding an OMB citation at the end of the section.

The revisions and addition read as follows:

§ 2.134 Contingency planning.

* * * * *

[4] Go to *www.regulations.gov*. Enter APHIS–2020–0101 in the Search field. The environmental assessment and finding of no significant impact will appear in the list of documents.

(b) * * * The APHIS Contingency Plan form may be used to keep and maintain the information required by § 2.38(l)(1) and (2).

(c) Dealers, exhibitors, intermediate handlers, and carriers must provide training for their personnel regarding their roles and responsibilities as outlined in the plan. For current licensees and registrants, training of dealer, exhibitor, intermediate handler, and carrier personnel must be completed within 60 days of the licensee and registrant putting their contingency plan in place; for new dealers, exhibitors, intermediate handlers, or carriers licensed or registered after July 5, 2022, training of personnel must be completed within 60 days of the dealer, exhibitor, intermediate handler, or carrier putting their contingency plan in place. This deadline applies to employees hired before and up to 30 days after the date the licensee or registrant puts its contingency plan in place. For employees hired more than 30 days after the date the licensee or registrant puts its contingency plan in place, training must be conducted within 30 days of their start date. Any substantive changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

(Approved by the Office of Management and Budget under control number 0579–0479)

Done in Washington, DC, this 26th day of November 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–26174 Filed 12–2–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0801; Airspace Docket No. 20–ASO–29]

RIN 2120–AA66

Establishment of Class E Airspace; Fulton, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface for Fulton Airport, Fulton, KY, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Effective 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace for Fulton Airport, Fulton, KY.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 52622, September 22, 2021) for Docket No. FAA–2021–0801 to establish Class E airspace extending upward from 700 feet above the surface for Fulton Airport, Fulton, KY.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 7.3-mile radius at Fulton Airport, Fulton, KY, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. These changes are necessary for continued safety and management of IFR operations in the area.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is minimal. Since this is a routine matter that only affects air traffic procedures an air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO KY E5 Fulton, KY [New]

Fulton Airport, KY

(Lat. 36°31′32″ N, long. 88°55′04″ W)

That airspace extending upward from 700 feet above the surface within a 7.3-mile radius of Fulton Airport.

Issued in College Park, Georgia, on November 29, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–26237 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31400; Amdt. No. 3983]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 3, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 3, 2021.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff

Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on November 12, 2021.

Thomas J. Nichols,

Flight Standards Service Manager, Aviation Safety, Standards Section, Flight Procedures & Airspace Group Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CRF part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 30 December 2021

Denver, CO, KAPA, RNAV (GPS) RWY 17L, Amdt 2
Atlanta, GA, KATL, ILS OR LOC RWY 10, ILS RWY 10 (SA CAT I), ILS RWY 10 (CAT II), ILS RWY 10 (CAT III), Amdt 5
Atlanta, GA, KATL, ILS PRM RWY 10 (CLOSE PARALLEL), ILS PRM RWY 10 (SA CAT I) (CLOSE PARALLEL), ILS PRM RWY 10 (CAT II) (CLOSE PARALLEL), ILS PRM RWY 10 (CAT III) (CLOSE PARALLEL), Amdt 5
Greenville, MS, KGLH, ILS OR LOC RWY 18L, Amdt 10
Tarboro, NC, Tarboro-Edgecombe, Takeoff Minimums and Obstacle DP, Amdt 1
Hammonton, NJ, N81, RNAV (GPS) RWY 3, Amdt 1E
New York, NY, KSWF, RNAV (GPS) RWY 34, Amdt 1E
Philadelphia, PA, KPNE, LOC BC RWY 6, Amdt 8, CANCELLED
Philadelphia, PA, KPNE, RNAV (GPS) RWY 6, Amdt 1
Pecos, TX, KPEQ, RNAV (GPS) RWY 14, Orig-B
Pecos, TX, KPEQ, RNAV (GPS) RWY 32, Orig-C

Effective 27 January 2022

Headland, AL, Headland Muni, Takeoff Minimums and Obstacle DP, Orig-A
Decatur, AR, 5M5, RNAV (GPS) RWY13, Orig-C
Fayetteville/Springdale/Rogers, AR, KXNA, ILS OR LOC RWY 16, Amdt 4A
Fayetteville/Springdale/Rogers, AR, KXNA, ILS OR LOC RWY 34, Amdt 4A
Vidalia, GA, KVDI, RNAV (GPS) RWY 25, Amdt 2B
Emmetsburg, IA, KEGQ, NDB RWY 13, Amdt 3B, CANCELLED
Emmetsburg, IA, KEGQ, NDB RWY 31, Amdt 3B, CANCELLED
Rock Rapids, IA, KRRQ, RNAV (GPS) RWY 16, Amdt 2
Sheldon, IA, KSHL, RNAV (GPS) RWY 15, Amdt 2
Concordia, KS, KCNK, RNAV (GPS) RWY 17, Orig-C, CANCELLED
Concordia, KS, KCNK, RNAV (GPS) RWY 18, Orig
Concordia, KS, KCNK, RNAV (GPS) RWY 35, Orig-B, CANCELLED
Concordia, KS, KCNK, RNAV (GPS) RWY 36, Orig
Concordia, KS, Blosser Muni, Takeoff Minimums and Obstacle DP, Orig
Concordia, KS, Blosser Muni, Takeoff Minimums and Obstacle DP, Amdt 1A, CANCELLED
Ottawa, KS, Ottawa Muni, Takeoff Minimums and Obstacle DP, Amdt 3
Syracuse, KS, Syracuse-Hamilton County Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Circle, MT, 4U6, RNAV (GPS) RWY 12, Amdt 1
Circle, MT, 4U6, RNAV (GPS) RWY 30, Amdt 1
Miles City, MT, Frank Wiley Fld, Takeoff Minimums and Obstacle DP, Amdt 2
Reidsville, NC, Rockingham County NC Shiloh, Takeoff Minimums and Obstacle DP, Amdt 3
Carlsbad, NM, KCNM, RNAV (GPS) RWY 21, Amdt 1B
Albion, NY, 9G6, RNAV (GPS)-B, Orig-A
Dunkirk, NY, KDKK, RNAV (GPS)-A, Orig-B
Ashtabula, OH, KHZY, VOR RWY 27, Amdt 7A, CANCELLED
Ashtabula, OH, KHZY, VOR–A, Orig-A, CANCELLED
Cleveland, OH, KCGF, ILS OR LOC RWY 24, Amdt 16C
Zanesville, OH, Zanesville Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Johnstown, PA, KJST, VOR Y RWY 15, Amdt 9B
Eagle Butte, SD, Cheyenne Eagle Butte, Takeoff Minimums and Obstacle DP, Amdt 1
Gettysburg, SD, 0D8, RNAV (GPS) RWY 13, Amdt 2B
Gettysburg, SD, 0D8, RNAV (GPS) RWY 31, Amdt 2B
Alpine, TX, Alpine-Casparis Muni, ODKAE ONE Graphic DP
Alpine, TX, Alpine-Casparis Muni, Takeoff Minimums and Obstacle DP, Amdt 6

Amarillo, TX, KTDW, RNAV (GPS) RWY 35, Orig-C
Corsicana, TX, KCRS, NDB RWY 14, Amdt 4D, CANCELLED
Fort Worth, TX, KFWS, ILS OR LOC RWY 36L, Amdt 2D
Fort Worth, TX, KFWS, RNAV (GPS) RWY 18R, Amdt 1D
Fort Worth, TX, KFWS, RNAV (GPS) RWY 36L, Amdt 1C
Fort Worth, TX, Fort Worth Spinks, Takeoff Minimums and Obstacle DP, Amdt 3A
San Antonio, TX, 5C1, RNAV (GPS) RWY 17, Amdt 1D
San Antonio, TX, 5C1, RNAV (GPS) RWY 35, Amdt 1C
Viroqua, WI, Y51, RNAV (GPS) RWY 11, Orig

[FR Doc. 2021–26286 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31401; Amdt. No. 3984]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 3, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 3, 2021.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a

''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on November 12, 2021.

Thomas J. Nichols,

Flight Standards Service Manager, Aviation Safety, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, (is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Dec–21	AL	Enterprise	Enterprise Muni	1/0144	8/17/21	RNAV (GPS) RWY 5, Amdt 1A.
30–Dec–21	AL	Enterprise	Enterprise Muni	1/0160	8/17/21	VOR RWY 5, Amdt 4A.
30–Dec–21	NH	Whitefield	Mount Washington Rgnl	1/0321	9/3/21	RNAV (GPS) Y RWY 10, Orig.
30–Dec–21	AL	Fayette	Richard Arthur Fld	1/0444	9/3/21	RNAV (GPS) RWY 1, Amdt 1C.
30–Dec–21	MO	Farmington	Farmington Rgnl	1/0498	9/9/21	RNAV (GPS) RWY 20, Orig-A.
30–Dec–21	AR	Morrilton	Petit Jean Park	1/0673	7/30/21	RNAV (GPS) RWY 3, Orig.
30–Dec–21	KY	Danville	Stuart Powell Fld	1/0681	10/28/21	LOC RWY 30, Amdt 1D.
30–Dec–21	KY	Danville	Stuart Powell Fld	1/0683	10/28/21	NDB–A, Amdt 8A.
30–Dec–21	KY	Danville	Stuart Powell Fld	1/0684	10/28/21	RNAV (GPS) RWY 30, Orig-A.
30–Dec–21	NJ	Hammonton	Hammonton Muni	1/1207	9/3/21	VOR–B, Amdt 2D.
30–Dec–21	TX	Childress	Childress Muni	1/1210	7/30/21	RNAV (GPS) RWY 36, Amdt 1A.
30–Dec–21	TX	Childress	Childress Muni	1/1211	7/30/21	VOR RWY 36, Amdt 10A.
30–Dec–21	AZ	Springerville	Springerville Muni	1/1216	7/20/21	RNAV (GPS) RWY 21, Amdt 1C.
30–Dec–21	SC	Barnwell	Barnwell Rgnl	1/1223	8/17/21	RNAV (GPS) RWY 17, Amdt 2A.
30–Dec–21	SC	Barnwell	Barnwell Rgnl	1/1224	8/17/21	RNAV (GPS) RWY 35, Orig.
30–Dec–21	ND	Bottineau	Bottineau Muni	1/1258	7/1/21	RNAV (GPS) RWY 31, Orig.
30–Dec–21	SC	Pelion	Lexington County	1/1749	8/16/21	VOR–A, Amdt 3A.
30–Dec–21	AL	Ozark	Ozark-Blackwell Fld	1/1770	8/16/21	RNAV (GPS) RWY 13, Orig-B.
30–Dec–21	AL	Ozark	Ozark-Blackwell Fld	1/1771	8/16/21	RNAV (GPS) RWY 31, Orig-B.
30–Dec–21	AL	Ozark	Ozark-Blackwell Fld	1/1772	8/16/21	VOR RWY 31, Amdt 7B.
30–Dec–21	NH	Portsmouth	Portsmouth Intl At Pease	1/1805	11/3/21	RADAR 1, Amdt 1.
30–Dec–21	TX	Junction	Kimble County	1/1811	7/30/21	RNAV (GPS) RWY 17, Orig.
30–Dec–21	TX	Junction	Kimble County	1/1812	7/30/21	VOR–A, Amdt 12.
30–Dec–21	CO	Longmont	Vance Brand	1/1815	7/1/21	RNAV (GPS)-B, Amdt 1.
30–Dec–21	CO	Longmont	Vance Brand	1/1816	7/1/21	VOR/DME–A, Amdt 2A.
30–Dec–21	MT	Laurel	Laurel Muni	1/1844	11/5/21	VOR RWY 22, Amdt 2C.
30–Dec–21	SC	Aiken	Aiken Rgnl	1/1853	11/4/21	ILS OR LOC/DME RWY 7, Orig-D.
30–Dec–21	SC	Aiken	Aiken Rgnl	1/1855	11/4/21	NDB RWY 25, Amdt 10D.
30–Dec–21	SC	Aiken	Aiken Rgnl	1/1858	11/4/21	RNAV (GPS) RWY 7, Amdt 1D.
30–Dec–21	PA	East Stroudsburg	Stroudsburg-Pocono	1/1913	10/28/21	RNAV (GPS) RWY 8, Orig-A.
30–Dec–21	NJ	Robbinsville	Trenton-Robbinsville	1/2194	11/8/21	RNAV (GPS) RWY 11, Orig-B.
30–Dec–21	NJ	Robbinsville	Trenton-Robbinsville	1/2195	11/8/21	RNAV (GPS) RWY 29, Amdt 1B.
30–Dec–21	NJ	Robbinsville	Trenton-Robbinsville	1/2196	11/8/21	VOR RWY 29, Amdt 11B.
30–Dec–21	AL	Greenville	Mac Crenshaw Meml	1/2250	9/13/21	RNAV (GPS) RWY 14, Orig-B.
30–Dec–21	AL	Greenville	Mac Crenshaw Meml	1/2252	9/13/21	RNAV (GPS) RWY 32, Orig-B.
30–Dec–21	TN	Jackson	Mc Kellar-Sipes Rgnl	1/2503	11/3/21	RNAV (GPS) RWY 20, Orig-A.
30–Dec–21	MO	Farmington	Farmington Rgnl	1/2516	9/8/21	RNAV (GPS) RWY 2, Orig-A.
30–Dec–21	PA	Chambersburg	Franklin County Rgnl	1/2616	8/16/21	RNAV (GPS) RWY 6, Orig-C.
30–Dec–21	PA	Chambersburg	Franklin County Rgnl	1/2617	8/16/21	RNAV (GPS) RWY 24, Orig-C.
30–Dec–21	PA	Chambersburg	Franklin County Rgnl	1/2618	8/16/21	VOR/DME–B, Amdt 2A.
30–Dec–21	NH	Haverhill	Dean Meml	1/2641	9/3/21	RNAV (GPS) RWY 19, Orig.
30–Dec–21	IN	North Vernon	North Vernon	1/2808	10/28/21	RNAV (GPS) RWY 5, Orig-B.
30–Dec–21	IN	North Vernon	North Vernon	1/2812	10/28/21	RNAV (GPS) Y RWY 23, Orig.
30–Dec–21	IL	De Kalb	De Kalb Taylor Muni	1/2828	7/30/21	RNAV (GPS) RWY 2, Orig-A.
30–Dec–21	IL	De Kalb	De Kalb Taylor Muni	1/2829	7/30/21	RNAV (GPS) RWY 20, Orig.
30–Dec–21	IL	De Kalb	De Kalb Taylor Muni	1/2830	7/30/21	RNAV (GPS) RWY 27, Amdt 1.
30–Dec–21	IL	De Kalb	De Kalb Taylor Muni	1/2831	7/30/21	RNAV (GPS) RWY 9, Amdt 1.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Dec–21	TN	Jackson	Mc Kellar-Sipes Rgnl	1/2832	11/3/21	RNAV (GPS) RWY 2, Orig-A.
30–Dec–21	PA	Clearfield	Clearfield-Lawrence	1/2900	11/4/21	RNAV (GPS) RWY 30, Amdt 1B.
30–Dec–21	IL	Vandalia	Vandalia Muni	1/3490	10/28/21	RNAV (GPS) RWY 36, Orig-A.
30–Dec–21	IL	Vandalia	Vandalia Muni	1/3497	10/28/21	RNAV (GPS) RWY 18, Orig-A.
30–Dec–21	WI	Necedah	Necedah	1/3542	10/28/21	RNAV (GPS) RWY 36, Orig-D.
30–Dec–21	AL	Brewton	Brewton Muni	1/3670	9/3/21	VOR/DME RWY 30, Amdt 8A.
30–Dec–21	MA	Chatham	Chatham Muni	1/3682	8/16/21	NDB–A, Amdt 1B.
30–Dec–21	MA	Chatham	Chatham Muni	1/3684	8/16/21	RNAV (GPS)-B, Orig-B.
30–Dec–21	OK	Muskogee	Muskogee-Davis Rgnl	1/3769	10/28/21	RNAV (GPS) RWY 13, Orig-C.
30–Dec–21	OK	Muskogee	Muskogee-Davis Rgnl	1/3777	10/28/21	RNAV (GPS) RWY 31, Amdt 1D.
30–Dec–21	AR	West Memphis	West Memphis Muni	1/3877	9/7/21	ILS OR LOC RWY 17, Amdt 5B.
30–Dec–21	AR	West Memphis	West Memphis Muni	1/3878	9/7/21	RNAV (GPS) RWY 17, Orig-A.
30–Dec–21	AR	West Memphis	West Memphis Muni	1/3879	9/7/21	RNAV (GPS) RWY 35, Orig-A.
30–Dec–21	SC	Aiken	Aiken Rgnl	1/4010	11/4/21	VOR/DME–A, Amdt 1B.
30–Dec–21	CA	Porterville	Porterville Muni	1/4218	7/28/21	VOR OR GPS–A, Amdt 1.
30–Dec–21	CA	Porterville	Porterville Muni	1/4222	7/28/21	GPS RWY 30, Orig-A.
30–Dec–21	CA	Porterville	Porterville Muni	1/4223	7/28/21	GPS RWY 12, Orig.
30–Dec–21	MA	Great Barrington	Walter J Koladza	1/4367	9/3/21	RNAV (GPS)-B, Orig.
30–Dec–21	IL	Savanna	Tri-Township	1/4513	7/30/21	RNAV (GPS) RWY 13, Orig-C.
30–Dec–21	CA	Shafter	Shafter-Minter Fld	1/4583	7/8/21	VOR–A, Amdt 1.
30–Dec–21	CA	Shafter	Shafter-Minter Fld	1/4584	7/8/21	RNAV (GPS) RWY 12, Amdt 1A.
30–Dec–21	NC	Jacksonville	Albert J Ellis	1/4875	9/3/21	ILS OR LOC RWY 5, Amdt 9B.
30–Dec–21	NC	Jacksonville	Albert J Ellis	1/4876	9/3/21	RNAV (GPS) RWY 23, Orig-A.
30–Dec–21	PA	Clearfield	Clearfield-Lawrence	1/4877	11/4/21	VOR RWY 30, Amdt 6A.
30–Dec–21	NC	Jacksonville	Albert J Ellis	1/4878	9/3/21	RNAV (GPS) RWY 5, Amdt 1B.
30–Dec–21	PA	Clearfield	Clearfield-Lawrence	1/4881	11/4/21	RNAV (GPS) RWY 12, Orig-A.
30–Dec–21	TX	Mount Pleasant	Mount Pleasant Rgnl	1/5136	7/30/21	RNAV (GPS) RWY 35, Amdt 1.
30–Dec–21	FL	Jacksonville	Jacksonville Exec At Craig	1/5138	8/16/21	ILS OR LOC RWY 32, Amdt 5A.
30–Dec–21	FL	Jacksonville	Jacksonville Exec At Craig	1/5140	8/16/21	RNAV (GPS) RWY 14, Amdt 1A.
30–Dec–21	FL	Jacksonville	Jacksonville Exec At Craig	1/5141	8/16/21	RNAV (GPS) RWY 32, Amdt 1A.
30–Dec–21	MN	Hawley	Hawley Muni	1/5160	7/30/21	RNAV (GPS) RWY 34, Orig-A.
30–Dec–21	MN	Hawley	Hawley Muni	1/5162	7/30/21	VOR/DME–A, Amdt 2A.
30–Dec–21	TX	Caldwell	Caldwell Muni	1/5169	7/30/21	RNAV (GPS) RWY 33, Orig-B.
30–Dec–21	TX	Caldwell	Caldwell Muni	1/5170	7/30/21	RNAV (GPS) RWY 15, Orig-A.
30–Dec–21	TX	Caldwell	Caldwell Muni	1/5174	7/30/21	VOR/DME–A, Amdt 3.
30–Dec–21	IN	Angola	Tri-State Steuben County	1/5495	10/21/21	RNAV (GPS) RWY 23, Orig-E.
30–Dec–21	AR	Morrilton	Morrilton Muni	1/5515	10/20/21	RNAV (GPS) RWY 27, Orig-A.
30–Dec–21	FL	Cross City	Cross City	1/5745	8/16/21	RNAV (GPS)-B, Orig-A.
30–Dec–21	FL	Cross City	Cross City	1/5746	8/16/21	RNAV (GPS)-A, Orig-A.
30–Dec–21	FL	Cross City	Cross City	1/5747	8/16/21	VOR RWY 31, Amdt 19A.
30–Dec–21	AR	Paragould	Kirk Fld	1/5869	9/3/21	VOR RWY 4, Amdt 5A.
30–Dec–21	VA	Norfolk	Chesapeake Rgnl	1/5946	8/16/21	ILS OR LOC RWY 5, Amdt 1B.
30–Dec–21	VA	Norfolk	Chesapeake Rgnl	1/5947	8/16/21	RNAV (GPS) RWY 5, Amdt 1B.
30–Dec–21	MI	Alma	Gratiot Community	1/5994	9/7/21	VOR RWY 18, Amdt 1B.
30–Dec–21	OK	Muskogee	Muskogee-Davis Rgnl	1/6586	10/28/21	RNAV (GPS) RWY 22, Orig-C.
30–Dec–21	FL	Palm Coast	Flagler Exec	1/6694	11/3/21	RNAV (GPS) RWY 6, Amdt 2A.
30–Dec–21	IA	Hampton	Hampton Muni	1/6841	10/27/21	VOR/DME RWY 35, Amdt 1F.
30–Dec–21	MI	Frankfort	Frankfort Dow Meml Fld	1/6884	9/7/21	RNAV (GPS) RWY 33, Amdt 1A.
30–Dec–21	IL	De Kalb	De Kalb Taylor Muni	1/6890	9/7/21	ILS OR LOC RWY 2, Orig-E.
30–Dec–21	MI	Mount Pleasant	Mount Pleasant Muni	1/7017	10/8/21	VOR RWY 27, Amdt 1B.
30–Dec–21	KS	Benton	Lloyd Stearman Fld	1/7440	8/16/21	RNAV (GPS) RWY 17, Orig-A.
30–Dec–21	WV	Pineville	Kee Fld	1/7445	9/9/21	RNAV (GPS) RWY 26, Orig-C.
30–Dec–21	WV	Pineville	Kee Fld	1/7446	9/9/21	RNAV (GPS) RWY 8, Orig-C.
30–Dec–21	OH	Elyria	Elyria	1/7497	9/14/21	VOR OR GPS–A, Amdt 7C.
30–Dec–21	WI	Sparta	Sparta/Fort Mc Coy	1/7686	7/30/21	RNAV (GPS) RWY 11, Amdt 1A.
30–Dec–21	WI	Sparta	Sparta/Fort Mc Coy	1/7687	7/30/21	NDB RWY 29, Amdt 4A.
30–Dec–21	WI	Sparta	Sparta/Fort Mc Coy	1/7688	7/30/21	RNAV (GPS) RWY 29, Amdt 1A.
30–Dec–21	NH	Claremont	Claremont Muni	1/7703	11/3/21	NDB–A, Amdt 1C.
30–Dec–21	NH	Claremont	Claremont Muni	1/7704	11/3/21	RNAV (GPS) RWY 29, Orig-B.
30–Dec–21	WY	Saratoga	Shively Fld	1/7911	11/5/21	RNAV (GPS)-B, Orig-B.
30–Dec–21	WY	Saratoga	Shively Fld	1/7914	11/5/21	RNAV (GPS) RWY 5, Orig-C.
30–Dec–21	MI	Beaver Island	Beaver Island	1/7987	8/16/21	RNAV (GPS) RWY 27, Orig-A.
30–Dec–21	WY	Saratoga	Shively Fld	1/8391	11/5/21	NDB–A, Amdt 1B.
30–Dec–21	NY	Poughkeepsie	Hudson Valley Rgnl	1/8475	9/3/21	ILS OR LOC RWY 6, Amdt 6E.
30–Dec–21	NY	Poughkeepsie	Hudson Valley Rgnl	1/8476	9/3/21	RNAV (GPS) RWY 6, Orig-E.
30–Dec–21	NY	Poughkeepsie	Hudson Valley Rgnl	1/8477	9/3/21	RNAV (GPS) RWY 24, Orig-E.
30–Dec–21	NY	Poughkeepsie	Hudson Valley Rgnl	1/8478	9/3/21	VOR RWY 24, Amdt 4F.
30–Dec–21	NY	Poughkeepsie	Hudson Valley Rgnl	1/8479	9/3/21	VOR–A, Amdt 11E.
30–Dec–21	FL	Bartow	Bartow Exec	1/8480	9/17/21	VOR RWY 09L, Amdt 2F.
30–Dec–21	CA	Ukiah	Ukiah Muni	1/8529	7/19/21	RNAV (GPS)-B, Orig.
30–Dec–21	CA	Ukiah	Ukiah Muni	1/8530	7/19/21	LOC RWY 15, Amdt 5C.
30–Dec–21	CA	Ukiah	Ukiah Muni	1/8532	7/19/21	VOR–A, Amdt 4.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Dec–21	KS	Wichita	Colonel James Jabara	1/8668	8/16/21	ILS OR LOC RWY 18. Orig-B.
30–Dec–21	KS	Wichita	Colonel James Jabara	1/8669	8/16/21	RNAV (GPS) RWY 18, Orig-C.
30–Dec–21	KS	Wichita	Colonel James Jabara	1/8670	8/16/21	RNAV (GPS) RWY 36, Orig-B.
30–Dec–21	KS	Wichita	Colonel James Jabara	1/8671	8/16/21	RNAV (GPS)-E, Orig-A.
30–Dec–21	NY	Montgomery	Orange County	1/8691	9/3/21	ILS OR LOC RWY 4, Orig.
30–Dec–21	NC	Louisburg	Triangle North Exec	1/8907	10/29/21	VOR–A, Amdt 2D.
30–Dec–21	NC	Louisburg	Triangle North Exec	1/8908	10/29/21	RNAV (GPS) RWY 23, Amdt 1A.
30–Dec–21	NC	Louisburg	Triangle North Exec	1/8909	10/29/21	RNAV (GPS) RWY 5, Amdt 1A.
30–Dec–21	NC	Louisburg	Triangle North Exec	1/8910	10/29/21	ILS OR LOC RWY 5, Amdt 4B.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8935	11/4/21	RNAV (GPS) RWY 4, Amdt 1C.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8936	11/4/21	RNAV (GPS) RWY 12R, Amdt 2C.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8937	11/4/21	RNAV (GPS) RWY 22, Amdt 1C.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8938	11/4/21	RNAV (GPS) RWY 30L, Amdt 2C.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8939	11/4/21	VOR RWY 12R, Amdt 14D.
30–Dec–21	FL	Vero Beach	Vero Beach Rgnl	1/8940	11/4/21	VOR RWY 30L, Amdt 4C.
30–Dec–21	OK	Tahlequah	Tahlequah Muni	1/9347	11/3/21	RNAV (GPS) RWY 17, Amdt 1.
30–Dec–21	OK	Tahlequah	Tahlequah Muni	1/9349	11/3/21	RNAV (GPS) RWY 35, Amdt 1A.
30–Dec–21	IN	Shelbyville	Shelbyville Muni	1/9553	7/30/21	RNAV (GPS) RWY 19, Amdt 1C.
30–Dec–21	IN	Shelbyville	Shelbyville Muni	1/9554	7/30/21	RNAV (GPS) RWY 1, Amdt 1B.
30–Dec–21	IN	Shelbyville	Shelbyville Muni	1/9555	7/30/21	VOR RWY 19, Amdt 1B.
30–Dec–21	NE	Hastings	Hastings Muni	1/9563	11/4/21	VOR RWY 32, Amdt 14A.

[FR Doc. 2021–26283 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 21–18]

RIN 1515–AE69

Extension of Import Restrictions Imposed on Certain Archaeological and Ethnological Material of Bolivia

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect an extension of import restrictions on certain archaeological and ethnological material of the Plurinational State of Bolivia (Bolivia). The restrictions, which were originally imposed by Treasury Decision (T.D.) 01–86 and last extended by CBP Decision (CBP Dec.) 16–24, are due to expire on December 4, 2021. The Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that factors continue to warrant the imposition of import restrictions and no cause for suspension exists. Pursuant to the exchange of diplomatic notes to extend the agreement, the import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this further extension until December 4, 2026. T.D. 01–86 contains the Designated List of archaeological and ethnological material from Bolivia to which the restrictions apply.

DATES: Effective December 4, 2021.

FOR FURTHER INFORMATION CONTACT: For legal aspects, W. Richmond Beevers, Branch Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325–0084, *otrculturalproperty@cbp.dhs.gov.* For operational aspects, Julie L. Stoeber, Chief, 1USG Branch, Trade Policy and Programs, Office of Trade, (202) 945–7064, *1USGBranch@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Convention on Cultural Property Implementation Act, Public Law 97–446, 19 U.S.C. 2601 *et seq.,* which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)), the United States entered into a bilateral agreement with the Plurinational State of Bolivia (Bolivia) [1] on December 4, 2001, concerning the imposition of import restrictions on certain archaeological and ethnological material of Bolivia. On December 7, 2001, the U.S. Customs Service (U.S. Customs and Border Protection's predecessor agency) published Treasury Decision (T.D.) 01–86 in the **Federal Register** (66 FR 63490), which amended section 12.104g(a) of title 19 of the Code of Federal Regulations (19 CFR 12.104g(a)) to reflect the imposition of these restrictions and included a list designating the types of articles covered by the restrictions.

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period may be extended for additional periods of not more than five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists.

Since the initial final rule was published on December 7, 2001, the import restrictions were subsequently extended three (3) times. First, on December 1, 2006, following the exchange of diplomatic notes, U.S. Customs and Border Protection (CBP) published a final rule (CBP Dec. 06–26) in the **Federal Register** (71 FR 69477) to extend the import restrictions for a period of five years to December 4, 2011. Second, on December 1, 2011, following the exchange of diplomatic notes, CBP published a final rule (CBP Dec. 11–24) in the **Federal Register** (76

[1] In 2009, the new constitution of Bolivia changed the country's official name from the ''Republic of Bolivia'' to the ''Plurinational State of Bolivia.''

FR 74690) to extend the import restrictions for an additional five-year period to December 4, 2016. Third, on December 6, 2016, following the exchange of diplomatic notes, CBP published a final rule (CBP Dec. 16–24) in the **Federal Register** (81 FR 87804) to extend the import restrictions for an additional five-year period to December 4, 2021.

On September 14, 2020, the United States Department of State proposed in the **Federal Register** (85 FR 56681) to extend the Memorandum of Understanding (MOU) between the United States and Bolivia concerning the imposition of import restrictions on certain categories of archaeological and ethnological material from Bolivia. On April 20, 2021, the Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, after consultation with and recommendations by the Cultural Property Advisory Committee, determined that the cultural heritage of Bolivia continues to be in jeopardy from pillage of certain archaeological and ethnological material, and that the import restrictions should be extended for an additional five years. Pursuant to the exchange of diplomatic notes to extend the agreement, the import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this further extension until December 4, 2026.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The restrictions on the importation of archaeological and ethnological material are to continue in effect until December 4, 2026. Importation of such material from Bolivia continues to be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: *https://eca.state.gov/cultural-heritage-center/cultural-property-advisory-committee/current-import-restrictions* by selecting the material for ''Bolivia.''

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1), pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

Troy A. Miller, the Acting Commissioner, having reviewed and approved this document, is delegating the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12) is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

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■ 2. In § 12.104g, amend the table in paragraph (a) by revising the entry for Bolivia to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
*	*	*
Bolivia	Archaeological and Ethnological Material from Bolivia	T.D. 01–86 extended by CBP Dec. 21–18.
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Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade U.S. Customs and Border Protection.

Approved: November 30, 2021.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 21–17]

RIN 1515–AE70

Extension and Amendment of Import Restrictions on Archaeological Material and Imposition of Import Restrictions on Ethnological Material of Egypt

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Customs and Border Protection (CBP) regulations to reflect an extension and amendment of import restrictions on certain archaeological material and the imposition of import restrictions on ethnological material of the Arab Republic of Egypt (Egypt). The restrictions on archaeological material, which were originally imposed by CBP Dec. 16–23, were extended and amended on November 30, 2021. The Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for extending and updating the import restrictions that previously existed, and the Governments of the United States and Egypt entered into a new agreement to reflect the extension of these import restrictions. Additionally, the Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for adding import restrictions on certain categories of ethnological material. The new agreement, which entered into force on November 30, 2021, supersedes the existing Memorandum of Understanding (MOU) that became effective on November 30, 2016, and enabled the promulgation of the existing import restrictions. Accordingly, the current import restrictions and new import restrictions will be effective until November 30, 2026, and the CBP regulations are being amended to reflect this extension and imposition. To fulfill the terms of the new MOU, the Designated List of cultural property, which was described in CBP Dec. 16–23, is amended in this document to reflect the addition and revision of categories of archaeological material of Egypt ranging in date from approximately 300,000 B.C. to A.D. 1750, and to include certain ethnological material ranging from A.D. 1517 to 1914.

DATES: Effective on December 1, 2021.

FOR FURTHER INFORMATION CONTACT: For legal aspects, W. Richmond Beevers, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325–0084, *otrculturalproperty@cbp.dhs.gov.* For operational aspects, Julie L. Stoeber, Chief, 1USG Branch, Trade Policy and Programs, Office of Trade, (202) 945–7064, *1USGBranch@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Convention on Cultural Property Implementation Act, Public Law 97–446, 19 U.S.C. 2601 *et seq.* (hereinafter, ''the Cultural Property Implementation Act''), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (hereinafter, ''the Convention'' (823 U.N.T.S. 231 (1972)), the United States entered into a bilateral agreement with the Arab Republic of Egypt (Egypt) on November 30, 2016. The Memorandum of Understanding (MOU) enabled the promulgation of import restrictions on certain archaeological material representing Egypt's cultural heritage ranging from approximately 300,000 B.C. to A.D. 1750.

On December 6, 2016, U.S. Customs and Border Protection (CBP) published CBP Dec. 16–23 in the **Federal Register** (81 FR 87805), which amended § 12.104g(a) of title 19 of the Code of Federal Regulations (19 CFR 12.104g(a)) to reflect the imposition of import restrictions and included a list designating the types of archaeological material covered by the restrictions.

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period may be extended for additional periods of not more than five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists. *See* 19 CFR 12.104g(a).

On February 5, 2021, the United States Department of State proposed in the **Federal Register** (86 FR 8476), to extend and amend the MOU between the United States and Egypt concerning the import restrictions on certain categories of archeological material of Egypt. On August 15, 2021, after consultation with and recommendations by the Cultural Property Advisory Committee, the Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, determined that: (1) Egypt's cultural heritage continues to be in jeopardy from pillage of archeological resources and that the import restrictions should be updated and extended for an additional five years; and (2) Egypt's cultural heritage is in jeopardy from pillage of certain types of ethnological material, from Egypt, ranging in date from A.D. 1517 to A.D. 1914, and import restrictions on such types of ethnological material should be imposed.

Subsequently, on November 30, 2021, the Governments of the United States and Egypt entered into a new agreement, titled ''Memorandum of Understanding Between the Government of the United States of America and the Government of the Arab Republic of Egypt Concerning the Imposition of Import Restrictions on Categories of Cultural Property of Egypt.'' The new MOU supersedes the existing agreement that first entered into force on November 30, 2016. Pursuant to the new MOU, the import restrictions for archaeological material are updated and will be effective until November 30, 2026, along with the imposition of additional import restrictions on certain categories of ethnological material, which will also be effective until November 30, 2026.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions and amending the Designated List of cultural property described in CBP Dec. 16–23 with the addition and revision of categories of archaeological material of Egypt ranging in date from approximately 300,000 B.C. to A.D. 1750, as set forth below. The Designated List of cultural property described in CBP Dec. 16–23 is also amended by adding certain categories of ethnological material of Egypt ranging

in date from A.D. 1517 to 1914, as set forth below. The restrictions on the importation of archaeological and ethnological material will be in effect through November 30, 2026. Importation of such material of Egypt, as described in the Designated List below, will be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: *https://eca.state.gov/cultural-heritage-center/cultural-property-advisory-committee/current-import-restrictions* by selecting the material for ''Egypt.''

Designated List of Archaeological and Ethnological Material of Egypt

The Designated List contained in CBP Dec. 16–23, which describes the types of articles to which the import restrictions apply, is amended to reflect the inclusion of additional archaeological material and certain ethnological material in the Designated List. In order to clarify certain provisions of the Designated List contained in CBP Dec. 16–23, the amendment also includes minor revisions to the language and numbering of the Designated List. For the reader's convenience, CBP is reproducing the Designated List contained in CBP Dec. 16–23 in its entirety, with the changes, below.

The Designated List includes archaeological material from Egypt ranging in date from approximately 300,000 B.C. to A.D. 1750, and certain ethnological material from Egypt ranging in date from A.D. 1517 to 1914.

Categories of Archaeological and Ethnological Material

I. Archaeological
- A. Stone
- B. Metal
- C. Ceramic and Clay
- D. Wood
- E. Faience and Glass
- F. Ivory, Bone, and Shell
- G. Plaster and Cartonnage
- H. Textile, Basketry, and Rope
- I. Leather and Parchment
- J. Papyrus
- K. Painting and Drawing
- L. Mosaics
- M. Writing
- N. Human and Animal Remains

II. Ethnological
- A. Stone
- B. Metal
- C. Ceramic and Clay
- D. Wood
- E. Bone, Ivory, and Shell
- F. Glass and Semi-Precious Stone
- G. Leather, Parchment, and Paper
- H. Textiles

Approximate chronology of well-known periods and sites:

(a) Paleolithic period (c. 300,000–8800 B.C.): Bir Sahara East, Bir Tarfawi, el-Kab (Nekheb), Jebel Sahaba, Taramsa-1, Wadi Tushka

(b) Neolithic period (c. 8800–4000 B.C.): Armant, Bir Kiseiba, Deir Tasa, el-Badari, el-Omari, el Tarif, Hammamiya, Hierakonpolis (Nekhen), Merimde Beni-salame, Nabta Playa

(c) Predynastic period (c. 4000–3200 B.C.): Abydos, Adaïma, Deir el Ballas, el-Amra, el-Badari, el-Mahasna, Gerza, Hierakonpolis (Nekhen), Ma'adi, Minshat Abu Omar, Mostagedda, Naga ed-Deir, Naqada, Tell el-Fara'in (Buto), Tell el-Farkha, Tjenu (Thinis), Wadi Digla

(d) Early Dynastic period (c. 3200–2686 B.C.): Abusir, Abydos, Coptos/Koptos, Giza, Elephantine, Memphis, Minshat Abu Omar, Helwan, Hierakonpolis (Nekhen), Saqqara, Tarkhan, Tell el-Fara'in (Buto), Tell el-Farkha

(e) Old Kingdom period (c. 2686–2125 B.C.): Ayn Sokhna, Abu Ghurob, Abusir, Abydos, Aswan, Bet Khallaf, Dashur, Dendera, Elephantine, Giza, Heliopolis, Hierakonpolis (Nekhen), Kom el-Hisn, Maidum/Meidum, Memphis, Naga el-Deir, Naqada, Sais, Saqqara, Tell Edfu, Wadi Maghara, Zawiyet el-Aryan

(f) First Intermediate period (c. 2125–2055 B.C.): Asyut, Hierakonpolis (Nekhen), Ihnasya el-Medina (Herakleopolis), Kom Dara, Memphis, Naga el-Dier, Saqqara, Tell Edfu

(g) Middle Kingdom period (c. 2055–1650 B.C.): Asyut, Abydos, Beni Hasan, Dashur, Deir el-Bahri, Crocodopolis (Fayum) Deir el Ballas, Hawara, Elephantine, Heliopolis, Herakleopolis, Hierakonpolis (Nekhen), Kahun, Karnak/Thebes, Lisht, Memphis, Qau el-Kebir, Tell el-Dab'a (Avaris), Tell Edfu, Wadi Hammamat, Wadi el-Hudi

(h) Second Intermediate period (c. 1650–1550 B.C.): Abydos, Bubastis, Tell el-Daba, Karnak/Thebes, Deir el Ballas, el-Kab, Memphis, Tell el-Yahudiyeh, Tura

(i) New Kingdom period (c. 1550–1069 B.C.): Abydos, Abu Simbel, Akhmim, Armant, Asyut, Aswan, Bubastis, Coptos/Koptos, Dakhla Oasis, Deir el-Medina, Dendera, Elephantine, Heliopolis, Hermopolis, el-Kab, Karnak/Thebes, Kharga Oasis, Luxor, Medamud, Memphis, Qantir, Saqqara, Serabit el-Khadim, Tell el-Amarna, Tell el-Daba, Tod, Wadi Hammamat, Wadi Natron

(j) Third Intermediate period (c. 1069–664 B.C.): Abusir, Armant, Bubastis, Elephantine, el-Kab, el-Asasif, el-Hiba, Herakleopolis, Hermopolis, Karnak/Thebes, Kharga Oasis, Leontopolis, Memphis, Tell el-Fara'in (Buto), Tanis, Tell Defanna, Tell el Herr, Tell el-Maskhuta, Tanis, Wadi Tumilat

(k) Late period (c. 664–332 B.C.): Bubastis, Busiris, Dendera, Heliopolis, Herakleopolis, Hermopolis, el-Hiba, Karnak/Luxor, Kom Ombo, Kharga Oasis, Memphis, Mendes, Philae, Sais, Saqqara, Sebennytos, Siwa Oasis, Tell Edfu

(l) Greco-Roman/Ptolemaic period (332 B.C.–A.D. 395): Abu Sha'ar, Ain el-Tabinieh, Alexandria, Amheida (Trimithis), Antinoöpolis, Antinoe, Aswan (Syene), Bahariya Oasis, Berenike, Busiris, Canopus, Coptos/Koptos, Dakhla Oasis, Damietta, Dendera, Farafra Oasis, el-Haiz, Karanis, Kellis, Kharga Oasis, Kom Ombo, Hawara, Marina al-Alamein, Medinet Madi, Memphis, Naukratis, Oxyrhynchus, Philae, Ptolemais, Quseir el-Qadim (Myos Hormos), Soknopaiou Nesos, Tebtynis (Tebtunis), Tell Edfu

(m) Byzantine period (c. A.D. 395–640): Abu Fano, Alexandria, el-Kab, Abu Mina, Arsinoe, Aswan, Athribis (both Delta Athribis and Sohag Athribis), Bawit, Coptos/Koptos, Dakhla Oasis, Dayr el-Muharraq, Dendur, Douch, Tell Edfu, Fayoum monasteries (Dayr al-Malek Gabriel), Herakleopolis Magna, Hermopolis Magna (city and necropolis Tuna el-Gebel), Jeme (Medinet Habu), Karanis, Kellia, Kharga Oasis, Kom el-Dikka, Medinet Madi, Menouthis, Mons Claudianus, Mons Porpyrites, Mount Sinai, Nag Hammadi, Old Cairo, Oxyrhynchos, Panopolis (Akhmim) and area monasteries, Pelusion, Philae, Raithou, Red Sea Monasteries (SS. Antony and Paul), Saqqara, Sinai, Sohag, Tall al-Farama, Tell el-Amarna, Thebes, Wadi Natrun, Wadi Pharan (Sinai, Monastery)

(n) Islamic/Medieval period (A.D. 640–1517): Alexandria, al-Ashmunayn, Aswan, Athribis (Sohag), Aydhab, al-Bahnasa, al-Fustat, al-Rashid (Rosetta), Antinoopolis, Aswan, Cairo, Damietta, Tell Edfu, Giza, Hamouli, Jeme, Luxor, Madinat al-Fayyum, Minya, Qūs, Qusayr, Red

Sea Monasteries (SS. Antony and Paul), Rosetta, Sohag, Thebes, Wadi Natrun

(o) Ottoman and early Muhammad 'Ali periods (A.D. 1517–1914): Alexandria, al-Rashid (Rosetta), Aswan, Asyut, Cairo, Damietta, Ibrim, Red Sea Monasteries (SS. Antony and Paul), Tanta, Qusayr, Salihiyya, Suez, Thebes

I. Archaeological Material

Archaeological material includes categories of objects from the Paleolithic to the middle of the Ottoman period in Egypt, ranging in date from approximately 300,000 B.C. to A.D. 1750.

A. Stone

1. Sculpture

i. Architectural Elements—This category includes architectural elements from temples, tombs, palaces, mosques, churches, monasteries, commemorative monuments, and domestic architecture, including doors, door frames, window fittings, columns, capitals, bases, lintels, jambs, roofs, pediment, archways, friezes, pilasters, engaged columns, prayer niches (*mihrabs*), fountains, inlays, and blocks from walls, floors, and ceilings. Examples are often decorated in relief with ornamental Pharaonic, Greco-Roman, Coptic, and Islamic motifs and inscriptions. Limestone, sandstone, and granite are most commonly used. Stone is often reused.

ii. Statues—Types include large- and small-scale representations of humans, animals, and hybrid figures with a human body and animal head. Human figures may be standing, usually with the left foot forward, seated on a block or on the ground, kneeling, or prone. Figures in stone may be supported by a slab of stone at the back. Greco-Roman examples use traditional Egyptian poses with Hellenistic modeling. Limestone, granite, basalt, sandstone (including greywacke), and diorite are most commonly used. Reuse of statues is common with re-inscription of cartouche and other visible re-carving.

iii. Relief Sculpture—Types include large- and small-scale sculpture, including Neolithic and Predynastic greywacke votive and cosmetic palettes, limestone wall reliefs depicting scenes of daily life and rituals, and steles/stelae and plaques in a variety of stones for funerary and commemorative purposes.

iv. Tombstones—This category includes tombstones and grave markers made of marble, limestone, or other kinds of stone. They may be carved in relief and/or have decorative moldings.

2. Vessels and Containers—This category includes conventional shapes such as bowls, cups, jars, and lamps. This category also includes vessels having the form of human, animal, hybrid, plant, hieroglyphic signs, and combinations or parts thereof.

3. Funerary Objects and Equipment

i. Sarcophagi and Coffins—This category includes sarcophagi and coffins with separate lids, either in the form of a large rectangular box, or human-shaped (anthropoid) and carved with modeled human features. Both types are often decorated outside, and sometimes inside, with incised or painted images and text inscriptions.

ii. Canopic Shrines—This category includes shrines in the form of a box with space inside for four canopic jars.

iii. Canopic Jars—This category includes jars with plain lids or lids in the form of human or animal heads and used to hold the internal organs of the deceased. A full set includes four jars. Sometimes these jars are dummies, carved from a single piece of stone with no interior space.

4. Objects of Daily Use—This category includes chests and boxes, furniture, headrests, writing and painting equipment, games, and game pieces.

5. Tools and Weapons—Chipped stone types include large and small blades, borers, scrapers, sickles, burins, notches, retouched flakes, cleavers, knives, chisels, awls, harpoons, cores, loom weights, and arrowheads. Ground stone types include grinders (*e.g.,* mortars, pestles, millstones, whetstones, querns), choppers, axes, hammers, molds, weights, and mace heads.

6. Jewelry, Amulets, and Seals

i. Jewelry—This category includes jewelry of colored and semi-precious stones for personal adornment, including necklaces, chokers, pectorals, pendants, crowns, earrings, bracelets, anklets, belts, girdles, aprons, and finger rings.

ii. Amulets—This category includes amulets of colored and semi-precious stones in the form of humans, animals, hybrids, plants, hieroglyphic signs, and combinations or parts thereof.

iii. Stamp and Cylinder Seals—These are small devices with at least one side engraved (in intaglio and relief) with a design for stamping or sealing. The most common type is the scarab, in the form of a beetle with an inscription on the flat base.

7. Ostraca—Chips of stone used as surfaces for writing or drawing.

B. Metal

1. Sculpture

i. Statues—Types include large- and small-scale, including human, animal, and hybrid figures similar to those in stone. Metal statues usually lack the support at the back. The most common materials are bronze and copper alloys, but gold and silver are used as well.

ii. Relief sculpture—Types include plaques, appliques, and mummy masks. Reliefs may include inscriptions in various languages.

2. Vessels and Containers—This category includes conventional shapes such as bowls, cups, jars, plates, cauldrons, lamps, lampstands, scroll and manuscript containers, reliquaries, incense burners, and vessels in the form of humans, animals, hybrids, plants, hieroglyphic signs, and combinations or parts thereof.

3. Objects of Daily Use—This category includes musical instruments, including trumpets, clappers, and sistra.

4. Tools—Types include axes, adzes, saws, scrapers, trowels, locks, keys, nails, hinges, mirrors, ingots, thimbles, fibulae (for pinning clothing), drills, chisels, knives, hooks, needles, tongs, tweezers, and weights in copper alloy, bronze, and iron.

5. Weapons and Armor

i. Weapons—Types include mace heads, knives, daggers, swords, curved swords, axes, arrows, javelins, arrowheads, and spears in copper alloy, bronze, and iron.

ii. Armor—Early armor consisted of small metal scales, originally sewn to a backing of cloth or leather, later augmented by helmets, body armor (cuirasses, bracers, shin guards), shields, and horse armor.

6. Jewelry, Amulets, and Seals

i. Jewelry—This category includes jewelry made of gold, silver, copper, and iron for personal adornment, including necklaces, chokers, pectorals, finger rings, beads, pendants, bells, belts, buckles, earrings, diadems, straight pins and fibulae, bracelets, anklets, girdles, wreaths and crowns, cosmetic accessories and tools, metal strigils (scrapers), crosses, and lamp holders.

ii. Amulets—Types include amulets in the form of humans, human organs and parts, animals, hybrids, plants, hieroglyphic signs, deities, religious symbols, and combinations or parts thereof.

7. Late Antique Christian, Greek Orthodox, and Coptic Liturgical Objects—Types include censers, crosses, Bible caskets, lamps, patens, Eucharistic goblets, icons, and iconostases.

8. Coins—Types appear in copper or bronze, silver, and gold.

i. Dynasty 30—Coins of this type have the hieroglyphs *nwb nfr* on one side and a horse on the other.

ii. Dynasty 31—Coins of this type are Egyptian imitations of silver Athenian coins that depict the helmeted head of

Athena on the obverse and owl on the reverse with an inscription in Demotic (looks cursive) to the right of the owl. There are similar coins in silver but with an inscription in Aramaic (look angular) to the right of the owl. The former were struck under the authority of the Persian Great King Artaxerxes III when he recaptured Egypt in the mid-4th B.C.; the latter were struck under the Persian satraps of Egypt Sabaces and Mazakes in the 330s B.C. There are rare silver drachms marked NAU (Naucratis) instead of AΘE.

iii. Hellenistic and Ptolemaic—Coins of this type are struck in gold, silver, and bronze at Alexandria and any other mints that operated within the borders of the modern Egyptian state. Gold coins of and in honor of Alexander the Great, struck at Alexandria and Memphis, depict a helmeted bust of Athena on the obverse and a winged Victory on the reverse. Silver coins of Alexander the Great, struck at Alexandria and Memphis, depict a bust of Herakles wearing the lion skin on the obverse, or ''heads'' side, and a seated statue of Olympian Zeus on the reverse, or ''tails'' side. Gold coins of the Ptolemies from Egypt will have jugate portraits on both obverse and reverse, a portrait of the king on the obverse and a cornucopia on the reverse, or a jugate portrait of the king and queen on the obverse and cornucopias on the reverse. Silver coins of the Ptolemies from Egypt tend to depict a portrait of Alexander wearing an elephant skin on the obverse and Athena on the reverse or a portrait of the reigning king with an eagle on the reverse. Some silver coins have jugate portraits of the king and queen on the obverse. Bronze coins of the Ptolemies commonly depict a head of Zeus (bearded) on the obverse and an eagle on the reverse. These iconographical descriptions are non-exclusive and describe only some of the more common examples. There are other types and variants among the Hellenistic and Ptolemaic coinage. Approximate date: ca. 332 B.C. through ca. 31 B.C.

iv. Roman—Coins of this type are struck in bronze, silver, or gold at Alexandria and any other mints that operated within the borders of the modern Egyptian state until approx. A.D. 498. The iconography of the coinage in the Roman period varied widely, although a portrait of the reigning emperor is almost always present on the obverse of the coin. Approximate dates: ca. 31 B.C. through ca. A.D. 498.

v. Byzantine and Arab Byzantine—Coins of these types are struck in bronze and gold at Alexandria, Fustat, and other mints that operated within the borders of the modern Egyptian state between A.D. 498 and ca. A.D. 696. Iconography may include one, two, or three persons (busts or standing figures); large letters in Latin script (sometimes with smaller Latin, Greek, or Arabic letters along the edge); and crosses, stars, moons, and other symbols.

vi. Islamic/Medieval and Ottoman—Coins of this type are struck in copper, bronze, silver, and gold at Cairo, Fustat, Alexandria, and other mints that operated within the borders of the modern Egyptian state under the Umayyad, 'Abbasid, Tulunid, Ikhshidid, Fatimid, Ayyubid, Mamluk, and Ottoman (up to A.D. 1750) dynasties. Iconography is mostly writing in Arabic script, sometimes with stars, circles, flowers, or other ornaments placed at center or among the text, and rarely with human figures or trees.

C. Ceramic and Clay

1. Sculpture—This category includes terracotta statues and statuettes (figurines), including human, animal, and hybrid figures. Ceramic sculptures may be undecorated or decorated with paint, appliques, or inscribed lines.

2. Architectural Decorations—These are baked clay (terracotta) elements used to decorate buildings. Examples include carved and molded brick, panels, acroteria, antefixes, painted and relief plaques, revetments, carved and molded bricks, knobs, plain or glazed roof tiles, and glazed tile wall ornaments and panels.

3. Vessels and Containers

i. Neolithic—Types are made of red Nile clay with blackened rim, thin walls, and rippled surface. Others have smoothed surfaces, but otherwise plain. Decorations may include painting or incised designs.

ii. Predynastic Period—Types typically have a burnished red body with or without a white-painted decoration, or a burnished red body and black top, or a burnished black body sometimes with incised decoration, or an unburnished light brown body with dark red painted decoration, including human and animal figures and boats, spirals, or an abstract design.

iv. Dynastic Periods—Types are primarily utilitarian but also come as ornate forms, typically undecorated and sometimes burnished. New Kingdom examples may have elaborate painted, incised, and molded decorations, especially floral motifs depicted in blue paint.

v. Greco-Roman Period—Types include vessels with riled decoration, pilgrim flasks, and *terra sigillata,* a high-quality table ware made of red to reddish brown clay and covered with a glossy slip.

vi. Byzantine Period/Coptic—pilgrim flasks and decorated ceramic jars and bowls.

vii. Islamic/Medieval and Ottoman Periods—Types include glazed, molded, and painted forms in a variety of shapes and sizes.

4. Coffins—This category includes baked clay coffins, either rectangular or human-shaped (anthropoid). Examples are sometimes painted.

5. Objects of Daily Use—This category includes game pieces carved from ceramic sherds, loom weights, toys, incense burners, tobacco pipes, andirons, and lamps.

6. Writing

i. Ostraca—Ostraca are pottery sherds used as surfaces for writing or drawing.

ii. Cuneiform Tablets—These objects are typically small pillow-shaped rectangles of unbaked clay incised with patterns of wedge-shaped cuneiform symbols.

D. Wood

1. Sculpture

i. Statues—Types include large- and small-scale examples, including human, animal, and hybrid figures. Shabti statuettes and small mummiform human figures are especially common. Wood statues usually lack the support at the back.

ii. Relief sculpture—Types include large- and small-scale examples, including relief plaques for funerary purposes.

2. Architectural Elements

i. Late Antique Christian, Greek Orthodox, and Coptic—This category includes carved and inlaid panels, doors, ceilings, altars, episcopal thrones, pulpits, lecterns, and iconostases, often decorated with floral, geometric, and Christian motifs.

ii. Islamic/Medieval—This category includes carved and inlaid wood rooms, balconies, stages, panels, ceilings, and doors.

3. Funerary Objects and Equipment

i. Sarcophagi and Coffins—This category includes sarcophagi and coffins with separate lid, either in the form of a large rectangular box or human-shaped and carved with modeled human features. Both types are often decorated inside and outside with painted, inlaid, or incised images, and with inscriptions.

ii. Mummy masks—This category includes masks that were laid over the face of the deceased. They were often painted, inlaid, and covered with gold foil.

iii. Funerary models—Types include boats, buildings, food, and activities from everyday life.

iv. Shrines—This category includes shrines used to house sarcophagi or statuettes of deities.

v. Food Containers—Types include containers in the shape of the product they contain, such as a loaf of bread or a duck.

4. Objects of Daily Use—This category includes furniture such as chairs, stools, beds, chests and boxes, headrests, writing and painting equipment, musical instruments, game boxes and pieces, walking sticks, chariots, and chariot fittings.

5. Tools and Weapons—This category includes adzes, axes, bow drills, carpenter's levels and squares, bows, arrows, and spears.

6. Vessels and Containers—This category includes wooden vessels and containers including ciboria (Christian shrine-shaped receptacles for the Eucharist).

7. Furniture—This category includes moveable furniture, such as iconostases, lecterns, pulpits, and episcopal thrones.

E. Faience and Glass

1. Egyptian Faience—This category includes objects made from faience: A glossy, silicate-based fired material, is usually blue or turquoise, but other colors are found as well. Object types include vessels and containers, canopic jars, game pieces, seals, amulets, jewelry, inlays, and statuettes in human, animal, and hybrid forms.

2. Glass

i. Pharaonic—This category includes parts of statues, and glass containers that are typically small and often elaborately decorated with multi-colored bands.

ii. Roman—Types in this category include a great variety of hand-blown vessel and container shapes.

iii. Byzantine—Types include hand-blown vessels, hanging lamps, and chandeliers (polycandela), painted windows, stained glass, and mosaic tesserae.

iv. Islamic/Medieval and Ottoman—This category includes vessels and containers such as glass and enamel mosque and sanctuary lamps, coin weights, and architectural elements including glass inlay and tesserae pieces from floor and wall mosaics, mirrors, and windowpanes.

F. Ivory, Bone, and Shell

1. Sculpture—This category includes statuettes of human, animal, and hybrid figures in bone or ivory.

2. Objects of Daily Use—This category includes writing and painting equipment, musical instruments, games, cosmetic containers, combs, tools (such as awls, burnishers, needles, spatulas and fishhooks), jewelry, amulets, and seals. This category also includes inlays of these materials from luxury objects including furniture, chests, and boxes.

3. Reliefs, Plaques, Steles, and Inlays—These are carved and sculpted and may have figurative, floral, and/or geometric motifs. Examples may also have inscriptions in various languages.

G. Plaster and Cartonnage

1. Plaster—This category includes objects made of plaster, such as mummy masks, jewelry, and other objects in imitation of expensive materials. They are typically molded and then decorated with paint or gilding. Plaster objects also occur as life masks and sculptor's models.

2. Cartonnage—This category includes pieces of papyrus or linen covered with plaster and molded into a shape, similar to *papier-mâché,* and then painted or gilded. Cartonnage was used for coffins and mummy masks. Today, cartonnage objects are sometimes dismantled in hopes of extracting inscribed papyrus fragments.

3. Stucco—This category includes architectural decoration in stucco. Stucco is a fine plaster used for coating wall surfaces, or molding and carving into architectural decorations, such as reliefs, plaques, steles, and inlays

H. Textile, Basketry, and Rope

1. Textile

i. Linen—This category includes Pharaonic and Greco-Roman period mummy wrapping, shrouds, garments, and sails made from linen cloth.

ii. Late Antique Christian, Greek Orthodox, and Coptic—This category includes Christian garments and hangings made from linen and wool.

iii. Islamic/Medieval and Ottoman—This category includes textile fragments in linen, wool, and cotton.

2. Basketry—This category includes baskets and containers in a variety of shapes and sizes, sandals, and mats made from plant fibers.

3. Rope—This category includes rope and string from archaeological contexts. Rope and string were used for a great variety of purposes, including binding planks together in shipbuilding, rigging, lifting water for irrigation, fishing nets, measuring, and stringing beads for jewelry and garments.

I. Leather and Parchment

1. Leather—This category includes shields, sandals, clothing (including undergarments), and horse trappings made from leather. It also includes leather sheets used occasionally as an alternative to papyrus as a writing surface.

2. Parchment—This category includes documents such as illuminated ritual manuscripts that may occur in single leaves or bound as a book or ''codex'' written or painted on specially prepared animal skins (cattle, sheep/goat, camel) known as parchment.

J. Papyrus—This category includes scrolls, books, manuscripts, and documents, including religious, ceremonial, literary, and administrative texts written on papyrus. Scripts include hieroglyphic, hieratic, Aramaic, Syriac, Hebrew, Greek, Latin, Coptic, Arabic, Georgian, Slavonic, Ethiopian, Armenian, and Persian.

K. Painting and Drawing

1. Tomb Paintings—This category includes paintings on plaster or stone, either flat or carved in relief. Typical subjects include the tomb owner and family, gods, and scenes from daily life.

2. Domestic Wall Paintings—This category includes paintings on stone, mud plaster, or lime plaster (wet—*buon fresco*—and dry—*secco fresco*), sometimes to imitate marble. Types include simple applied color, bands and borders, landscapes, and scenes of people and/or animals in natural or built settings.

3. Rock Art—Rock art can be painted and/or chipped and incised drawings on natural rock surfaces. Common motifs include humans, animals, geometric, and/or floral elements.

4. Ostraca—This category includes paintings and drawings on stone chips, bone, and pottery shards.

5. Mummy Portrait Panels and Funerary Masks—This category includes panels and masks that either covered the upper body of the deceased or appear on the outer coffin/sarcophagus. These objects were made in wood, plaster, and cartonnage, and they were often painted to depict the head and upper body of the deceased.

6. Late Antique Christian, Greek Orthodox, and Coptic Painting

i. Wall and Ceiling Paintings—This category includes paintings on various kinds of plaster, and which generally portray religious images and scenes of biblical events. Surrounding paintings may contain animal, floral, or geometric designs, including borders and bands.

ii. Panel Paintings (Icons)—This category includes smaller versions of the scenes on wall paintings, and may be partially covered with gold or silver, sometimes encrusted with semi-precious or precious stones or glass, and are usually painted on a wooden panel, often for inclusion in a wooden screen (iconostasis). Icons also occur painted on ceramic.

L. Mosaics

1. Floor Mosaics—Floor mosaics are made from stone cut into small bits (tesserae) or glass and laid into a plaster matrix. Subjects may include landscapes, scenes of humans or gods, and activities such as hunting and fishing. There may also be vegetative, floral, or decorative motifs.

2. Wall and Ceiling Mosaics—Wall and ceiling mosaics are made from stone or glass cut into small bits (tesserae) and laid into a plaster matrix. Subjects may include religious images and scenes of Biblical events. Surrounding panels may contain animal, floral, or geometric designs.

M. Writing—This category includes objects made from papyrus, wood, ivory, stone, metal, textile, clay, and ceramic that exhibit forms of writing including hieroglyphic, hieratic, Aramaic, Assyrian, Babylonian, Persian, Hebrew, Greek, Latin, Coptic, Syriac, Georgian, Slavonic, Ethiopian, Armenian, Persian, and Arabic scripts.

N. Human and Animal Remains—This category includes human and animal mummies.

II. Ethnological Material

Ethnological material covered by the Agreement includes architectural elements, manuscripts, ecclesiastical objects, and ceremonial and ritual objects of the Islamic culture, ranging in date from A.D. 1517 to 1914. This would exclude Jewish ceremonial or ritual objects.

A. Stone

1. Architectural Elements—This category includes doors, door frames, window fittings, columns, capitals, plinths, bases, lintels, jambs, roofs, archways, friezes, pilasters, engaged columns, altars, prayer niches (*mihrabs*), screens, fountains, inlays, and blocks from walls, floors, and ceilings of buildings. Architectural elements may be plain, molded, or carved and are often decorated with motifs and inscriptions. Marble, limestone, and sandstone are most commonly used.

2. Architectural and Non-Architectural Relief Sculpture—This category includes slabs, plaques, steles, capitals, mosaic panels, and plinths carved with religious, figural, floral, or geometric motifs or inscriptions in Arabic for ceremonial and ritual use. Examples occur primarily in marble, limestone, and sandstone.

3. Memorial Stones and Tombstones—This category includes tombstones, grave markers, and cenotaphs. Examples occur primarily in marble and are engraved with Arabic script.

4. Vessels and Containers—This category includes ceremonial and ritual stone lamps and containers.

B. Metal

1. Architectural Elements—This category includes doors, door fixtures, such as knockers, bolts and hinges, chandeliers, screens, taps, spigots, fountains, and sheets. Copper, brass, lead, and alloys are most commonly used.

2. Architectural and Non-Architectural Relief Sculpture—This category includes appliques, plaques, and steles, primarily made of bronze and brass, for ceremonial and ritual use. Examples often include religious, figural, floral, or geometric motifs. They may also have inscriptions in Arabic.

3. Lamps—This category includes handheld lamps, candelabras, braziers, sconces, chandeliers, and lamp stands for ceremonial, ritual, and funerary use.

4. Vessels and Containers—This category includes containers used for religious services, such as Koran (*Qur'an*) cases, Greek Orthodox and Coptic Bible caskets, patens, Eucharistic goblets, amulet boxes, and incense burners. Brass, copper, silver, and gold are most commonly used. Containers may be plain, engraved, hammered, or otherwise decorated. Bible caskets may be made of wood and covered with embossed silver sheets attached by nails.

5. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals such as cymbals and trumpets.

C. Ceramic and Clay

1. Architectural Elements—This category includes carved and molded brick and engraved and/or painted and glazed tile wall ornaments and panels, sometimes with Arabic script.

2. Lamps—This category includes glazed mosque and sanctuary lamps that may have straight or round, bulbous bodies with a flared top and several branches.

D. Wood

1. Architectural Elements—This category includes doors, door frames and fixtures, windows, window frames, panels, beams, balconies, stages, screens, prayer niches (*mihrabs*), minbars, icons, wall shelves, cupolas, and ceilings. Examples may be decorated with religious, geometric, or floral motifs or inscriptions, and may be either carved, turned (on a lathe), and/or painted. Icons may be partially covered with gold or silver, sometimes encrusted with semi-precious or precious stones or glass, and are usually painted on a wooden panel, often for inclusion in a wooden screen (iconostasis).

2. Architectural and Non-Architectural Relief Sculpture—This category includes panels, roofs, beams, balconies, stages, panels, ceilings, and doors for ceremonial and ritual use. Examples are carved, inlaid, or painted with decorations of religious, floral, or geometric motifs or Arabic inscriptions.

3. Furniture—This category includes furniture, such as minbars, *dikkas,* professorial chairs, episcopal thrones, lectures, divans, stools, altars, and tables from Islamic, Greek Orthodox, and Coptic ceremonial or ritual contexts. Examples can be carved, inlaid, or painted and are made from various types of wood.

4. Vessels and Containers—This category includes containers used for religious purposes such as Koran (*Qur'an*) cases or Greek Orthodox and Coptic Bible caskets and ciboria. Examples may be carved, inlaid, or painted with decorations in religious, floral, or geometric motifs, or Arabic script. Bible caskets may be covered with embossed silver sheets attached by nails.

5. Writing Implements—This category includes printing blocks, writing tablets, and Islamic study tablets inscribed in Arabic and used for teaching the Koran (*Qur'an*).

6. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals, such as frame drums (*banadir*).

7. Beads—This category includes Islamic prayer beads (*mas'baha*). Examples may be plain or decorated with carved designs.

E. Bone, Ivory, and Shell

1. Architectural Elements—This category includes lintels and doorframes (often carved), and inlays for religious decorative and architectural elements.

2. Ceremonial Paraphernalia—This category includes boxes, reliquaries (and their contents), plaques, pendants, candelabra, and stamp and seal rings.

F. Glass and Semi-Precious Stone

1. Architectural Elements—This category includes windowpanes, mosaic elements, inlays, and stained glass from ceremonial or ritual contexts.

2. Vessels and Containers—This category includes glass and enamel lamps and vessels used for Islamic, Greek Orthodox, and Coptic religious services. It also includes Greek Orthodox and Coptic Bible caskets that may include glass decoration (cabochons) as part of the embossed silver cover.

3. Beads—This category includes Islamic prayer beads (*mas'baha*) in glass or semi-precious stones.

G. Leather, Parchment, and Paper

1. Books and Manuscripts—Manuscripts can be written or painted on paper or papyrus. They occur as

single leaves, bound with leather or wood as a book or codex, or rolled into a scroll. Types include the Koran (*Qur'an*) and other Islamic books, Greek Orthodox and Coptic Bibles, prayer books, and manuscripts. Books and manuscripts are often written in black or brown ink, and sometimes embellished with painted colorful floral, geometric, or human motifs.

2. Vessels and Containers—This category includes containers used for Islamic, Greek Orthodox, and Coptic religious services, such as leather Koran (*Qur'an*) cases or pouches.

3. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals, such as leather drums (*banadir*).

H. Textiles—

This category includes hangings, curtains, shrine covers, prayer rugs used in Islamic/Sufi religious ceremonies or rituals, and Greek Orthodox and Coptic funeral shrouds and tapestries. Examples can be made from linen, silk, cotton, and/or wool.

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The Treasures of Islamic Art in the Museums of Cairo, 2006, B. O'Kane (editor), American University in Cairo Press, Cairo and New York.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

Troy A. Miller, the Acting Commissioner, having reviewed and approved this document, is delegating the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12) is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, the table in paragraph (a) is amended by revising the entry for Egypt to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
*	* * * * * *	*
Egypt	Archaeological material representing Egypt's cultural heritage ranging approximately from 300,000 B.C. to A.D. 1750, and ethnological material ranging from A.D. 1517 to 1914.	CBP Dec. 21–17.
*	* * * * * *	*

* * * * *

Robert F. Altneu,

Director, Regulations & Disclosure Law Division Regulations & Rulings, Office of Trade U.S. Customs and Border Protection.

Approved:

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2021–26348 Filed 12–1–21; 11:15 am]

BILLING CODE 9111–14–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 645

[Docket No. FHWA–2019–0037]

RIN 2125–AF92

Broadband Infrastructure Deployment

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FHWA amends its regulations governing the accommodation of utilities on the right-of-way (ROW) of Federal-aid or direct Federal highway projects to implement requirements of the Consolidated Appropriations Act, 2018, for broadband infrastructure deployment. The requirements, which will apply to each State that receives Federal funds under Chapter 1 of title 23, United States Code (U.S.C.), aim to facilitate the installation of broadband infrastructure.

DATES: This rule is effective March 3, 2022.

ADDRESSES: This document, the Notice of Proposed Rulemaking (NPRM), the supporting economic analysis, and the public comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Julie Johnston, Office of Preconstruction, Construction and Pavements (HICP–10), (202) 591–5858, or via email at *Julie.Johnston@dot.gov,* or Mr. Lev Gabrilovich, Office of the Chief Counsel (HCC–30), (202) 366–3813, or via email at *Lev.Gabrilovich@dot.gov.* Office hours are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Utility facilities, unlike most other fixed objects that may be present within the highway environment, are not owned nor are their operations directly controlled by State or local public agencies. Federal laws and FHWA regulations contained in 23 U.S.C. 109, 111, 116, and 123 and 23 CFR parts 1, 635, 645, and 710 regulate the accommodation, relocation, and reimbursement of utilities located within the highway ROW. State departments of transportation (State DOT) are required to develop Utility Accommodation policies that meet these regulations. 23 CFR 645.211.

Legal Authority, Statement of the Problem, and Regulatory History

The Consolidated Appropriations Act, 2018 (Pub. L. 115–141), Division P, Title VII (''MOBILE NOW Act''), Section 607, Broadband Infrastructure Deployment (47 U.S.C. 1504), directs the Secretary of Transportation to promulgate regulations to ensure that States meet specific registration, notification, and coordination requirements to facilitate broadband infrastructure deployment in the ROW of applicable Federal-aid highway projects. Accordingly, this rulemaking is required by statute. This regulation addresses the need to update FHWA regulations to implement the Section 607 requirements.

FHWA published a NPRM on August 13, 2020 (85 FR 49328), seeking public comment on proposed revisions to its regulations governing the accommodation of utilities on the ROW of Federal-aid or direct Federal highway projects to implement the Section 607 requirements. FHWA also requested public comments on an economic analysis summarized in the preamble to the proposed rule and presented in a supporting statement and a spreadsheet found in the rulemaking docket (FHWA–2019–0037). FHWA received 30 public comment submissions. Commenters included several State DOTs, industry associations, associations of State and local officials, companies, and individuals. After carefully considering the comments received in response to the NPRM in light of the statutory requirements, FHWA is promulgating final regulations without changes to the proposed regulations.

Overview of the Final Rule

The final rule, which aims to facilitate the installation of broadband infrastructure, will apply to each State that receives Federal funds under Chapter 1 of title 23, U.S.C., including the District of Columbia and the Commonwealth of Puerto Rico. The MOBILE NOW Act defines the term ''State'' and other terms that are used in the final rule such as ''appropriate State agency,'' ''broadband infrastructure,'' and ''broadband infrastructure entity,'' as discussed in the preamble to the proposed rule. See 85 FR at 49329.

In § 645.307(a), FHWA sets out four new requirements of Section 607 of the MOBILE NOW Act. First, § 645.307(a)(1) requires that the State DOT, in consultation with appropriate State agencies, identify a broadband utility coordinator who is responsible for facilitating the infrastructure ROW efforts within the State.

Second, § 645.307(a)(2) requires the State DOT, in consultation with appropriate State agencies, to establish a registration process for broadband infrastructure entities that seek to be included.

Section 645.307(a)(3) requires the State DOT, in consultation with appropriate State agencies, to establish a process for electronically notifying broadband infrastructure entities identified under § 645.307(a)(2), on an annual basis, of the State Transportation Improvement Program (STIP) and providing other notifications as necessary. FHWA assumes that to comply with this provision, States will create an electronic notification process, update their utility accommodation policies to include this new process, and also notify broadband companies of these changes, as discussed in the preamble to the proposed rule. See 85 FR at 49330.

Finally, § 645.307(a)(4) requires that the State DOT, in consultation with appropriate State agencies, coordinate initiatives under Section 607 of the MOBILE NOW Act with other statewide telecommunication and broadband plans and State and local transportation and land use plans, including strategies to minimize repeated excavations that involve broadband infrastructure installation in a ROW. FHWA assumes a statewide coordinator will carry out these responsibilities, as discussed in the preamble to the proposed rule. See 85 FR at 49330.

Section 645.307(b) contains the Section 607 of the MOBILE NOW Act provision that, if a State chooses to provide for the installation of broadband infrastructure in the ROW of an applicable Federal-aid highway project, the State DOT must ensure that any existing broadband infrastructure entities are not disadvantaged, as compared to other broadband

infrastructure entities, with respect to the Section 607 program.

Consistent with Section 607 of the MOBILE NOW Act, § 645.309 provides that nothing in part 645, Subpart C, requires that a State install or allow the installation of broadband infrastructure in a highway ROW, and that nothing in part 645, Subpart C, authorizes the Secretary to withhold or reserve funds or approval of a Title 23 project.

Discussion of Comments Received in Response to the NPRM

FHWA received 30 public comment submissions in response to the NPRM. Commenters included several State DOTs, industry associations, associations of State and local officials, companies, and individuals. The following summarizes the comments received and FHWA's responses to the most significant issues raised in the comments.

General Comments

FHWA received general comments on the NPRM that do not concern specific provisions of the rule. The general comments covered commenters' views on the rule and topics such as the rule's relationship to other regulations and authorities, timely implementation and compliance, suggested best practices, the eligibility of certain activities for Federal-aid funds, the need for the rule, the supporting economic analysis, and National Environmental Policy Act (NEPA) compliance.

Multiple commenters expressed support for the rule. Commenters cited the rule's potential to facilitate efficient broadband infrastructure deployment, including in rural areas, to complement efforts by other Federal entities, and to lay the groundwork for ''smart roads'' or other emerging applications. The commenters' support is noted.

One State DOT noted that the proposal broadly categorized all Broadband Facilities as utilities that are subject to 23 CFR part 645, which the commenter believed may be an unintended consequence of the rule.

This rule does not change the definition of the term ''[u]tility'' under 23 CFR 645.105. Further, under 23 CFR 645.209(m) regarding utility determinations, in determining whether a proposed installation is a utility, the most important consideration is how the State DOT views it under its own State laws and regulations.

One commenter suggested that language be added to the rule to require a State DOT implementing this subpart to abide by the provisions of Title 47 of the U.S.C. and various rules and regulations issued by the Federal Communications Commission (FCC) under title 47.

This rule meets the mandate provided by Congress in Section 607 of the MOBILE NOW Act. It does not change the applicability of other requirements enacted by Congress or promulgated by the FCC.

One commenter stated that FHWA should ensure that policies developed pursuant to this directive are implemented in a timely manner and comport with existing regulations regarding ROW fees for telecommunications infrastructure. Another commenter suggested a 90-day deadline from the effective date of the final rule for States to achieve compliance.

While these comments emphasize the importance of implementing the final rule in a timely manner, including by providing a compliance date, other comments received on the NPRM state that implementing the final rule will involve additional responsibilities beyond existing practices and corresponding resources. FHWA appreciates both perspectives from the commenters and has included an effective date that is 90 days after the date of publication of the final rule in the **Federal Register**. This effective date acknowledges and reflects both the need for time to prepare to implement the final rule and the importance of timely implementation. Consistent with the statutory requirement codified at 47 U.S.C. 1504(c), § 645.303 provides that this subpart applies only to activities for which Federal obligations or expenditures are initially approved on or after the effective date of this final rule.

One State DOT requested more direction about the purpose and objectives of the requirement for Webinars. The State DOT also asked FHWA to allow State DOTs to hold as many or as few Webinars or other engagements as may be necessary to satisfy the State's goals for broadband infrastructure deployment in transportation ROW and the needs of the State's telecommunications providers.

In the preamble to the proposed rule, FHWA explained that it assumed, for purposes of the economic analysis for the proposed rule, that FHWA employees would prepare and present one external and one internal Webinar to explain the proposed requirements to State DOTs. See 85 FR at 49329–49330. The reference to Webinars was limited to FHWA's NPRM rollout and was not intended to suggest expectations for State DOTs going forward. Like the proposed rule, the final rule contains no requirements that State DOTs or others hold Webinars.

One commenter noted that the utility coordination personnel in each State should require subsurface utility engineering (SUE) for placement of broadband as a best practice.

This comment is outside the scope of this rulemaking, which implements the Section 607 requirements. Since 1991, however, FHWA has been encouraging the use of SUE on Federal-aid and Federal Lands Highway projects as an integral part of the preliminary engineering process. Utility coordination personnel may consider the use of SUE for placement of broadband.

One State DOT recommended that FHWA consider that broadband in ROW for roads, transit, and rail is vital for intelligent transportation systems (ITS) and other infrastructure management purposes. The commenter noted that in addition to offering benefits today, such data flow options can benefit future users of the infrastructure. Therefore, the commenter asserts that such projects could be eligible for Title 23 and Title 49 funds, where transportation purposes are carried out with such broadband infrastructure deployment in transportation ROW. Further, the commenter suggests that FHWA should encourage States to handle broadband infrastructure in a similar fashion as other utilities within the State.

FHWA appreciates the comment. This rule does not change any eligibilities for Title 23 or Title 49 funds as the underlying statutory authority does not make such a change. Moreover, each State has individual laws governing utilities. States continue to have the autonomy to implement or amend their laws to meet the requirements of this rule in a manner that fits with their existing practices and meets their needs and objectives.

One commenter noted concerns about match rates and installation of broadband because, the commenter stated, many rural areas and communities are struggling for funding and need to balance priorities. The commenter also mentioned that if rural areas have limited communication capabilities, pedestrian issues and automated vehicle technologies will not be maximized in rural areas.

FHWA notes that the purpose of the rule, which implements Section 607 of the MOBILE NOW Act, is to facilitate deployment of broadband infrastructure, including in rural areas. However, the specific issues raised by the commenter are outside the scope of this rulemaking.

One State DOT commented that the requirements in this rule are not needed

nor would they provide additional benefits for the deployment of broadband infrastructure on Federal-aid highways. The commenter added that the requirements appear to create or duplicate work as the State already has established efficient processes and strong relationships with utility partners including broadband companies in their State.

This rule satisfies the mandate provided by Congress in Section 607 of the MOBILE NOW Act. Further, the rule allows flexibility for States to use their existing processes to meet the requirements of this rule.

One commenter urged FHWA to reduce the assumed cost in the economic analysis because some States may already be in compliance. The commenter also suggested that cost savings, or economic benefits, of a Dig Once Policy should also be included in the economic analysis.

FHWA recognizes that some States already may be implementing some of the requirements of this rule. For example, in the Supporting Statement on the economic analysis for the proposed rule, FHWA noted that some States may add the broadband utility coordinator responsibility onto the role of an existing employee. However, FHWA lacks data and information on specific States' practices that would facilitate a more refined analysis. Although FHWA requested data and information to inform the economic analysis in the NPRM, FHWA did not receive relevant data or information.

As discussed in response to a comment on proposed § 645.307(a)(1), FHWA expects that the duties of a broadband utility coordinator are likely to vary across all States, but would be less than a full-time commitment. In the economic analysis for the final rule, FHWA assumes that roughly 50 percent of an employee's time might be taken up by performing the duties related to this provision, which represents the expected average burden of the broadband utility coordinator across all States.

Regarding the benefits of a Dig Once Policy, FHWA explained in the economic analysis for the proposed rule that the rule is expected to result in benefits from increased coordination between government agencies and broadband entities at different levels. FHWA expects this increased coordination generally would increase the efficiency of broadband projects and potentially result in fewer disruptions for area residents. FHWA, however, lacks the data and information needed to quantify these potential benefits. While FHWA in the NPRM requested data and information to inform the economic analysis, FHWA did not receive relevant data or information. Accordingly, FHWA acknowledges the potential benefits of a Dig Once approach on a qualitative basis.

One State DOT noted that the NPRM indicates the proposed rulemaking action is categorically excluded under 23 CFR 771.117(c)(1), and asked how FHWA made that determination.

This rule implements the requirements of section 607 of the MOBILE NOW Act (47 U.S.C. 1504) that are applicable to States that receive Title 23 Federal-aid highway funds. This rule does not involve and will not lead directly to construction. This rule establishes coordination, registration, and notification requirements that State DOTs will implement.

Comments on § 645.307(a)(1)

Multiple commenters expressed concern that the requirement to identify a broadband utility coordinator is an unfunded mandate.

For the reasons explained in the ''Rulemaking Analyses and Notices'' section of this preamble, this rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48).

Multiple State DOTs disagreed with FHWA's estimates of the level of effort that is necessary to meet the rule's requirements. These State DOTs estimate a significantly higher resource impact from this rule than that estimated by FHWA. In particular, some State DOTs commented that there will be increased administrative, coordination, and inventory needs as a result of this rule and that the broadband utility coordinator may need to have specialized expertise due to the nature of the broadband industry.

FHWA expects that it is likely the duties of a broadband utility coordinator will vary across all States, but would be less than a full-time employee (FTE) commitment. As discussed in the NPRM, FHWA assumed in the economic analysis for the proposed rule that 30 percent of an employee's time would be utilized for these duties. After considering the public comments received in response to the NPRM and revisiting the time assumptions used in the economic analysis for the proposed rule, FHWA assumes that roughly 50 percent of an FTE's time might be utilized for the duties related to the broadband utility coordinator provision. This represents the estimated average burden of the broadband utility coordinator position across all States. FHWA has revised the economic analysis for the final rule to reflect the 50 percent assumption.

Two State DOTs sought clarification on ''efforts within the State'' and suggested that ''ROW'' be specifically confined to transportation ROW.

The language in the final rule tracks the statutory language in Section 607 of the MOBILE NOW Act. The efforts in each State to implement the final rule may vary based on State law, policies, and practices for broadband infrastructure deployment.

One State DOT stated that more specificity regarding the duties of broadband utility coordinator may be helpful.

FHWA has not defined the duties of the broadband utility coordinator in this regulation in order to allow for any flexibility States may need to implement this regulation.

One State DOT asked to what extent are the other appropriate State agencies to have approval pertaining to the selection of the coordinator, who is to identify the other State agencies for consultation, and what level of documentation FHWA will require to verify that consultation has occurred.

Aside from providing for a State DOT's consultation with appropriate State agencies, the final rule does not include requirements relating to such agencies. Each State has flexibility to identify the other State agencies and to establish any other requirements or procedures, such as the level of documentation of consultation, to implement this regulation.

One State DOT asked whether, if the broadband utility coordinator resides in another agency besides the State DOT, Federal funds could be used to reimburse time and expenses of that coordinator and what documentation would be required.

This rule does not change any eligibilities for Title 23 funding consistent with governmentwide administrative requirements and cost principles in 2 CFR part 200.

One State DOT asked if FHWA will provide a list of minimum requirements that a non-DOT coordinator should possess concerning knowledge and understanding of the Federal guidelines concerning utilization of the ROW.

The final rule does not include such requirements and FHWA does not anticipate establishing such requirements. Rather, each State retains flexibility to determine the minimum requirements needed to implement this regulation.

Comments on § 645.307(a)(2)

FHWA also received comments on § 645.307(a)(2), which requires a State

DOT, in consultation with appropriate State agencies, to establish a process for the registration of broadband infrastructure entities.

Multiple commenters asked that flexibility be given to allow States to rely on existing processes, avoid unnecessary duplication of effort, and limit the wasteful expenditure of limited State resources.

FHWA generally agrees with the commenters' suggestion. The final rule reflects the statutory requirements of Section 607 of the MOBILE NOW Act (47 U.S.C. 1504) but allows States flexibility to rely on existing processes and avoid duplication of efforts to meet the requirements.

One State DOT requested clarification on the purpose and meaning of ''registration of broadband infrastructure entities'' and ''goals''. The comment suggested that FHWA define ''goals'' with specific criteria.

Consistent with Section 607 of the MOBILE NOW Act, the final rule in § 645.307(a)(2) requires a State DOT to establish a process for the registration of broadband infrastructure entities that seek to be included in broadband infrastructure ROW facilitation efforts within the State. The final rule in § 645.307(a)(3) requires a State DOT to establish a process for electronically notifying broadband infrastructure entities of the STIP annually and as necessary to achieve the goals of the rule. FHWA has not included more specific goals or criteria in the rule in order to allow State DOTs the flexibility to implement this rule consistent with their respective State laws, policies, and practices.

One commenter requested clarification that the definition of ''broadband infrastructure entity'' is not limited to private companies but also includes any formal or informal entity serving broadband. As examples of such entities, the commenter cited municipal, State, and Tribal governments or agencies, associations of governments or agencies or intergovernmental bodies, rural electric cooperatives or public utilities, public-private partnerships, and non-profits.

Under 47 U.S.C. 1504(a)(3) and § 645.305, the term ''broadband infrastructure entity'' means any entity that (A) installs, owns, or operates broadband infrastructure; and (B) provides broadband services in a manner consistent with the public interest, convenience, and necessity, as determined by the State. States have flexibility to determine which entities fit within this definition.

One State DOT asked for clarification regarding the registration process for broadband infrastructure entities that seek to be included. Specifically, the commenter asked whether FHWA will provide a list of qualifications that are necessary for a company to become registered, whether the broadband coordinator will handle the registration process and maintain the registration, whether the list of registered companies is disclosable under public records requests, and whether only registered broadband infrastructure entities will be permitted to occupy the State ROW.

States have flexibility to determine which entities fall within the definition of the term ''broadband infrastructure entity'' in 47 U.S.C. 1504(a)(3) and any qualifications such entities need to have. States also have flexibility to establish a process, or use an existing process, for registration. Public records requests will be subject to applicable State laws, regulations, and policies. This rule does not require that only registered broadband infrastructure entities be permitted to occupy the State ROW.

Comments on § 645.307(a)(3)

Several comments concerned § 645.307(a)(3), which requires that a State DOT, in consultation with appropriate State agencies, establish a process to notify electronically broadband infrastructure entities identified under § 645.307(a)(2) of the STIP on an annual basis and provide additional notifications as necessary to achieve the goals of 23 CFR subpart C.

One State DOT recommended that FHWA place additional emphasis for States to utilize the STIP and States' other medium- and long-range planning activities to convey Dig Once type opportunities to telecommunications companies as they plan and fund their construction of broadband.

Under the final rule, States have flexibility to establish a process, or use an existing process, to implement the registration and notification requirements. States may choose to convey Dig Once opportunities in connection with their STIP or their planning activities as they implement those requirements, and FHWA encourages States to do so.

One commenter stated that to facilitate general notification as required by the rule, FHWA should encourage States to maintain publicly accessible databases of ongoing projects along with any third-parties that have been contracted to review applications for projects. A database, maintained on a deemed consented basis, would allow for self-policing of potential conflicts and increase accountability for these projects, the commenter added.

States have flexibility to establish a process, or use an existing process, to implement the registration and notification requirements.

One State DOT asked why, since the STIP is made available for review and comment via electronic and other means, broadband infrastructure entities must be provided a separate, exclusive notice that is not necessarily afforded to other sectors of the public.

This rule implements the mandate provided by Congress in Section 607 of the MOBILE NOW Act and codified at 47 U.S.C. 1504(b)(1)(C).

One State DOT asked if ''other notifications'' will be determined by the broadband utility coordinator and if metropolitan planning organizations (MPO) also will be required to notify broadband entities annually of the metropolitan transportation improvement programs.

Again, States have flexibility to establish a process, or use an existing process, to implement the registration and notification requirements, as well as to shape the role of the broadband utility coordinator. This rule applies to each State that receives funds under Chapter 1 of Title 23, U.S.C., including the District of Columbia and the Commonwealth of Puerto Rico. 47 U.S.C. 1504(b)(1); 23 CFR 645.303. It does not apply to MPOs.

One State DOT noted that for a Dig Once program to be most effective, broadband entities would have to be required to register and then actively participate in the program. The commenter asserted that industry so far has shown no interest in joint trenching or Dig Once types of voluntary programs and that without more willingness on the part of industry, a proactive notification system prescribed by this rule would not be significantly more effective than the State DOT's current notice approach where the data on projects is posted and updated on their website.

In Section 607 of the MOBILE NOW Act, Congress required FHWA to issue regulations that ensure that a State DOT, in consultation with appropriate State agencies, establishes a registration process for broadband infrastructure entities that seek to be included in broadband infrastructure ROW facilitation efforts within the State. The final rule adopts the language of Section 607 as proposed but does not establish additional requirements. Nothing in the final rule limits a State's ability to adopt additional registration requirements consistent with the regulation adopted through this rulemaking.

Comments on § 645.307(a)(4)

In addition, FHWA received comments on § 645.307(a)(4), which requires that a State DOT, in consultation with appropriate State agencies, coordinate initiatives carried out under this subpart with other statewide telecommunication and broadband plans and State and local transportation and land use plans, including strategies to minimize repeated excavations that involve the installation of broadband infrastructure in a right-of-way.

One commenter appreciated the need to work with other State agencies to coordinate a Dig Once program, but felt that a mandate, instead of guidance, from the Federal government goes too far. Another commenter stated that many cities already have a Dig Once policy and coordinate with utilities frequently, calling for fewer requirements and streamlining the delivery of Federal highway projects.

Congress expressly required FHWA to promulgate regulations containing this requirement. This rule meets the mandate in Section 607 of the MOBILE NOW Act. States have flexibility to establish a process, or use an existing process, to meet the requirements of this rule, and States' processes may include streamlining the delivery of Federal highway projects.

Two commenters stated that FHWA should require States to adopt registration processes that are streamlined, efficient, and non-duplicative, and provide States guidance on strategies that minimize repeated excavations while preserving other laws and policies that promote infrastructure deployment.

FHWA has not included such requirements in the final rule. While FHWA generally supports streamlined, efficient, and non-duplicative processes and strategies, FHWA believes that States are well-positioned to determine their own appropriate approaches. Accordingly, States have flexibility to establish a process or strategy, or use an existing process or strategy, to meet the requirements of the final rule.

One State DOT stated that strategies to minimize repeated excavation of broadband infrastructure and other utilities are unsuccessful, and that broadband and communications companies are on their own schedule mainly due to customer demand and available budgets. The State DOT noted that while every effort is made to minimize repeated ROW excavations, it would be unfair to any broadband company to exclude them from installing infrastructure in the same corridor simply on the basis that a competitor installed its infrastructure weeks, months, or perhaps the year before they did.

States have the flexibility to establish a process, or use an existing process, to meet the requirements of the final rule. Also, under § 645.309, nothing in this rule requires that a State install or allow the installation of broadband infrastructure in a highway ROW.

One commenter recommended that certain best practices be implemented to ensure no undue delays are experienced in minimizing repeated excavations, Federal regulations for ROW access fees are followed, and transparency is provided by any third-party entities contracted by the State. The commenter added that FHWA should use this rulemaking as an opportunity to encourage efficient processes like micro trenching.

The final rule implements the requirements in Section 607 of the MOBILE NOW Act (47 U.S.C. 1504) but does not establish additional requirements. Nor does this final rule change the applicability of any other Federal regulations. States have flexibility to establish a process, or use an existing process, to meet the requirements of this rule and to encourage best practices that they consider appropriate.

One State DOT stated that it anticipates difficulties resulting from a lack of jurisdiction and control over sister agencies or Local Public Agencies to obtain or have ready access to documents such as local land use plans. The State DOT would like clarification regarding ''consultation with appropriate State agencies'' and the expectation of formality, frequency and decisionmaking authority.

Consistent with Section 607 of the MOBILE NOW Act, the final rule requires that State DOTs, in consultation with appropriate State agencies, carry out the requirements of this rule. The final rule does not specify requirements for formality, frequency, and decisionmaking authority. Rather, each State DOT has flexibility to implement this rule under its own State laws, regulations, policies, and procedures.

One State DOT asked if the broadband coordinator is supposed to request all plans and strategies from broadband infrastructure entities and whether those plans and strategies are subject to disclosure under a public records request.

The intent of this section is to minimize excavations through project planning and coordination with other statewide broadband and land use plans. However, the final rule does not specify the duties of the broadband utility coordinator. States have flexibility to establish a process, or use an existing process, to meet the requirements of this rule and to determine the role of the broadband utility coordinator. Public records requests will be subject to applicable State laws, regulations, and policies.

One State DOT asked if a State DOT contractor's claims of construction delays or damage would increase if broadband entities are allowed to work within an active roadway construction project implemented by the State DOT contractor. They asked how this would impact the State DOT contractor's bond and what liability might the State DOT or its contractor assume for the broadband company working within the State DOT contractor's traffic control limits.

Utility work is commonly done within the project limits of an active roadway construction project. However, the final rule does not address the issues raised in the comment. They are outside the scope of this rulemaking.

Comments on § 645.307(b)

One State DOT requested clarity on the use of the terms ''existing'' and ''disadvantaged'' to assist States in determining how broadly the terms are defined.

The final rule implements the requirements of and uses the language in Section 607 of the MOBILE NOW Act. The final rule does not define these terms. States have flexibility to interpret these terms to meet the requirements of this rule. Nothing in this rule prohibits the installation of additional broadband facilities where facilities already exist.

One State DOT recommended that FHWA provide additional guidance and clarity on how to ensure existing entities are not disadvantaged with respect to the Section 607 program while also ensuring no broadband entity receives exclusive access to ROW. The rules should explicitly allow State DOTs to deny access based on physical, financial, operational, and safety constraints, the commenter recommended.

Nothing in the final rule or 23 CFR part 645 requires a State DOT to install or allow to be installed broadband infrastructure. Further, 23 CFR part 645, subpart B, Accommodation of utilities, applies to the installation of utilities within the Federal-aid ROW such that the use and occupancy of the highway ROW does not adversely affect highway or traffic safety, or otherwise impair the highway or its aesthetic quality, and does not conflict with the provisions of

Federal, State, or local laws or regulations.

One commenter stated that while they support this proposal, it lacks instruction on the selection of the broadband provider beyond requiring that the State DOT ensure that any existing broadband infrastructure entities are not disadvantaged, as compared to other broadband infrastructure entities, with respect to the Section 607 program. The single sentence instruction is simply insufficient to safeguard against gaming the system or politics dictating the process of selection of providers, the commenter added, and this lack of instruction could result in State monopolies for service providers that may not be providing the greatest benefit to the public.

Neither Section 607 of the MOBILE NOW Act nor the final rule requires a State to select a broadband infrastructure provider.

One commenter suggested adding that any third-party administrator contracted by a State DOT to facilitate broadband infrastructure deployment should not have a conflict of interest in administering access to the ROW (*e.g.,* a subsidiary relationship to one broadband infrastructure entity that could affect competitors).

Each State has flexibility to determine the minimum requirements needed to meet this regulation.

Comments on § 645.309

One State DOT noted that it seems contradictory to require and implement this rule if broadband infrastructure installation is not allowed on State highways.

This rule meets the mandate provided by Congress in Section 607 of the MOBILE NOW Act. Nothing in this rule requires that a State install or allow the installation of broadband infrastructure in a highway ROW.

One State DOT asked with regard to § 645.309, whether there are penalties or other consequences that FHWA may impose on State DOTs for not complying with Subpart C.

Consistent with 47 U.S.C. 1504(c), § 645.309 provides that nothing in this subpart authorizes the Secretary of Transportation to withhold or reserve funds or approval of a project under Title 23 of the U.S.C.

One State DOT asked what consequence FHWA may impose on a State DOT if the coordinator residing in another agency fails to meet the broadband deployment goals, or performance measures that may be enacted in the future.

Consistent with 47 U.S.C. 1504(c), § 645.309 provides that nothing in this subpart authorizes the Secretary to withhold or reserve funds or approval of a project under Title 23 of the U.S.C.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, OMB has not reviewed it. This action complies with E.O. 12866 and 13563 to improve regulation. FHWA anticipates that the rule would not adversely affect, in a material way, any sector of the economy. In addition, the rule would not interfere with any action taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. The rule also does not raise any novel legal or policy issues.

The following is a summary of the results of the economic analysis for this rule. A supporting statement and a spreadsheet in the rulemaking docket (FHWA–2019–0037) contain additional details.

As discussed in the ''Discussion of Public Comments Received in Response to the NPRM'' section of the preamble, FHWA revised the economic analysis for the proposed rule in light of comments received suggesting that the required broadband utility coordinator position would take up more than 30 percent of a State employee's time, as FHWA assumed at the proposed rule stage. FHWA still expects that the duties of a broadband utility coordinator are likely to vary across all States, but that they would be less than a full-time commitment. For the final rule, though, FHWA assumed that roughly 50 percent of an employee's time might be taken up by performing the duties related to this provision, which represents the expected average burden of the broadband utility coordinator across all States.

With this revised assumption, the economic impacts of the final rule that FHWA is able to quantify are the costs that the rule would impose on States, and also on FHWA. The rule would result in total 10-year costs of $37.1 million or $30.7 million in 2018 dollars at discount rates of 3 percent or 7 percent, respectively. On an annualized basis, the rule would result in $4.3 million or $4.4 million in costs at 3 percent and 7 percent discount rates, respectively, and again in 2018 dollars. The costs of the proposed rule are primarily borne by States, with less than 1 percent of the total costs accruing to FHWA, and the remaining more than 99 percent of costs accruing to States. Based on the estimated economic impacts and the other criteria for a significant regulatory action under section 3(f) of E.O. 12866 and as supplemented by E.O. 13563, this rule is not a significant regulatory action.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this rule on small entities and has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. The rule affects States, and States are not included in the definition of small entity set forth in 5 U.S.C. 601. The rule would also affect broadband entities, but the impact on these entities is expected to be beneficial and also to involve potential cost savings. The rule is thus not expected to result in increased costs for broadband entities. Therefore, FHWA certifies that the action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48). This rule would not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $155 million or more in any one year (2 U.S.C. 1532). In addition, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility. Finally, this rule only implements requirements specifically set forth in statute.

Executive Order 13132 (Federalism Assessment)

This rule has been analyzed in accordance with the principles and criteria contained in E.O. 13132, and FHWA has determined that this rule would not have sufficient federalism

implications to warrant the preparation of a federalism assessment. FHWA also has determined that this rule would not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 13175 (Tribal Consultation)

FHWA has analyzed this rule in accordance with the principles and criteria contained in E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' The rule implements statutory requirements that apply to States that receive Title 23 Federal-aid highway funds, and it would not have substantial direct effects on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal laws. Accordingly, the funding and consultation requirements of E.O. 13175 do not apply and a Tribal summary impact statement is not required.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. FHWA has determined that this rule does not contain collection of information requirements for the purposes of the PRA.

National Environmental Policy Act

The Agency has analyzed this rulemaking action pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded under 23 CFR 771.117(c)(1), which applies to activities that do not involve or lead directly to construction. Categorically excluded actions meet the criteria for categorical exclusions under the Council on Environmental Quality regulations and under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA. This rulemaking includes in FHWA regulations the coordination, registration, and notification requirements of 47 U.S.C. 1504 that are applicable to States that receive Title 23 Federal-aid highway funds. This rulemaking does not involve and will not lead directly to construction. FHWA does not anticipate any environmental impacts, and there are no unusual circumstances present under 23 CFR 771.117(b).

Executive Order 12898 (Environmental Justice)

E.O. 12898 requires that each Federal Agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. FHWA has determined that this rule does not raise any environmental justice issues.

Regulation Identification Number

A Regulation Identification Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 645

Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements, Utilities.

Issued under authority delegated in 49 CFR 1.81 and 1.85 on.

Stephanie Pollack,

Acting Administrator, Federal Highway Administration.

In consideration of the foregoing, FHWA amends part 645 of title 23 of the CFR as set forth below:

PART 645—UTILITIES

■ 1. Revise the authority citation for part 645 to read as follows:

Authority: 23 U.S.C. 101, 109, 111, 116, 123, and 315; 47 U.S.C. 1504; 23 CFR 1.23 and 1.27; 49 CFR 1.48(b); and E.O. 11990, 42 FR 26961 (May 24, 1977).

■ 2. Add subpart C to read as follows:

Subpart C—Broadband Infrastructure Deployment

Sec.

Subpart C—Broadband Infrastructure Deployment

§ 645.301 Purpose.

To prescribe additional requirements to facilitate the installation of broadband infrastructure pursuant to 47 U.S.C. 1504.

§ 645.303 Applicability.

This subpart applies to each State that receives funds under Chapter 1 of Title 23 of the U.S.C. and only to activities for which Federal obligations or expenditures are initially approved on or after the effective date of this subpart.

§ 645.305 Definitions.

For purposes of this subpart, the terms defined in 47 U.S.C. 1504(a) shall have the same meaning where used in these regulations, notwithstanding other provisions of this part or Title 23 of the U.S.C.

§ 645.307 General requirements.

(a) A State department of transportation, in consultation with appropriate State agencies, shall:

(1) Identify a broadband utility coordinator, whether in the State department of transportation or in another State agency, that is responsible for facilitating the broadband infrastructure right-of-way efforts within the State. The broadband utility coordinator may have additional responsibilities.

(2) Establish a process for the registration of broadband infrastructure entities that seek to be included in those broadband infrastructure right-of-way facilitation efforts within the State.

(3) Establish a process to notify electronically broadband infrastructure entities identified under subsection (2) of the State Transportation Improvement Program on an annual basis and provide additional notifications as necessary to achieve the goals of this subpart; and

(4) Coordinate initiatives carried out under this subpart with other statewide telecommunication and broadband plans and State and local transportation and land use plans, including strategies to minimize repeated excavations that involve the installation of broadband infrastructure in a right-of-way.

(b) If a State chooses to provide for the installation of broadband infrastructure in the right-of-way of an applicable Federal-aid highway project under this section, the State department of transportation shall carry out any appropriate measures to ensure that any existing broadband infrastructure entities are not disadvantaged, as compared to other broadband infrastructure entities, with respect to the program under this section.

§ 645.309 Limitations.

Nothing in this subpart establishes a mandate or requirement that a State install or allow the installation of broadband infrastructure in a highway right-of-way. Nothing in this subpart

authorizes the Secretary to withhold or reserve funds or approval of a project under Title 23 of the U.S.C.

[FR Doc. 2021–26231 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

[Docket No. OSHA–2021–0007]

RIN 1218–AD42

COVID–19 Vaccination and Testing; Emergency Temporary Standard

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Interim final rule; extension of comment period.

SUMMARY: The period for submitting public comments is being extended by 45 days to allow stakeholders interested in the COVID–19 vaccination and testing emergency temporary standard (ETS) additional time to review the ETS and collect information and data necessary for comment.

DATES: The comment period for the interim final rule on the ETS, which was published November 5, 2021 at 86 FR 6140, and effective on November 5, 2021, is extended. Comments on any aspect of the ETS and whether the ETS should be adopted as a permanent standard must be submitted by January 19, 2022.

ADDRESSES:

Written comments: You may submit comments and attachments, identified by Docket No. OSHA–2021–0007, electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the online instructions for making electronic submissions. The Federal e-Rulemaking Portal at *www.regulations.gov* is the only way to submit comments on this rule.

Instructions: All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2021–0007). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA–2021–0007 at *www.regulations.gov.* All comments and submissions are listed in the *www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number (OSHA–2021–0007) plus a unique four-digit or five-digit code (*e.g.,* OSHA–2021–0007–0001). When citing materials in the docket, OSHA includes the term ''Document ID'' followed by the last four or five digits of the Document ID number (*e.g.,* Document ID 0001). Document ID numbers are used to identify docket materials in this notice. However, OSHA identified supporting information in the ETS (86 FR 61402) by author name and publication year, when appropriate. The agency has also provided a spreadsheet in the docket that identifies the full Document ID for each reference cited in the ETS (see Document ID 0493). This information can be used to search for a supporting document in the docket at *www.regulations.gov.* Contact the OSHA Docket Office at 202–693–2350 (TTY number: 877–889–5627) for assistance with locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Contact Frank Meilinger, Director, Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email *OSHAComms@dol.gov.*

For technical inquiries: Contact Andrew Levinson, Directorate of Standards and Guidance, U.S. Department of Labor; telephone (202) 693–1950; email *ETS@dol.gov.*

SUPPLEMENTARY INFORMATION: On November 5, 2021, OSHA issued an ETS to protect unvaccinated employees of large employers (100 or more employees) from the risk of contracting COVID–19 by strongly encouraging vaccination. Covered employers must develop, implement, and enforce a mandatory COVID–19 vaccination policy, with an exception for employers that instead adopt a policy requiring employees to either get vaccinated or elect to undergo regular COVID–19 testing and wear a face covering at work in lieu of vaccination.

The public comment period for the ETS was to close on December 6, 2021. However, OSHA received requests from several stakeholders to extend the comment period. Most requested an additional 60 days, which would result in a new comment deadline of February 4, 2022 (see, *e.g.,* Document ID 0503; 0525; 0574; 0575; 0576; 0577; 0578). These stakeholders explained that they need additional time to thoroughly review the ETS, gather input from members, and prepare comprehensive comments (see, *e.g.,* Document ID 0503; 0525; 0574; 0575; 0576; 0577; 0578).

OSHA agrees to an extension and believes a 45-day extension of the public comment period is sufficient and strikes an appropriate balance between the agency's need for timely input and stakeholders' requests for additional time to prepare comprehensive comments. Therefore, the public comment period will be extended until January 19, 2022.

Authority and Signature

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this document pursuant to the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8–2020 (85 FR 58393 (Sept. 18, 2020)); 29 CFR part 1911; and 5 U.S.C. 553.

Signed at Washington, DC, on November 29, 2021.

Douglas L. Parker,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–26268 Filed 12–2–21; 8:45 am]

BILLING CODE 4510–26–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets; Expected Retirement Age

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans by substituting a

new table for determining expected retirement ages for participants in pension plans undergoing distress or involuntary termination with valuation dates falling in 2022. This table is needed to compute the value of early retirement benefits and, thus, the total value of benefits under a plan.

DATES: This rule is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Hilary Duke (*duke.hilary@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–229–3839. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–229–3839.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) administers the pension plan termination insurance program under title IV of the Employee Retirement Income Security Act of 1974 (ERISA). PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) sets forth (in subpart B) the methods for valuing plan benefits of terminating single-employer plans covered under title IV. Guaranteed benefits and benefit liabilities under a plan that is undergoing a distress termination must be valued in accordance with subpart B of part 4044. In addition, when PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart B valuation rules to determine the amount of the plan's underfunding.

Under § 4044.51(b) of the asset allocation regulation, early retirement benefits are valued based on the annuity starting date, if a retirement date has been selected, or the expected retirement age, if the annuity starting date is not known on the valuation date. Sections 4044.55 through 4044.57 set forth rules for determining the expected retirement ages for plan participants entitled to early retirement benefits. Appendix D of part 4044 contains tables to be used in determining the expected early retirement ages.

Table I in appendix D (Selection of Retirement Rate Category) is used to determine whether a participant has a low, medium, or high probability of retiring early. The determination is based on the year a participant would reach ''unreduced retirement age'' (*i.e.,* the earlier of the normal retirement age or the age at which an unreduced benefit is first payable) and the participant's monthly benefit at unreduced retirement age. The table applies only to plans with valuation dates in the current year and is updated annually by PBGC to reflect changes in the cost of living, etc.

Tables II–A, II–B, and II–C (Expected Retirement Ages for Individuals in the Low, Medium, and High Categories respectively) are used to determine the expected retirement age after the probability of early retirement has been determined using Table I. These tables establish, by probability category, the expected retirement age based on both the earliest age a participant could retire under the plan and the unreduced retirement age. This expected retirement age is used to compute the value of the early retirement benefit and, thus, the total value of benefits under the plan.

This document amends appendix D to replace Table I–21 with Table I–22 to provide an updated correlation, appropriate for calendar year 2022, between the amount of a participant's benefit and the probability that the participant will elect early retirement. Table I–22 will be used to value benefits in plans with valuation dates during calendar year 2022.

PBGC has determined that notice of, and public comment on, this rule are impracticable, unnecessary, and contrary to the public interest. PBGC's update of appendix D for calendar year 2022 is routine. If a plan has a valuation date in 2022, the plan administrator needs the updated table being promulgated in this rule to value benefits. Accordingly, PBGC finds that the public interest is best served by issuing this table expeditiously, without an opportunity for notice and comment, and that good cause exists for making the table set forth in this amendment effective less than 30 days after publication to allow the use of the proper table to estimate the value of plan benefits for plans with valuation dates in early 2022.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866 and Executive Order 13771.

Because no general notice of proposed rulemaking is required for this regulation, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. Appendix D to part 4044 is amended by removing Table I–21 and adding in its place Table I–22 to read as follows:

Appendix D to Part 4044—Tables Used To Determine Expected Retirement Age

TABLE I–22—SELECTION OF RETIREMENT RATE CATEGORY

[For valuation dates in 2022 [1]]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low [2] if monthly benefit at URA is less than—	Medium [3] if monthly benefit at URA is—		High [4] if monthly benefit at URA is greater than—
		From—	To—	
2023	691	691	2,919	2,919
2024	706	706	2,984	2,984
2025	723	723	3,052	3,052
2026	739	739	3,122	3,122
2027	756	756	3,194	3,194
2028	774	774	3,268	3,268
2029	791	791	3,343	3,343
2030	810	810	3,420	3,420
2031	828	828	3,498	3,498

TABLE I–22—SELECTION OF RETIREMENT RATE CATEGORY—Continued

[For valuation dates in 2022 [1]]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low [2] if monthly benefit at URA is less than—	Medium [3] if monthly benefit at URA is—		High [4] if monthly benefit at URA is greater than—
		From—	To—	
2032 or later	847	847	3,579	3,579

[1] Applicable tables for valuation dates before 2022 are available on PBGC's website (*www.pbgc.gov*).
[2] Table II–A.
[3] Table II–B.
[4] Table II–C.

* * * * *

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2021–26234 Filed 12–2–21; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0885]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Southwest Pass Sea Buoy to Mile Marker 101, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone around the heavy load carrier vessel ZHEN HUA 23 as she transits the Lower Mississippi River between the Southwest Pass Sea Buoy and Port of New Orleans Terminal, mile marker 101. The moving safety zone extends from bank to bank encompassing one-mile ahead and one-mile astern of the vessel. This safety measure is necessary to protect persons and vessels from the potential safety hazards associated with congested maritime traffic on the Lower Mississippi River and the limited maneuverability and visibility of the vessel.

DATES: This rule is effective from December 5, 2021 through December 15, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0885 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander William Stewart, Sector New Orlean, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AHP Above Head of Passes
BHP Below Head of Passes
BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
COTP Captain of the Port Sector New Orleans
DHS Department of Homeland Security
FR Federal Register
LMR Lower Mississippi River
LNM Local Notice to Mariners
MM Mile Marker
NPRM Notice of proposed rulemaking
MSIB Marine Safety Informtion Bulletin
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the expected arrival of the vessel is less than two weeks away. It is impracticable to publish an NPRM because we must establish this safety zone prior to the vessel's arrival on December 5, 2021.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with potential safety hazards associated with congested maritime traffic on the Lower Mississippi River and the limited maneuverability and visibility of the heavy load carrier vessel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port New Orleans (COTP) has determined that temporary moving safety zone is necessary to provide for the safety of persons, vessels, and the marine environment during the transit of the heavy load carrier vessel ZHEN HUA 23 to the Port of New Orleans with limited maneuverability and visibility. Potential hazards include risk of injury if normal vessel traffic were to interfere with the vessel's movement. The transit is scheduled to take place from 6 a.m. on December 5, 2021 through 8 p.m. on December 15, 2021, in the navigable waters of the Lower Mississippi River. This rule is needed to protect persons, vessels, and the marine environment from hazards associated with the vessel's limited maneuverability and visibility in the navigable waters within the safety zone while the vessel transits.

IV. Discussion of the Rule

This rule establishes a temporary moving safety zone from December 5, 2021 through December 15, 2021. The safety zone will cover all navigable waters around the heavy load carrier vessel ZHEN HUA 23 as she transits the Lower Mississippi River between the Southwest Pass Sea Buoy and Port of New Orleans Terminal, MM 101. The moving safety zone extends from bank to bank encompassing one-mile ahead and one-mile astern of the vessel. This safety measure is necessary to protect persons and vessels from the potential

safety hazards associated with congested maritime traffic on the Lower Mississippi River and the limited maneuverability and visibility of the vessel. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on minimal impacts on routine navigation expected. The temporary moving safety zone will not interfere with a vessel's ability to make passing and overtaking arrangements. Routine navigation around and near the proposed safety zone will not be impacted. The temporary moving safety zone is intended to enable early notification of passing or overtaking arrangements, providing additional time and opportunity to negotiate navigational arrangements and to maneuver without causing delay in transit for both the heavy load carrier and the other vessels operating in the area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary moving safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a temporary moving safety zone one mile ahead, one mile astern and bank to bank of heavy load carrier vessel ZHEN HUA 23 on the LMR, lasting ten days. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0885 to read as follows:

§ 165.T08–0885 Safety Zone; Lower Mississippi River, Southwest Pass Sea Buoy to Mile Marker 101, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters within the Lower Mississippi River and Southwest Pass, around heavy lift carrier vessel ZHEN HUA 23 transiting between the Southwest Pass Entrance Lighted Buoy ''SW'', at approximate position 28°52′42″ N, 89°25′54″ W [NAD 83] and Port of New Orleans at approximate LMR MM 101 in New Orleans, Louisiana. The temporary moving safety zone extends bank to bank, encompassing all waters one-mile ahead and one-mile astern of the vessel. The zone remains in effect during the entire transit of the vessel.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port New Orleans (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative, except as provided for in paragraph (c)(3) of this section.

(2) For this section the Pilot directing the movement of the heavy load carrier vessel ZHEN HUA 23 under the authority of the master has the authority to allow other vessels to enter the safety zone when necessary.

(3) All vessels are prohibited from entering this safety zone unless authorized as follows:

(i) Vessels that have made suitable passing or overtaking arrangements with the pilot onboard the vessel ZHEN HUA 23 may enter into this safety zone in accordance with those agreed upon arrangements.

(ii) Moored vessels or vessels anchored in a designated anchorage area may remain in their current moored or anchored position while the vessel ZHEN HUA 23 transits the area.

(iii) Barge Fleets or vessels working a fleet may continue their current operations while the vessel ZHEN HUA 23 transits the area.

(4) Vessels requiring a deviation from this rule must request permission from the Captain of the Port New Orleans. The Captain of the Port New Orleans may be contacted at (504) 365–2545.

(d) *Enforcement period.* This section will be enforced from 6 a.m. on December 5, 2021 through 8 p.m. on December 15, 2021.

(e) Information broadcasts. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: November 29, 2021

W.E. Watson,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2021–26281 Filed 12–2–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0808]

RIN 1625–AA00

Safety Zone; Tchefuncte River, Madisonville, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a fireworks display on December 4, 2021 from 9 p.m. through 10 p.m. The safety zone is needed to protect people and the environment on these navigable waters of the Tchefuncte River, LA. This proposed rulemaking would prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port (COTP) Sector New Orleans or a designated representative.

DATES: This rule is effective from 9 p.m. to 10 p.m. on December 4, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0808 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander William A. Stewart, Waterways Management Division Chief, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LNM Local Notice to Mariners
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On October 19, 2021, the Coast Guard received a marine event permit application for a fireworks display on December 4, 2021 from 9 p.m. through 10 p.m. Fireworks display will be launched from a barge in the Tchefuncte River in the approximate position 30 23–52.4 N, 90 09–14.48 W. In response, on November 10, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zone; Tchefuncte River, Madisonville, LA'' (86 FR 62500). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended November 22, 2021, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with this fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP New Orleans has determined that potential hazards associated with the fireworks to be used in this December 4, 2021 display will be a safety concern for anyone within a 200 yard radius of the barge on the Tchefuncte River at 30 23–52.4 N, 90 09–14.48 W. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on November 10, 2021. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 9 p.m. to 10 p.m. on December 4, 2021. The safety zone will cover all navigable waters within 200 yards of a barge on the Tchefuncte River located at 30 23–52.4 N, 90 09–14.48 W. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 9:30 p.m. to 9:40 p.m. fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on establishing a temporary safety zone within a 200 yard radius of the deck barge located on the Tchefuncte River at 30 23–52.4 N, 90 09–14.48 W on December 4, 2021 from 9 p.m. to 10 p.m. Moreover, the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting one hour that would prohibit entry within a 200 yard radius around the deck barge located on the Tchefuncte River at 30 23–52.4 N, 90 09–14.48 W. It is categorically excluded from further review under paragraph L60 (a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0808 to read as follows:

§ 165.T08–0808 Safety Zone; Tchefuncte River, Madisonville, LA.

(a) *Location.* The following area is a safety zone: All navigable waters within a 200 yard radius of the deck barge at position 30 23–52.4 N, 90 09–14.48 W on the Tchefuncte River, Madisonville, LA.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector New Orleans (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, persons and vessels may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM radio channels 16 or 67. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 9 p.m. through 10 p.m. on December 4, 2021.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

Dated: November 29, 2021

W.E. Watson,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2021–26309 Filed 12–2–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0784]

RIN 1625–AA11

Safety Zone; Oil Pipeline Repairs; San Pedro Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the oil pipeline repair operations in the vicinity of a damaged pipeline, off the coast of Orange County and near San Pedro Bay, CA. The safety zone is necessary to reduce significant hazards to vessels, the harbor, and the public during ongoing pipeline repair and oil recovery operations. Entry of persons or vessels into this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port, Los Angeles—Long Beach, or her designated representative.

DATES: This rule is effective without actual notice from December 3, 2021 11:59 p.m. on December 8, 2021. For purposes of enforcement, actual notice will be used from 12:00 a.m. on November 24, 2021 until December 3, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0784 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357–1603, email *Maria.C.Wiener@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule to ensure the safety of response personnel and mariners during repairs of the damaged pipeline, as well as the potential oil recovery of said pipeline. It is impracticable to publish an NPRM, because we must establish this safety zone by November 24, 2021, due to immediate action needed to minimize potential danger to the public during oil recovery operations for the discharge of oil from pipeline.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the pipeline repair operations for the damaged pipeline.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP), Los Angeles—Long Beach has determined that potential hazards associated with the pipeline repair and potential oil recovery operations in the vicinity of the damaged pipeline will be a safety concern for anyone within the following coordinates: 33°39.320′ N, 118°06.851′ W; 33°39.141′ N, 118°06.247′ W; 33°38.632′ N, 118°06.453′ W; 33°38.809′ N, 118°07.064′ W. This rule is necessary to safeguard the public during repair operations in response to an emergency situation; it would be impracticable for the Coast Guard to provide a public comment period on the rule.

IV. Discussion of the Rule

This rule establishes a safety zone that will be enforced November 24, 2021 through December 8, 2021. The safety zone will encompass all navigable waters from the surface to the sea floor in an area bound by the following coordinates: 33°39.320′ N, 118°06.851′ W; 33°39.141′ N, 118°06.247′ W; 33°38.632′ N, 118°06.453′ W; 33°38.809′ N, 118°07.064′ W. No vessel or person will be permitted to enter the safety zone without obtaining permission from

the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order.

This regulatory action determination is based on the size, location, and duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of Newport Beach in the vicinity of the repair operations. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule will allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will be enforced from November 24, 2021 through December 8, 2021, within the following coordinates: 33°39.320′ N, 118°06.851′ W; 33°39.141′ N, 118°06.247′ W; 33°38.632′ N, 118°06.453′ W; 33°38.809′ N, 118°07.064′ W. It is categorically excluded from further review under paragraph L60(c) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1. Revision No. 01.2.

■ 2. Add § 165. T11–085 to read as follows:

§ 165.T11–085 Safety Zone; Oil Pipeline Repairs, San Pedro Bay, CA.

(a) *Location.* The safety zone encompasses all navigable waters from the surface to the sea floor in an area of

the following coordinates: 33°39.320′ N, 118°06.851′ W; 33°39.141′ N, 118°06.247′ W; 33°38.632′ N, 118°06.453′ W; 33°38.809′ N, 118°07.064′ W.

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

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in § 165.23 of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail Coast Guard Sector Los Angeles—Long Beach on VHF–FM Channel 16 or call the 24-hour Command Center at (310) 521–3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from November 24, 2021, through December 8, 2021, or as announced via local Broadcast Notice to Mariners.

Dated: November 24, 2021.

R.E. Ore,

Captain, U.S. Coast Guard, Captain of the Port, Los Angeles, Long Beach.

[FR Doc. 2021–26203 Filed 12–2–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2019–0031; FRL–8822–03–R5]

Air Plan Approval; Illinois; 2008 Ozone Moderate VOC RACT for Chicago; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correcting amendment.

SUMMARY: This action corrects codification errors in the Illinois State Implementation Plan (SIP) regarding the moderate volatile organic compound (VOC) reasonably available control technology (RACT) requirements of the Clean Air Act (CAA) for the 2008 Ozone National Ambient Air Quality Standards (NAAQS).

DATES: *Effective Date:* This final rule is effective on December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Katie Mullen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–3490, *mullen.kathleen@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: On August 13, 2021, the Environmental Protection Agency (EPA) made inadvertent codification errors when it approved elements of a SIP submission from Illinois regarding the VOC RACT requirements of CAA section 182(b)(2) for the 2008 ozone NAAQS. In the final rule published in the **Federal Register** on August 13, 2021 (86 FR 44616), on page 44617, EPA correctly added an entry to the table entitled ''EPA Approved—Illinois Source-Specific Requirements'', but mistakenly omitted instructions to add entries to the table entitled ''EPA-Approved Illinois Nonregulatory and Quasi-Regulatory Provisions.'' In § 52.720, the table in paragraph (e) should also have been amended under the heading ''Moderate Area & Above Ozone Requirements'' by adding the following entries: ''2008 8-hour Ozone Negative Declarations'', ''2008 8-hour Ozone Section 182(b)(2) VOC RACT Rules Certification'', and ''2008 8-hour Ozone Non-CTG RACT Demonstration''.

This action amends the regulatory text to correct these errors. Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making this rule final without prior proposal and opportunity for comment because we are merely correcting an incorrect citation in a previous action. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

Statutory and Executive Order Reviews

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the **SUPPLEMENTARY INFORMATION** section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by E.O. 13175 (65 FR 67249, November 9, 2000). This rule will not 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 governments, as specified by E.O. 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to E.O. 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This technical correction action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by E.O. 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of E.O. 12988 (61 FR 4729, February 7, 1996). EPA has complied with E.O. 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive

order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA had made such a good cause finding, including the reasons therefore, and established an effective date of December 3, 2021. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This correction to 40 CFR 52 for Illinois is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Dated: November 24, 2021.

Debra Shore,

Regional Administrator, Region 5.

Accordingly, 40 CFR part 52 is corrected by making the following correcting amendments:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.720, the table in paragraph (e) is amended under the heading ''Moderate Area & Above Ozone Requirements'' by adding entries for ''2008 8-hour Ozone Negative Declarations'', ''2008 8-hour Ozone Section 182(b)(2) VOC RACT Rules Certification'', and ''2008 8-hour Ozone Non-CTG RACT Demonstration'' immediately following the entry for ''Negative declaration—Shipbuilding and ship repair industry'' to read as follows:

§ 52.720 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED ILLINOIS NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Name of SIP provision	Applicable geographical or non-attainment area	State submittal date	EPA approval date	Comments
*	*	*	*	*
Moderate Area & Above Ozone Requirements				
*	*	*	*	*
2008 8-hour Ozone Negative Declarations.	Chicago area	1/10/2019	8/13/2021, 86 FR 44616	Includes: Aerospace Manufacturing and Rework Facilities, High-Density Polyethylene, Polypropylene, and Polystyrene Resins, Natural Gas/Gasoline Processing Plants, Oil and Natural Gas Industry, Shipbuilding and Ship Repair Industry, and Vegetable Oil Processing.
2008 8-hour Ozone Section 182(b)(2) VOC RACT Rules Certification.	Chicago area	1/10/2019	8/13/2021, 86 FR 44616.	
2008 8-hour Ozone Non-CTG RACT Demonstration—.	Chicago area	1/10/2019	8/13/2021, 86 FR 44616	Industrial Wastewater Category.
*	*	*	*	*

* * * * *

[FR Doc. 2021–26138 Filed 12–2–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201209–0332; RTID 0648–XB614]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfers From NJ to NY, DE to NC, and NH to RI

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfers.

SUMMARY: NMFS announces that the states of New Jersey, Delaware, and New Hampshire are transferring a portion of their 2021 commercial bluefish quota to the states of New York, North Carolina, and Rhode Island, respectively. These quota adjustments are necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for New Jersey, New York, Delaware, North Carolina, New Hampshire, and Rhode Island.

DATES: Effective November 30, 2021, through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, (978) 281–9225.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162 and the final 2021 allocations were published on December 16, 2020 (85 FR 81421).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a

mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

New Jersey is transferring 30,000 lb (13,608 kg) to New York; Delaware is transferring 30,000 lb (13,608 kg) to North Carolina; and New Hampshire is transferring 11,000 lb (4,990 kg) to Rhode Island through mutual agreement of the states. These transfers were requested to ensure that New York, North Carolina, and Rhode Island would not exceed their 2021 state quota. The revised bluefish quotas for 2021 are: New Jersey, 260,082 lb (117,971 kg); New York, 387,438 lb (175,739 kg); Delaware, 21,958 lb (79,713 kg); North Carolina, 987,377 lb (3,616 kg); New Hampshire, 473 lb (215 kg); and Rhode Island, 264,434 lb (119,945 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 30, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–26308 Filed 11–30–21; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 230
Friday, December 3, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1047; Airspace Docket No. 21–ASW–23]

RIN 2120–AA66

Proposed Amendment of Class D Airspace and Class E Airspace; Fort Worth and Dallas-Fort Worth, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D airspace at Fort Worth, TX, and the Class E airspace at Dallas-Fort Worth, TX. The FAA is proposing this action as the result of an airspace review due to the cancellation of the instrument procedures and implementation on new instrument procedures at Granbury Regional Airport, Granbury, TX, contained within the Dallas-Fort Worth, TX, Class E airspace legal description. The geographic coordinates of the Fort Worth Spinks Airport, Fort Worth, TX, would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before January 18, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–1047/Airspace Docket No. 21–ASW–23, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11 is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class D airspace at Fort Worth Spinks Airport, Fort Worth, TX, and the Class E airspace extending upward from 700 feet above the surface at Granbury Regional Airport, Granbury, TX, contained within the Dallas-Fort Worth, TX, airspace legal description, to support instrument flight rule operations at these airports.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–1047/Airspace Docket No. 21–ASW–23.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO

7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Amending the Class D airspace at Fort Worth Spinks Airport, Fort Worth, TX, by updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

And amending the Class E airspace extending upward from 700 feet above the surface within an 8.8-mile (increased from a 6.3-mile) radius of Granbury Regional Airport, Granbury, TX, contained within the Dallas-Fort Worth, TX, airspace legal description; and updating the geographic coordinates of Fort Worth Spinks Airport, Fort Worth, TX, also contained within the Dallas-Fort Worth, TX airspace legal description, to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review due to the cancellation of the instrument procedures and implementation of new instrument procedures at Granbury Regional Airport.

Class D and E airspace designations are published in paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASW TX D Fort Worth, TX [Amended]

Fort Worth Spinks Airport, TX
(Lat. 32°33′54″ N, long. 97°18′30″ W)

That airspace extending upward from the surface up to but not including 3,000 feet MSL within a 4.1-mile radius of Fort Worth Spinks Airport, and within 1 mile each side of the 173° bearing from the airport extending from the 4.1-mile radius to 4.8 miles south of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Dallas-Fort Worth, TX [Amended]

Dallas-Fort Worth International Airport, TX
(Lat. 32°53′50″ N, long. 97°02′16″ W)
McKinney National Airport, TX
(Lat. 33°10′37″ N, long. 96°35′20″ W)
Ralph M. Hall/Rockwall Municipal Airport, TX
(Lat. 32°55′50″ N, long. 96°26′08″ W)
Mesquite Metro Airport, TX
(Lat. 32°44′49″ N, long. 96°31′50″ W)
Mesquite Metro: RWY 18–LOC
(Lat. 32°44′03″ N, long. 96°31′50″ W)
Lancaster Regional Airport, TX
(Lat. 32°34′39″ N, long. 96°43′03″ W)
Point of Origin
(Lat. 32°51′57″ N, long. 97°01′41″ W)
Fort Worth Spinks Airport, TX
(Lat. 32°33′54″ N, long. 97°18′30″ W)
Cleburne Regional Airport, TX
(Lat. 32°21′14″ N, long. 97°26′02″ W)
Bourland Field, TX
(Lat. 32°34′55″ N, long. 97°35′27″ W)
Granbury Regional Airport, TX
(Lat. 32°26′40″ N, long. 97°49′01″ W)
Parker County Airport, TX
(Lat. 32°44′47″ N, long. 97°40′57″ W)
Bridgeport Municipal Airport, TX
(Lat. 33°10′26″ N, long. 97°49′42″ W)
Decatur Municipal Airport, TX
(Lat. 33°15′15″ N, long. 97°34′50″ W)

That airspace extending upward from 700 feet above the surface within a 30-mile radius of Dallas-Fort Worth International Airport, and within a 6.6-mile radius of McKinney National Airport, and within 1.8 miles each side of the 002° bearing from McKinney National Airport extending from the 6.6-mile radius to 9.2 miles north of the airport, and within a 6.3-mile radius of Ralph M. Hall/Rockwall Municipal Airport, and within 1.6 miles each side of the 010° bearing from Ralph M. Hall/Rockwall Municipal Airport extending from the 6.3-mile radius to 10.8 miles north of the airport, and within a 6.5-mile radius of Mesquite Metro Airport, and within 4 miles west and 7.9 miles east of the 001° bearing from the Mesquite Metro: RWY 18–LOC extending from the 6.5-mile radius of the Mesquite Metro Airport to 10 miles north of the Mesquite Metro: RWY 18–LOC, and within a 6.6-mile radius of Lancaster Regional Airport, and within 1.9 miles each side of the 140° bearing from Lancaster Regional Airport extending from the 6.6-mile radius to 9.2 miles southeast of the airport, and within 8 miles northeast and 4 miles southwest of the 144° bearing from the Point of Origin extending from the 30-mile radius of Dallas-Fort Worth International Airport to 35 miles southeast of the Point of Origin, and within a 6.5-mile radius of Fort Worth Spinks Airport, and within 8 miles east and 4 miles west of the 178° bearing from Fort Worth Spinks Airport extending from the 6.5-mile radius to 21 miles south of the airport, and within a 6.9-mile radius of Cleburne Regional Airport, and within 3.6 miles each side of the 292° bearing from the Cleburne Regional Airport extending from the 6.9-mile radius to 12.2 miles northwest of airport, and within a 6.5-mile radius of Bourland Field, and within a 8.8-mile radius of Granbury Regional Airport, and within a 6.3-mile radius of Parker County Airport, and within 8 miles east and 4 miles west of the 177° bearing from Parker County Airport extending from the 6.3-mile radius to 21.4 miles south of the airport, and within a 6.3-mile radius of Bridgeport Municipal Airport, and within 1.6 miles each side of the 040° bearing from Bridgeport Municipal Airport

extending from the 6.3-mile radius to 10.6 miles northeast of the airport, and within 4 miles each side of the 001° bearing from Bridgeport Municipal Airport extending from the 6.3-mile radius to 10.7 miles north of the airport, and within a 6.3-mile radius of Decatur Municipal Airport, and within 1.5 miles each side of the 263° bearing from Decatur Municipal Airport extending from the 6.3-mile radius to 9.2 miles west of the airport.

Issued in Fort Worth, Texas, on November 30, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–26260 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 1, 17, 19, 20, 22, 26, 27, 28, and 31

[Docket No. TTB–2021–0010; Notice No. 207]

RIN 1513–AC46

Modernization of Permit and Registration Application Requirements for Distilled Spirits Plants

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this notice of proposed rulemaking, the Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes deregulatory amendments to the regulations to modernize and streamline the permit application for distilled spirits plants and for users and dealers of specially denatured alcohol and tax-free alcohol. The proposed amendments also relax some reporting requirements associated with changes to the business of those holding such permits and registrations. Some of these proposed liberalizing amendments would also apply to all Federal Alcohol Administration Act basic permit holders (including wineries, and importers and wholesalers of distilled spirits, wine, and malt beverages) and to alcohol beverage dealers. The proposed amendments are a result of TTB's evaluation of its permit and registration application requirements and consideration of relevant public comments submitted to the Treasury Department in response to its request for recommendations concerning regulations that can be eliminated, modified, or streamlined in order to reduce burdens. TTB believes the amendments proposed in this document will significantly reduce the time needed to complete an application for a permit or registration.

DATES: Comments must be received on or before February 1, 2022.

ADDRESSES: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it within Docket No. TTB–2021–0010 as posted at *https://www.regulations.gov.* A direct link to that docket is available on the TTB website at *https://www.ttb.gov/distilled-spirits/notices-of-proposed-rulemaking* under Notice No. 207. Alternatively, you may submit comments via postal mail to the Director, Regulations and Ruling Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW. Box 12, Washington, DC 20005. Please see the Public Participation section of this document for further information on the comments requested regarding this proposal and on the submission, confidentiality, and public disclosure of comments.

FOR FURTHER INFORMATION CONTACT: Jesse Longbrake, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone (202) 453–1039, extension 066.

SUPPLEMENTARY INFORMATION:

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I. Background

A. TTB Evaluation of Permit and Registration Application Requirements

In fiscal year 2017, the Alcohol and Tobacco Tax and Trade Bureau (TTB) began an evaluation of the information collected during the course of TTB's permit and registration applications. The purpose was to identify ways to streamline the application and registration process, reduce burden on the regulated industry, and ensure that the process collects, where possible, only information that is necessary to meet the agency's statutory obligations. TTB's general approach was to identify information being collected that could be eliminated without hindering TTB's ability to evaluate an applicant's qualifications and to more narrowly focus the application questions to capture only the information that is needed. In addition, TTB also considered whether there were any requests made in the application process that were so commonly approved that the regulations themselves could be amended to accommodate them without the need to submit the request.

Similarly, on June 14, 2017, the Treasury Department (Treasury) published in the **Federal Register** (82 FR 27217) a Request for Information inviting members of the public to submit views and recommendations for Treasury regulations that can be eliminated, modified, or streamlined in order to reduce burdens. TTB reviewed comments received in response to this request and identified proposals that related to the permit application process or, more generally, to beginning business in a TTB-regulated industry.

Through TTB's internal evaluation and consideration of the public input, TTB has identified deregulatory actions that TTB can take by amending regulations and also, where rulemaking is not required, by amending guidance and forms. While this document addresses distilled spirits plants, users and dealers of specially denatured alcohol and tax-free alcohol, and Federal Alcohol Administration Act basic permit holders, TTB intends to engage in further rulemaking to address other regulated industries within the context of their respective statutory eligibility requirements. Specifically, TTB will address in separate rulemakings the Internal Revenue Code (IRC) registration and notice requirements for wine and beer producers, respectively, as well as IRC requirements for TTB-regulated tobacco businesses.

With respect to distilled spirits plants (DSPs), this document proposes to amend the regulations to eliminate or narrow the range of information that must be submitted with applications for permits or registrations to more directly respond to TTB's statutory obligations

and permit or registration eligibility criteria. Proposed amendments include:

- Eliminating various requirements to submit operational information. Specifically, TTB proposes eliminating eight (8) regulatory provisions requiring submission of information including, but not limited to, descriptions of production procedures and storage systems.
- Tailoring requirements to describe the DSP premises more narrowly to specifically correspond with statutory requirements, and consolidating requirements to provide descriptions of alternation operations with the general DSP premises description.
- Replacing requirements to submit narrative descriptions of DSP security with certifications that the applicant's security measures will comply with enumerated regulatory requirements.
- Eliminating requirements to provide serial numbers of DSP equipment in the application, thereby allowing equipment to be reported in the aggregate where applicable and allowing a DSP application to be submitted prior to physical receipt of the equipment.

TTB is also proposing to amend the regulations to increase industry flexibility without imposing regulatory burden. These amendments benefit DSPs, users and dealers of specially denatured alcohol and tax-free alcohol, and, where appropriate under statute, Federal Alcohol Administration Act basic permit holders. Proposed amendments include:

- Extending deadlines for reporting certain changes in the business from 30 days to 60 days.
- Allowing regulated businesses to add or remove trade names by submitting a notification to TTB rather than applying for TTB approval.
- Allowing regulated businesses to maintain required records at a location other than the permitted premises without first obtaining TTB approval.

Section II of this document includes more in-depth discussion of the proposed amendments.

As noted above, TTB's deregulatory strategy also includes streamlining longstanding policies and practices implementing existing regulations. TTB has already begun deploying such streamlining efforts in response to both TTB's internal evaluation of application processes and to comments received from the public.

For instance, TTB has implemented significant reductions in the information collected on form TTB F 5000.9, Personnel Questionnaire—Alcohol and Tobacco (the Personnel Questionnaire) and its electronic equivalent in response to comments submitted to Treasury through the Request for Information. TTB collects the Personnel Questionnaire as part of the application process for most types of permits or registrations. The Personnel Questionnaire collects information about individuals involved in an applicant's business (such as a business's officers, directors, or principal investors), including information about such individuals' identity, employment and residence history, investment in the business, prior involvement in TTB-regulated businesses, and criminal record, if any. The collection of this information has been approved by the Office of Management and Budget under Information Collection number 1513–0002.

TTB uses this information to determine whether the applicant, including the individuals involved in the applicant business, meet the statutory eligibility criteria for obtaining a permit or registration. These criteria are set forth in detail in section 1(B) of this document. Upon careful review, TTB recognized that it could reduce the information collected through the Personnel Questionnaire. TTB has revised form TTB F 5000.9 and its electronic equivalent in Permits Online to substantially reduce the number of required fields and to eliminate some of the most time-consuming fields (such as general employment history and residence history). TTB also has stopped collecting supporting documentation for certain types of investment in an applicant business (*e.g.,* bank statements, loan documentation, promissory notes, etc.).

B. TTB Authority

The Federal Alcohol Administration Act (FAA Act, 27 U.S.C. 201, *et seq.*) and chapter 51 of the IRC, 26 U.S.C. chapter 51, require persons intending to engage in certain distilled spirits-related businesses to obtain a permit, or approval of a registration, from the Secretary of the Treasury (Secretary) before beginning operations. Many distillers engage in operations that require both a permit under the FAA Act and a registration under the IRC. The amendments proposed in this document generally relate to the application requirements for such permits and registrations, including requirements to report certain changes in the regulated businesses. Additionally, amendments proposed in this document address application requirements for permits under the FAA Act for operations as importers or wholesalers of distilled spirits, wine, and/or malt beverages.

The FAA Act requires that persons seeking to engage in business as producers of distilled spirits, or as importers or wholesalers of distilled spirits, wine, and malt beverages, obtain a permit before beginning operations. See 27 U.S.C. 203. The term ''distilled spirits,'' when used in the context of the FAA Act, applies only to distilled spirits for nonindustrial use. The TTB regulations at 27 CFR 1.60 set out uses of spirits that are regarded as ''industrial.'' The FAA Act at 27 U.S.C. 204(c) provides that the Secretary will prescribe the manner and form of all applications for basic permits. Note that the FAA Act also requires permits for producing, rectifying, or blending wine and that these activities also require qualification under the IRC; TTB plans to modernize wine-specific permit requirements in a separate rulemaking document.

Chapter 51 of the IRC contains excise tax and related provisions concerning distilled spirits, wines, and beer. This includes requirements that persons intending to engage in certain activities related to producing, using, or dealing in distilled spirits obtain a registration and/or permit from the Secretary before beginning operations. As noted above, TTB will address in a separate rulemaking the application requirements under the IRC for bonded wine cellars, bonded wineries, taxpaid wine bottling houses, and brewer's notices.

The IRC requires each person seeking to establish a distilled spirits plant, before commencing operations, to apply for and receive notice of registration of the plant. See 26 U.S.C. 5171(c). Those persons whose distilled spirits plant operations are not required to obtain a basic permit under the FAA Act are required to obtain an IRC operating permit. See 26 U.S.C. 5171(d). The applications for registrations and permits are to be in such manner and form as the Secretary prescribes by regulation. See 26 U.S.C. 5172 (registrations); 5171(d)(1) and 5271(b)(1) (operating permits).

The IRC provides for the issuance of permits to establish plants for the purpose of producing, processing, storing, using, and/or distributing distilled spirits that are exclusively for fuel use (''alcohol fuel plants''). While alcohol fuel plants, as a type of distilled spirits plant, are generally subject to the registration and permitting requirements of sections 5171(c) and (d), and any associated qualification requirements, the IRC at 26 U.S.C. 5181 provides authority to prescribe by regulation a

streamlined application process for such plants, see 26 U.S.C. 5181, which TTB has done.

The IRC also governs permits relating to the procurement and use of denatured distilled spirits, and the use of non-beverage spirits for certain tax-free purposes. See 26 U.S.C. 5271. Section 5271 provides that no person may procure or use distilled spirits free of tax under the provisions of 26 U.S.C. 5214(a)(2) or (3); or procure, deal in, or use specifically denatured distilled spirits; or recover specifically or completely denatured distilled spirits, until he or she has applied for and received a permit to do so from the Secretary. The application for such permit is to be as prescribed by regulation. See 26 U.S.C. 5271(b)(1).

The IRC requires persons seeking to engage in the business of manufacturing vinegar by the vaporizing process to first apply for and receive approval of a registration from the Secretary, the application for which is to be as prescribed by regulation. See 26 U.S.C. 5502.

Finally, the IRC requires all wholesale dealers and retail dealers of distilled spirits, wine, and beer to register with the Secretary. See 26 U.S.C. 5124.

The FAA Act and IRC set forth eligibility criteria (including criteria rendering an applicant ineligible) for many of the above permits and registrations. The FAA Act provides that an applicant is not entitled to a basic permit—including those applying as producers of distilled spirits and those applying as importers or wholesalers of distilled spirits, wine, and beer—if the applicant has been convicted of a felony within the previous 5 years or a misdemeanor under any Federal law relating to liquor within the previous 3 years. See 27 U.S.C. 204(a)(2). Under this statutory provision, the ''applicant'' includes, in the case of a corporation, any of its officers, directors, or principal stockholders. Section 204(a)(2) also provides that an applicant is not entitled to a basic permit if the applicant is, by reason of his or her business experience, financial standing, or trade connections, not likely to maintain operations in conformity with Federal law.

The IRC similarly provides that an application for a distilled spirits operating permit may be denied if—among other reasons—the applicant (including the principal stockholders of a corporation) is, by reason of his or her financial standing or trade connections, not likely to maintain operations in compliance with chapter 51 of the IRC. See 26 U.S.C. 5271(c), 5171(d). Specifically, these eligibility criteria apply to permits required for distilled spirits plants that are not otherwise required to obtain an FAA Act basic permit, such as distilled spirits plants that distill for industrial use. These eligibility criteria also apply to permits for alcohol fuel plants under 26 U.S.C. 5181. See 27 CFR 19.678. A permit to use tax-free alcohol, to use or deal in specially denatured distilled spirits, or to recover specially or completely denatured distilled spirits may also be denied for the same reasons. See 26 U.S.C. 5271(c).

TTB administers chapter 51 (distilled spirits, wine, and beer) of the IRC, as well as the FAA Act, pursuant to Treasury Order 120–01, dated December 10, 2013, through which the Secretary has delegated to TTB certain IRC and FAA Act administrative and enforcement authorities, including those related to the issuance of the permits and registrations covered under this rulemaking.

Section 2(d) of the FAA Act, Public Law 74–401 (1935) authorizes the Secretary ''to prescribe such rules and regulations as may be necessary to carry out [its] powers and duties'' under the FAA Act. Section 7805(a) of the IRC (26 U.S.C. 7805(a)) provides the general authority to the Secretary to issue regulations to carry out the provisions of the IRC.

Pursuant to its delegated authorities described above, TTB has promulgated regulations setting forth the application requirements for permits or registrations related to distilled spirits operations in title 27 of the Code of Federal Regulations (CFR), at the following parts:

- 27 CFR part 1, FAA Act basic permits (*i.e.,* distillers, rectifiers, and blenders of distilled spirits; distilled spirits warehousemen; and alcohol importers and wholesalers);
- 27 CFR part 19, IRC registrations and operating permits for distilled spirits plants, vinegar plant permits, and alcohol fuel plant permits (categorized as small, medium, and large alcohol fuel plants);
- 27 CFR part 20, IRC permits for denatured spirits dealers and users;
- 27 CFR part 22, IRC permits for tax-free alcohol users; and
- 27 CFR part 31, IRC registrations for alcohol beverage dealers.

The following TTB forms and their electronic equivalents collect much of the information required to be submitted when applying for the above permits and/or registrations:

- TTB F 5100.24, Application for Basic Permit Under the Federal Alcohol Administration Act, approved by the Office of Management and Budget (OMB) under Information Collection number 1513–0018;
- TTB F 5100.18, Application for Amended Basic Permit Under the Federal Alcohol Administration Act, approved by OMB under Information collection number 1513–0019;
- TTB F 5110.25, Application for Operating Permit Under 26 U.S.C. 5171(d), approved by OMB under Information Collection number 1513–0040;
- TTB F 5110.41, Registration of Distilled Spirits Plant, approved by OMB under Information Collection number 1513–0048;
- TTB F 5110.74, Application for an Alcohol Fuel Producer Under 26 U.S.C. 5181, approved by OMB under Information Collection number 1513–0051;
- TTB F 5150.22, Application for an Industrial Alcohol User Permit, approved by OMB under Information Collection number 1513–0028; and
- TTB F 5000.9, Personnel Questionnaire—Alcohol and Tobacco Products, approved by OMB under Information Collection number 1513–0002.

Pursuant to TTB's IRC and FAA Act authorities described above, TTB has also promulgated regulations imposing procedural and substantive requirements on these regulated businesses. These include requirements to report certain changes in the business affecting the permit or registration (*e.g.,* changes in address or location, changes in stockholders or officers, directors, managers, etc.). These also include recordkeeping requirements that are generally set forth pursuant to other authority in the IRC. See, *e.g.,* 26 U.S.C. 5207 (records of distilled spirits plant proprietors), 26 U.S.C. 5275 (records of dealers and users of denatured spirits and/or industrial alcohol), and 26 U.S.C. 5121–5122 (records of wholesale and retail dealers of distilled spirits).

This notice of proposed rulemaking includes proposed amendments to these reporting and recordkeeping requirements. The regulations implementing such requirements are set forth in title 27 of the CFR, at the following parts:

- 27 CFR part 1, reporting of business changes for FAA Act basic permits;
- 27 CFR part 17, recordkeeping requirements for manufacturers of nonbeverage products claiming drawback on taxpaid distilled spirits used in the manufacturing process;
- 27 CFR part 19, recordkeeping and inventory requirements, and reporting of business changes, for distilled spirits plants, vinegar plants, and alcohol fuel plants;

- 27 CFR part 20, recordkeeping requirements, and reporting of business changes, for denatured spirits dealers and users;
- 27 CFR part 22, recordkeeping requirements, and reporting of business changes, for tax-free alcohol users;
- 27 CFR part 26, recordkeeping requirements concerning liquors and articles brought in from Puerto Rico and the Virgin Islands;
- 27 CFR part 27, recordkeeping requirements for importers of distilled spirits, wine, and beer;
- 27 CFR part 28, recordkeeping requirements concerning exportation of distilled spirits, wine, and beer; and
- 27 CFR part 31, recordkeeping requirements and reporting of business changes for alcohol beverage dealers (including wholesalers).

The electronic equivalent of each application form set forth above is available through the TTB Permits Online system. The Permits Online system eliminates redundancy by allowing the filer to input information only once, instead of repeating information on multiple paper application forms. Similarly, with respect to the reporting requirements described above, in instances where TTB's regulations refer to submitting a ''letterhead notice'' (as defined in 27 CFR 19.1), industry members may provide such notices electronically in Permits Online. Unlike applications, these types of notices do not require TTB approval.

C. Relationship to Other Notices of Proposed Rulemaking

TTB plans to publish notices of proposed rulemaking to propose generally similar amendments to regulations governing wine, beer, tobacco products, and processed tobacco-related applications and operations, set forth in 27 CFR parts 24, 25, 40, 41, and 44. Liberalizing amendments related to FAA Act basic permits as importers and wholesalers (including as importers or wholesalers of wine and/or malt beverages) and as wine producers are included in this document and will not be included in the notices of proposed rulemaking relating to wine or beer.

II. Proposed Changes to the Regulations

The amendments proposed in this document are intended to modernize and streamline the applications and application processes for distilled spirits-related permits and registrations under the IRC and FAA Act, and for FAA Act basic permits required for importers and wholesalers of alcohol beverages. As noted above, TTB's general approach was to identify information currently being collected that TTB no longer needs in order to evaluate an applicant's qualifications and to provide more clarity and specificity in the application questions and instructions. The proposed amendments also relax reporting requirements on certain changes to the business.

A. Operational Information Required for Distilled Spirits Plant Application

TTB is proposing to eliminate requirements to provide certain operational information when applying for a DSP registration. The TTB regulations at 27 CFR 19.73 prescribe, in general, information that must be included in an application for registration under the IRC as a DSP. Paragraphs (a)(13) through (15) of § 19.73 prescribe the operational information that must be submitted if the DSP applicant intends to operate as a distiller, warehouseman, or processor, respectively. (A ''warehouseman'' is a proprietor of a DSP who stores bulk distilled spirits.) TTB has determined that much of the information currently required by § 19.73(a)(13) through (15) is no longer needed for TTB to evaluate whether an applicant qualifies for a registration. As a result, TTB proposes to eliminate the following regulatory sections:

a. 27 CFR 19.73(a)(13)(ii), 19.77(a), and 19.121, requiring that an applicant intending to operate as a distiller submit a statement of production procedures, setting forth the contents of the statement, and requiring that a DSP proprietor report changes to its production procedures.

b. 27 CFR 19.73(a)(13)(iii) and 19.77(b), requiring that an applicant intending to operate as a distiller submit a statement as to whether spirits will be redistilled and referencing formula requirements associated with such redistillation.[1]

c. 27 CFR 19.73(a)(14)(i), requiring that an applicant intending to operate as a warehouseman submit a narrative description of its storage system.

d. 27 CFR 19.73(a)(14)(ii), requiring that an applicant intending to operate as a warehouseman submit a statement of the total amount of bulk wine gallons that can be stored.

e. 27 CFR 19.73(a)(15)(ii), requiring that an applicant intending to operate as a processor submit a narrative description of the storage system for spirits bottled and cased or otherwise packaged and placed in approved containers for removal from the bonded premises.

TTB is also proposing to amend 27 CFR 19.75 to eliminate the requirement to provide in the application for registration the serial number of each tank, still, and condenser to be used by the DSP. While such equipment must continue to be physically marked with a serial number on the DSP premises pursuant to 27 CFR 19.189, removing the requirement to provide serial numbers in the application will provide applicants greater flexibility to report their equipment in the aggregate. For instance, ten (10) of the same type of tank will not need to be listed separately to account for the different serial numbers. Additionally, allowing equipment to be reported on the application without serial numbers allows applicants to submit an application before equipment that has been ordered is physically received. TTB proposes similar amendments at 27 CFR 20.42 and 22.42 to remove requirements to provide serial numbers of equipment to be used by applicants for permits as users of denatured alcohol and of tax-free alcohol.

B. Premises Description and Security

TTB is proposing to relax or eliminate requirements to submit certain information describing the DSP premises and its security with an application for registration. As stated above, the TTB regulations at 27 CFR 19.73 prescribe, in general, information that must be included in an application for registration as a DSP. Among the information required to be submitted with such application are descriptions of the DSP premises and the security measures to be employed at the DSP. Much of this information is currently collected in an open-ended narrative format. TTB believes that, in general, more direct questions and certifications would enable applicants to better understand what information must be submitted, reduce the need for additional submissions and follow-up communication between TTB and applicants, and speed up the application review process. Further, TTB has determined that some of the information currently required in these areas is unnecessary or overly specific for the purpose of evaluating a registration application. As a result, TTB also proposes to relax or eliminate certain requirements to submit such information.

Therefore, TTB proposes to amend the following regulatory sections:

[1] Generally, applicable formula requirements prescribed under 27 CFR part 5 require DSPs to obtain formulas in connection with certain redistillation operations.

a. 27 CFR 19.74. Section 19.73(a)(8) requires that an application for registration as a DSP include a description of the plant in accordance with § 19.74. Section 19.74 sets forth the specific information to be included in the description, which includes: (1) A description of each tract of land covered by the plant; (2) identification of the bonded and any general premises; (3) descriptions of each building and outside tank that will be used for production, storage, and processing of spirits and for denaturing spirits, articles, or wines; and (4) identification of the room(s) or floor(s) of a building that will be used for plant operations, if the plant consists of less than the entire building in which it is situated. TTB proposes to amend § 19.74 to remove the requirement to provide a description of the tract of land and to further clarify the specific information to be submitted as follows: (1) Overall dimensions of the building(s) housing the DSP; (2) the dimensions of the bonded premises and any general premises; (3) any internal walls establishing the boundaries of the bonded premises and general premises; (4) the external doors of the DSP premises; (5) any portions of the plant premises that are outdoors, including the location of any outdoor tanks; and (6) any adjacent retail premises that are to be operated by the applicant. TTB believes that these descriptive elements are the minimum necessary to allow TTB to evaluate whether the premises is adequate to protect the revenue and otherwise complies with the statutory restrictions on DSP locations set forth at 26 U.S.C. 5178. The proposed amendments provide flexibility to submit this information in narrative form or diagram form, whichever is better suited to the applicant's circumstances. The proposed amendments also provide that photographs of any of the required elements must be submitted upon request of the appropriate TTB officer.

b. 27 CFR 19.119 and 19.122. Under current § 19.119, a DSP proprietor is required to amend his or her registration prior to extending or curtailing any part of the plant premises, except for certain operations described in §§ 19.142 (alternation for customs purposes) and 19.143 (alternation for other purposes). Section 19.122 currently requires that a DSP proprietor file a letterhead notice prior to making any material changes to the construction or use of the buildings or equipment at the DSP, other than changes covered by §§ 19.119, 19.142, and 19.143. TTB proposes to consolidate these requirements into a single § 19.119, and to further amend that section consistent with the proposed amendments to § 19.74. Specifically, in the revised § 19.119, the current text of § 19.119 regarding extension or curtailment of the premises would be maintained, but TTB proposes to incorporate as a new paragraph the provisions of the current § 19.122 relating to changes in construction or use of buildings. TTB further proposes to amend this new paragraph to no longer require the proprietor to describe in detail ''any material change in the construction or use of buildings or equipment'' but instead require the reporting of changes to the premises (other than those covered by current § 19.119, § 19.142, or § 19.143) that would render inaccurate the description submitted with the registration or submitted separately or previously by the proprietor with another amendment. TTB is also proposing to remove the requirement that the change described in the letterhead notice also be subsequently incorporated into the next submission of an application for amended registration on TTB F 5110.41 where such amendment would not otherwise require submission of a premises description. However, to the extent that subsequent applications for an amended registration make any further reportable changes to the premises, an up-to-date description must be submitted.

c. 27 CFR 19.673(b)(2), 19.675(b)(2), and 19.676(b)(2). TTB proposes amendments similar to those described above in point (a) to the requirements associated with applications for alcohol fuel plant permits, at §§ 19.673(b)(2), 19.675(b)(2), and 19.676(b)(2). Note that the illustration of adjacent retail premises is not applicable to alcohol fuel plants.

d. 27 CFR 19.643(b). TTB proposes amendments similar to those discussed in point (a) above to the requirement that applicants for a vinegar plant registration provide a ''description of the plant premises,'' at § 19.643(b). Note that the illustration of adjacent retail premises is not applicable to vinegar plants.

e. 27 CFR 19.141(a), 19.142(b), and 19.143(b). Sections 19.141 through 19.143 each provide procedures for alternation of the DSP premises. Specifically, § 19.141 prescribes procedures related to alternation of proprietors, § 19.142 prescribes procedures related to alternation for customs purposes, and § 19.143 prescribes procedures related to alternation for other purposes (such as use of the premises as a bonded wine cellar or brewery). One of the prescribed procedures to engage in each type of alternation is that the proprietor must submit with his or her application for registration as a DSP a diagram of the part of the plant that will be alternated, as well as a description of the areas, rooms or buildings, or combination of rooms or buildings that will be alternated. In the case of §§ 19.141(a) and 19.142(b), the applicant must also provide a description of the method that the applicant will use to separate the alternated premises from any premises not subject to alternation. TTB believes that the information collected under these sections can be consolidated into the premises description(s) required under § 19.73(a)(8). Accordingly, TTB proposes to amend these sections to require that such information be included in the description(s) submitted under § 19.73(a)(8). TTB also proposes conforming amendments to §§ 19.141(b) and 19.142(c).

f. 27 CFR 19.692(b)(2). TTB proposes amendments similar to those described in the previous paragraph to the qualification requirements for an alternating proprietorship as an alcohol fuel plant, at § 19.692(b)(2).

g. 27 CFR 19.73(a)(12), 19.76, and 19.192. Section 19.73(a)(12) requires that an application for registration as a DSP include a statement of plant security measures in accordance with § 19.76. Under § 19.76, the plant security statement must include a ''general description of plant security,'' a ''statement regarding the use of guard personnel,'' and other similar statements regarding the use of alarm systems and locks. Plant security as a continuing requirement for a permit is also addressed at § 19.192, which generally requires that a DSP proprietor provide adequate security to protect the revenue, and specifies requirements relating to building construction and the locking mechanisms to be used on storage tanks and points of entry to the DSP premises. Section 19.192(f) also sets forth specifications for locks to be used in DSPs. TTB believes that the narrative statements concerning plant security required under §§ 19.73(a)(12) and 19.76 are overly broad and should be more consistent with the ongoing requirements of the permit set forth in § 19.192. Accordingly, TTB proposes to eliminate § 19.76 and to amend § 19.73(a)(12) to instead require that an application for registration as a DSP include a certification that the plant's security will be compliant with the requirements of § 19.192. TTB also believes that the specifications for locks set forth in § 19.192(f) are unnecessarily specific, and proposes to replace those specifications with a requirement that the locks used to secure the plant be of

a class and construction that is usual and customary in the industry to secure commercial property.

h. 27 CFR 19.673(b)(6), 19.675(b)(6), and 19.676(b)(6). TTB proposes to amend the application requirements for alcohol fuel plant permits consistent with those described in the previous paragraph. The proposed amendments require, instead of narrative descriptions of the plant's security measures, a certification that plant security will be in accordance with the requirements of 27 CFR 19.703 and 19.704.

C. Statements of Interest

TTB proposes amendments to standardize and clarify the scope of the collection of information related to persons holding certain levels of ownership interest in an applicant business. These ''statements of interest'' are collected in accordance with statutory provisions setting forth eligibility criteria for obtaining such permits and/or registrations. Information about persons with ownership interests in applicant businesses also assists TTB in the protection and collection of the revenue.

The FAA Act at 27 U.S.C. 204(a)(2) provides that an applicant will not be entitled to a basic permit if—among other reasons—the applicant (including the principal stockholders of a corporate applicant) is, by reason of his or her business experience, financial standing, or trade connections, not likely to maintain operations in conformance with Federal law. Currently, TTB practice has been to interpret a ''principal stockholder'' to be any person holding ten (10) percent or more of any class of stock in a corporation or of any class of ownership in any other limited liability entity.[2]

The IRC at 26 U.S.C. 5271(c)(2) similarly provides that an application for a permit to use tax-free alcohol, or to use or deal in specially denatured distilled spirits, may be denied if—among other reasons—the applicant (including any ''principal stockholders'') is, by reason of his or her business experience, financial standing, or trade connections, not likely to maintain operations in compliance with chapter 51 of the IRC. Pursuant to 26 U.S.C. 5171(d), the eligibility criteria of section 5271(c) also apply to operating permit applications for DSPs that are not required to obtain an FAA Act basic permit, such as DSPs that produce distilled spirits for industrial use and alcohol fuel plants.

Further, the IRC at 26 U.S.C. 5172 requires that an application for a DSP registration identify the applicant and persons interested in the business. This provision applies to DSPs whether or not they are required to obtain an FAA Act basic permit. Note that, while alcohol fuel plants have separate application processes pursuant to 26 U.S.C. 5181, those application processes fulfill the qualification requirements of 26 U.S.C. 5171. Accordingly, TTB has implemented through regulation the requirement that alcohol fuel plant applicants report the principal persons involved in the business and/or the persons having an ownership interest in the business at 27 CFR 19.675 (for medium plant permit applications) and at 19.676 and 19.677 (for large plant permit applications).[3]

TTB has promulgated regulations under the above IRC authorities requiring statements of interest at: (1) 27 CFR 19.73, 19.92, and 19.93, for DSP registrations and operating permits; (2) 27 CFR 19.677, for large alcohol fuel plant permits; (3) 27 CFR 20.42 and 20.45, for specially denatured spirits dealer and user permits; and (4) 27 CFR 22.42 and 22.45, for tax-free alcohol user permits. Additionally, the application for an FAA Act basic permit requires a listing of the owners and principal stockholders of an applicant business, as well as details concerning their investment in the business. See 27 CFR 1.25, TTB F 5100.24 (approved by the Office of Management and Budget under Information Collection number 1513–0018).

TTB proposes amendments to §§ 19.93, 19.677, 20.45, and 22.45 to standardize the collection of the basic identifying information of persons with an interest in the applicant's business. The amendments provide that (1) the requirement to disclose basic identifying information (*i.e.,* names and addresses) of persons with an ownership interest applies to persons with an ownership interest of 10 percent or greater; and (2) where a ''person'' holding such an interest is a legal entity other than an individual, the applicant must provide the name, title, and place of residence (city and state) of a representative individual for that entity. The representative individual generally will be the individual designated by the entity to represent the entity's interest in the applicant business or, in the absence of a designated individual, an owner, chief officer or manager, or person with similar authority within the entity. TTB believes that this is the minimum amount of information required to allow TTB to identify the individuals with an interest in the applicant business and to evaluate the applicant as to its trade connections and financial standing, including in circumstances where business entities have substantial ownership interests in the applicant.

TTB proposes minor conforming amendments to 27 CFR 1.27, 1.42, 1.44, 19.114, 19.127, 19.130, 19.684, and 19.687 to incorporate the description of ownership interests set forth above into requirements for reporting changes in ownership interests. TTB also proposes conforming amendments to 27 CFR 1.24, 19.96, 19.678, and 31.114 to incorporate this description of ownership interests into regulations describing criteria for qualification or denial of permits.

D. 30-Day Filing Requirements for Certain Changes in the Business

TTB proposes to extend the deadline for reporting certain changes in a permitted business to 60 days. The TTB regulations generally require that when there is a change in the information filed with TTB as part of an application for a permit or registration under the FAA Act or IRC, the proprietor of the business must notify TTB of the change. The timing and form of this notification differs depending on the type of permit or registration, and the type of business change that has occurred or will occur.

Some business changes must be reported to TTB within a certain amount of time following the change, generally within 30 days. For example, the TTB regulations at 27 CFR 19.687 require that the proprietor of a medium or large alcohol fuel plant submit a letterhead notice to TTB within 30 days of any change to the list of officers, directors, members, managers, or other principal persons provided with the application for the permit.

In the case of a change in control of the business, a permit or registration may automatically terminate and/or become invalid following the change in control unless a new application is filed within 30 days of the change in control. The TTB regulations generally provide for the outstanding permit to remain in effect pending a final decision on the new application, as long as that application is timely filed.

Comments received in response to Treasury's request for information, described above in section I(A), suggest

[2] See TTB G 2018–6, ''Permits Online Tutorial'' at Owner/Officer Information, available at *https://www.ttb.gov/ponl/ponl-tutorial-part-2-page-11.*

[3] In addition to the proposed amendments concerning statements of interest, TTB proposes to eliminate requirements at §§ 19.675(b)(8) and 19.676(b)(8) to provide the Social Security Number and date and place of birth of each principal person involved in the alcohol fuel plant business. Names and addresses of such persons, as well as their titles with the applicant business, must still be reported.

that 30 days is too short a time for regulated entities to assemble the information that is required to be filed in connection with various changes in the business. These comments suggested that such filing deadlines should be extended to 60 days.

TTB reviewed these proposals and concluded that extending existing deadlines for reporting certain changes in the business (including in some cases by applying for a new or amended permit or registration) from 30 to 60 days would not, in general, pose risk to the revenue or raise other concerns with regard to permits and/or registrations issued under the authority of the IRC. Accordingly, TTB proposes to extend such deadlines as described immediately below. Requirements and timeframes related to FAA Act permits are discussed separately at the end of this section. FAA Act permits have a different statutory basis, which sets forth certain reporting timeframes that TTB is unable to modify by regulation. In some circumstances, industry members holding both an FAA Act permit and an IRC registration (such as DSPs producing nonindustrial spirits) will be limited by the shorter statutory reporting period of the FAA Act.

In 27 CFR part 19, TTB proposes to amend the following sections to extend reporting deadlines for changes in the permitted business to 60 days: §§ 19.112, 19.114, and 19.123 relating to DSP registrations; §§ 19.126, 19.127, and 19.130 relating to DSP operating permits; § 19.644 relating to vinegar plants; and §§ 19.683, 19.684, 19.686, 19.687, and 19.691 relating to alcohol fuel plants.

Concerning DSP registrations, 27 CFR 19.112 provides the general rules for amending a registration, and requires that, ''if there is a change in any of the information in the proprietor's current, approved notice of registration, the proprietor must amend the registration'' within 30 days of the change unless another time period is specified by another, more specific regulation. Section 19.114 requires that a DSP proprietor ''notify TTB of any changes in the list of stockholders or persons with interest that was filed with TTB'' as part of the registration application and provides that, ''if the change results in a change of control, the proprietor must file form TTB F 5110.41, Registration of Distilled Spirits Plant, within 30 days of the change.'' TTB proposes to extend each of these deadlines from 30 days to 60 days. Section 19.123 requires that a DSP proprietor notify TTB if any change is made to the statement of plant security filed under 27 CFR 19.76. TTB proposes in this document (as discussed above) to remove § 19.76 entirely, and accordingly proposes to remove § 19.123.

TTB also proposes conforming amendments in 27 CFR 19.80 to clarify that, when an IRC operating permit or an FAA Act permit remains in effect pending final TTB action on a new application for such a permit necessitated by a business change, the approved notice of registration associated with that permit also remains valid during that time.

Concerning DSP operating permits, which apply to industrial alcohol operations, § 19.126 provides the general rules for amending a permit and requires that, ''if there is a change in any of the information that the proprietor provided as part of the current approved application for an operating permit, the proprietor must amend the operating permit'' within 30 days of the change unless another time period is specified by another, more specific regulation. Section 19.127 provides for the automatic termination of a DSP operating permit under certain circumstances. In the case of a corporation, § 19.127 provides that the operating permit will terminate 30 days following a change in actual or legal control of the corporation, but if an application for a new permit is submitted within that 30 days, the outstanding permit may remain in effect until TTB takes final action on the new application. Section 19.130 requires that the proprietor notify TTB of any changes in the list of stockholders or persons with interest that was filed in connection with the operating permit application. If such a change results in a change in actual or legal control of the business, the proprietor must file an application for a new permit within 30 days. TTB proposes to extend each of these deadlines from 30 to 60 days. With respect to the automatic termination provisions of § 19.127, the proposed amendments also necessarily extend the timeframe for termination to 60 days.

Concerning vinegar plants, § 19.644 provides that the proprietor of a vinegar plant must ''immediately'' notify TTB in writing of ''any change in the information that was provided in an approved application.'' TTB proposes to amend this section to require the notification be made within 60 days of the change.

Concerning alcohol fuel plants, § 19.683 provides the general rules for amending a permit and requires that, ''if there is a change relating to any of the information contained in, or considered a part of, the application'' for an alcohol fuel plant permit, ''the proprietor must amend the information previously submitted within 30 days of the change'' unless another time period is specified by another, more specific regulation. Section 19.684 provides for the automatic termination of an alcohol fuel plant permit under certain circumstances. In the case of a corporation, the permit will terminate 30 days following a change in actual or legal control of the corporation, but if an application for a new permit is submitted within those 30 days, the outstanding permit may remain in effect until TTB takes final action on the new application. Section 19.686 provides that, ''When there is a change in the name of the individual, firm, corporation, or other entity holding the permit, the proprietor must file an application to amend the permit . . . within 30 days of the change.'' Section 19.687 requires that the proprietor provide TTB with letterhead notice within 30 days of any change to the list of officers, directors, members, managers, or other principal persons provided with the application for a permit as a medium or large alcohol fuel plant. Section 19.691 states that, ''if there is a change in the address of an alcohol fuel plant that does not involve a change in the location or area of the plant itself, the proprietor must submit a letterhead notice to the appropriate TTB officer within 30 days of the change.'' TTB proposes to extend each of these deadlines from 30 to 60 days. With respect to the automatic termination provisions of § 19.684, the proposed amendments also necessarily extend the timeframe for termination to 60 days.

Concerning permits for dealers or users of denatured alcohol and rum, TTB proposes to amend provisions in 27 CFR part 20 to extend a similar 30-day requirement to 60 days, and to remove one notification requirement. Section 20.56 requires that a permittee submit a written notification to TTB within 30 days of certain changes ''relating to any of the information contained in, or considered a part of[,] the application'' for a permit. Section 20.57 requires that the permit holder provide written notice to TTB within 10 days of a change in proprietorship or a change in actual or legal control of the business. Section 20.57 further provides that the permit will terminate 30 days following a change in proprietorship or control, unless the permit holder submits an application for a new permit within 30 days of the change, in which case the outstanding permit may remain in effect until TTB takes final action on the new application. TTB proposes to extend the

filing deadline of § 20.56 from 30 to 60 days, and to remove the 10-day notification requirement of § 20.57. With respect to the automatic termination provisions of § 20.57, the proposed amendments extend the timeframe for termination to 60 days.

Concerning permits for users of tax-free (industrial) alcohol, TTB proposes to amend §§ 22.57 and 22.58. Section 22.57 requires that such a permittee submit a written notification to TTB within 30 days of certain changes ''relating to any of the information contained in, or considered a part of[,] the application'' for a permit. Section 22.58 requires that the permit holder provide written notice to TTB within 10 days of a change in proprietorship or a change in actual or legal control of the business. Section 22.58 further provides that the permit will terminate 30 days following a change in proprietorship or control, unless the permit holder submits an application for a new permit within 30 days of the change, in which case the outstanding permit may remain in effect until TTB takes final action on the new application. TTB proposes to remove the 10-day notification requirement of § 22.58. TTB proposes to extend the filing deadline of § 22.57 from 30 to 60 days. With respect to the automatic termination provisions of § 22.58, the proposed amendments also extend the timeframe for termination to 60 days.

In 27 CFR part 31, concerning alcohol beverage dealers, TTB proposes to amend § 31.138 to provide 60 days for an alcohol beverage dealer to notify TTB of the discontinuance of their business, rather than the current 30 days.

As noted above, FAA Act basic permits are subject to certain reporting timeframes, similar to some of those IRC timeframes discussed above, that TTB is unable to extend by regulation because they are statutory. Specifically, the FAA Act at 27 U.S.C. 204(g) provides that FAA Act permits cannot be sold or transferred, and will automatically terminate 30 days after a transfer by operation of law or a change in actual or legal control of the permitted business. However, section 204(g)(2) also provides that if an application for a new permit is submitted within 30 days of such a change, the outstanding permit remains in effect until TTB takes final action on the new application. These provisions are implemented in TTB regulations at 27 CFR 1.44. TTB cannot extend the § 1.44 deadline for filing a new permit application from 30 to 60 days, because the 30-day provision is in the statute (cited above). However, TTB is proposing to amend 27 CFR 1.42 to clarify that any changes in the ownership, management, or control of the business, including changes that fall under § 1.44, must be reported to TTB within 30 days rather than ''immediately,'' as currently required. If the change requires the filing of a new application under § 1.44, a timely application will also satisfy the notification requirement of § 1.42.

Industry members who hold both a basic permit under the authority of the FAA Act and a registration under the authority of the IRC (such as DSPs producing nonindustrial spirits) should be aware that an extension of the timeframes applicable to the registration issued under the IRC does not apply in any way to the basic permit under the FAA Act. As a result, such DSPs must still report changes in the ownership or management of their business within 30 days (and submit any required applications within 30 days) to comply with the requirements of their FAA Act basic permit.

E. Changes in Trade Names

TTB proposes amendments to the regulations at 27 CFR 1.40, 19.129, 20.61, 22.62, and 31.132 to allow changes to, or additions of, trade names through a notification to TTB rather than through an amended permit or registration. These regulations apply to holders of FAA Act basic permits, DSP operating permits, specially denatured spirits user and dealer permits, tax-free alcohol user permits, and alcohol beverage dealer registrations, respectively. The regulations currently require that holders of such permits or registrations apply for and obtain an amended permit or submit an amended registration before engaging in operations under a new trade name (see, *e.g.,* 27 CFR 19.129) or requesting FAA Act label approval reflecting a new trade name (see 27 CFR 5.36(f)). Currently, TTB automatically approves trade name amendments. Consistent with this policy, TTB is also proposing to amend 27 CFR 19.94 to remove the requirement that an applicant for an original DSP operating permit submit supporting documentation for the trade names identified in the application. TTB's proposed amendments generally would update regulations to reflect that industry members may begin operations under the new name immediately after notifying TTB.

TTB notes that, while this amendment would allow industry members to immediately begin operations under a new trade name upon notifying TTB, it remains the responsibility of the permit holder or registered alcohol dealer to ensure that any trade name is properly registered with the applicable state or local government. Industry members should further note that the FAA Act prohibits false or misleading statements on alcohol beverage labels, and TTB will not approve an application for label approval proposing to use a trade name on a label that gives a misleading impression as to the age, origin, or identity of the product. The FAA Act also prohibits the use of misleading trade names when advertising distilled spirits for beverage purposes.

F. Retention of Records Off-Premises

As part of its evaluation of permit and registration applications, TTB sought to identify types of requests to vary from the regulations that were commonly submitted along with a permit or registration application. One common request relevant to distilled spirits is to retain required records at a location other than the premises covered under the permit or registration. TTB is proposing amendments to recordkeeping requirements in parts 17, 20, 22, 26, 27, 28, and 31 to allow records to be stored at a location other than the permitted premises, and allow applicants to notify TTB of their intention to store records at an off-premises location as part of the application process. The amendments provide that required records must still be made available at the permitted premises upon request, but that copies (including electronic copies) will generally satisfy this requirement.

The TTB regulations at 27 CFR 19.573 provide that a DSP's records may be maintained at the DSP or at a central recordkeeping location maintained by the DSP proprietor. In the latter case, the proprietor must submit a letterhead notice to TTB informing TTB of the location where the records are kept. Section 19.574, concerning availability of records, further provides that if records are kept at a location other than the DSP premises, they must nonetheless be made available at the DSP premises upon request, generally within two days of the request.

The current recordkeeping requirements applicable to TTB-regulated manufacturers of nonbeverage products, specially denatured spirits dealers and users, tax-free alcohol users, importers, wholesalers, and alcohol beverage dealers do not similarly allow records to be maintained at a location other than the premises covered by the permit or registration. As a result, such proprietors generally must submit a request for specific authorization to retain records at a central recordkeeping location rather than at the premises covered by the permit or registration. TTB proposes to amend the record

retention requirements applicable to such entities (*i.e.,* record retention requirements in 27 CFR parts 17, 20, 22, 26, 27, 28, and 31) to reflect those set forth in §§ 19.573 and 19.574, described above. TTB also proposes amendments to § 19.574, as well as other record retention provisions in part 19, intended to clarify that an industry member generally may satisfy a request for documents by providing copies of such documents, including electronic copies.

III. Public Participation

A. Comments Invited

TTB invites comments from interested members of the public on this proposed rulemaking. TTB also invites comments on any additional means to streamline application processes within the parameters of TTB's statutory obligations.

B. Submitting Comments

You may submit comments on this proposal as an individual or on behalf of a business or other organization via the *Regulations.gov* website or via postal mail, as described in the **ADDRESSES** section of this document. Your comment must reference Notice No. 207 and must be submitted or postmarked by the closing date shown in the **DATES** section of this document. You may upload or include attachments with your comment. You also may submit a comment requesting a public hearing on this proposal. The TTB Administrator reserves the right to determine whether to hold a public hearing. If TTB schedules a public hearing, it will publish notification of the date, time, and place for the hearing in the **Federal Register**.

C. Confidentiality and Disclosure of Comments

All submitted comments and attachments are part of the rulemaking record and are subject to public disclosure. Do not enclose any material in your comments that you consider confidential or that is inappropriate for disclosure.

TTB will post, and you may view, copies of this document, its supporting materials, and any comments TTB receives about this proposal within the related *Regulations.gov* docket. In general, TTB will post comments as submitted, and it will not redact any identifying or contact information from the body of a comment or attachment.

Please contact TTB's Regulations and Rulings division by email using the web form available at *https://www.ttb.gov/contact-rrd,* or by telephone at 202–453–2265, if you have any questions regarding comments on this proposal or to request copies of this document, its supporting materials, or the comments received in response.

IV. Regulatory Analysis and Notices

A. Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, a regulatory impact assessment is not required.

B. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), TTB has analyzed the potential economic effects of this action on small entities. In lieu of the initial regulatory flexibility analysis required to accompany proposed rules under 5 U.S.C. 603, section 605 allows the head of an agency to certify that a rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The following analysis provides the factual basis for TTB's certification under section 605.

Impact on Small Entities

While TTB believes the majority of businesses subject to this proposed rule are small businesses, the changes proposed in this document will not have a significant impact on those small entities. The proposed amendments are generally aimed at reducing burden on regulated entities of all sizes by: (1) Eliminating the collection of certain information from applications for permits or registrations; (2) replacing required narrative descriptions of an applicant's premises with more specific description requirements; (3) extending deadlines for reporting certain changes in a permitted or registered business; (4) relaxing the requirements associated with amending the trade names available for use by a permitted or registered business; (5) allowing the maintenance of required records at locations other than the permitted or registered premises; and (6) clarifying and limiting which individuals are required to submit certain background information in connection with an application for permit or registration. Many of the proposed changes are consistent with recommendations submitted by industry in response to Treasury's request for recommendations for Treasury regulations that can be eliminated, modified, or streamlined in order to reduce burdens.

Examples of eliminating the collection of information from applications for permits or registrations are the proposed amendments to §§ 19.73(a)(12), 19.76, and 19.123, which eliminate a requirement that an applicant for a DSP registration submit a statement of plant security measures and replace it with a requirement that the applicant certify its premises is in compliance with the security specifications already established at § 19.192. Additionally, proposed amendments to § 19.75 eliminate the requirement to provide in the application for registration the serial numbers of the tanks, stills, and condensers to be used on the DSP premises, allowing an application to be filed when equipment is on order but not yet received.

The proposed amendments to §§ 19.73, 19.74, 19.141, 19.142, 19.143, 19.643, 19.673, 19.675, 19.676, and 19.692 replace requirements for narrative descriptions of an applicant's DSP premises with requirements to submit more specific information regarding the premises. For example, in connection with an application for registration as a DSP, § 19.74 currently requires a detailed narrative description of the DSP premises, including each tract of land covered by the DSP, featuring ''directions and distances in enough detail to enable the appropriate TTB officer to readily determine the boundaries of the plant.'' The proposed amendments to § 19.74 remove the narrative description requirements and instead require the submission of more limited information illustrating certain specified attributes.

An example of extending deadlines for reporting changes in a permitted or registered business is the proposed amendment to § 19.112, which provides the general rules for notifying TTB of any changes in the information included in a DSP's notice of registration. Section 19.112 generally requires that when such changes occur, the proprietor must file specified documentation with TTB to amend the registration within 30 days. The proposed amendments to § 19.112 extend this deadline to 60 days. TTB proposes similar amendments at §§ 19.114, 19.126, 19.127, 19.130, 19.644, 19.683, 19.684, 19.686, 19.687, 19.691, 20.56, 20.57, 22.57, 22.58, and 31.138.

An example of relaxing the reporting requirements associated with changes in the trade names available for use by a permitted or registered business is the proposed amendment to § 19.129. Section 19.129 currently requires that a proprietor of a DSP apply for, and receive approval of, an amended operating permit prior to operating under a new trade name. The proposed amendment to § 19.129 allows the

addition of a new trade name through a letterhead notice that does not require TTB approval. TTB proposes similar amendments at §§ 1.40, 20.61, 22.62, and 31.132.

Concerning records maintenance, current recordkeeping requirements applicable to manufacturers of nonbeverage products, specially denatured spirits dealers and users, tax-free alcohol users, importers, wholesalers, and alcohol beverage dealers do not allow records to be maintained at a location other than the premises covered by the permit or registration. The proposed amendments to §§ 17.161, 17.171, 20.267, 22.164, 26.174, 26.275, 26.310, 27.136, 28.45, 31.152, 31.172, and 31.181 generally allow for the maintenance of required records at locations other than the permitted or registered premises upon letterhead notice to TTB.

With respect to the collection of applicant background information, TTB proposes amendments to 27 CFR 19.93, 19.677, 20.45, and 22.45 to clarify the individuals who are required to submit statements of financial interest in a business applying for a distilled spirits-related permit or registration. The proposed amendments clarify that: (1) Such statements of interest are required only from persons with an ownership interest in the applicant of 10 percent or greater; and (2) where a ''person'' holding such an interest is a legal entity other than an individual, an applicant must submit basic identifying information about a representative individual for that entity.

In conclusion, while the entities affected by the proposed rule include a substantial number of small entities, the effects of the changes in this proposed rule are expected to be positive for the affected entities.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), TTB certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The proposed rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposed rule is not expected to have significant secondary or incidental effects on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. Pursuant to 26 U.S.C. 7805(f), TTB will submit the proposed regulations to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the proposed regulations on small businesses.

C. Paperwork Reduction Act

Regulations addressed in this document contain current collections of information that have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(h)) and assigned control numbers 1513–0002, 1513–0018, 1513–0019, 1513–0028, 1513–0040, 1513–0041, 1513–0044, 1513–0048, 1513–0051, 1513–0052, 1513–0059, 1513–0060, 1513–0061, 1513–0062, 1513–0065, 1513–0066, 1513–0073, 1513–0075, 1513–0088, 1513–0089, and 1513–0112. The specific regulatory sections in this proposed rule that contain collections of information, either current or proposed, are §§ 1.27, 1.40, 1.42, 1.44, 17.161, 19.73, 19.74, 19.75, 19.93, 19.94, 19.112, 19.114, 19.119, 19.126, 19.127, 19.129, 19.130, 19.141, 19.142, 19.143, 19.192, 19.574, 19.643, 19.644, 19.673, 19.675, 19.676, 19.677, 19.683, 19.684, 19.686, 19.687, 19.691, 19.692, 20.42, 20.45, 20.56, 20.57, 20.61, 20.267, 22.42, 22.45, 22.57, 22.58, 22.62, 22.164, 26.174, 26.275, 26.310, 27.136, 28.45, 31.114, 31.132, 31.138, 31.152, 31.172, and 31.181. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The amendments that TTB proposes in this document, along with certain corresponding policy changes, are designed to reduce the overall burden associated with the information collections noted above. In general, the proposed amendments involve: (1) Eliminating the collection of certain information from applications for permits or registrations; (2) replacing required narrative descriptions of an applicant's premises with more specific information; (3) extending deadlines for reporting certain changes in a permitted or registered business; (4) relaxing the requirements associated with amending the trade names available for use by a permitted or registered business; (5) allowing the maintenance of required records at locations other than the permitted or registered premises; and (6 clarifying which individuals are required to submit certain background information in connection with an application for permit or registration.

To reduce the amount of information collected in applications for distilled spirits-related permits or registrations, TTB proposes to amend 27 CFR 19.73, 19.75, and 19.192, and to eliminate 27 CFR 19.76, 19.77, and 19.123. Proposed amendments to § 19.73(a)(13) and the elimination of § 19.77 eliminate requirements that an applicant for a DSP registration intending to operate as a distiller submit a statement of its production procedures and a statement as to whether spirits will be redistilled. Proposed amendments to current § 19.73(a)(14) eliminate requirements that an applicant for a DSP registration intending to operate as a warehouseman submit a narrative description of its storage system and a statement of the total amount of bulk wine gallons that can be stored. Additionally, proposed amendments to current § 19.73(a)(15) eliminate requirements that an applicant for a DSP registration intending to operate as a processor submit a narrative description of the storage system for spirits bottled and cased or otherwise packaged and placed in approved containers for removal from the bonded premises. Proposed amendments to §§ 19.73(a)(12) and 19.192, and the elimination of §§ 19.76 and 19.123, eliminate a requirement that an applicant for a DSP registration submit a statement of plant security measures and replace it with a requirement that the applicant certify its premises is in compliance with the security specifications already established at § 19.192. The amendments to § 19.192 also generalize the required specifications for locks to be used on the DSP premises. The proposed amendments to § 19.75 eliminate the requirement to provide in the application for registration the serial numbers of the tanks, stills, and condensers to be used on the DSP premises. Sections 19.73, 19.75, 19.76, 19.77, 19.123, and 19.192 are currently included in the collection of information assigned OMB control number 1513–0048. TTB has submitted to OMB a revision of that information collection to account for the reduced burden of the proposed amendments.

Similar to the amendments to § 19.75 described in the previous paragraph, TTB proposes amendments 27 CFR 20.42 and 22.42 to remove requirements to provide serial numbers of equipment to be used by applicants for permits as users of denatured alcohol and of tax-free alcohol. Sections 20.42 and 22.42 are currently included in the collection of information assigned OMB control number 1513–0028. TTB has submitted to OMB a revision of that information collection to account for the reduced burden of the proposed amendments.

To replace required narrative descriptions of applicant premises with more specific information and certifications, TTB proposes amendments to 27 CFR 19.73, 19.74, 19.141, 19.142, 19.143, 19.643, 19.673, 19.675, 19.676, and 19.692. The

proposed amendments to § 19.74 eliminate requirements to submit detailed narrative descriptions of the plant and certain of its attributes, and replace these requirements with a more specific set of information and certifications. TTB proposes similar amendments with respect to applications for alcohol fuel plant permits at §§ 19.673, 19.675, and 19.676; and with respect to applications for vinegar plants at § 19.643. Sections 19.141, 19.142, and 19.143 each relate to qualifying to alternate the DSP premises. TTB proposes amendments to these sections to eliminate requirements to submit narrative statements describing the areas to be alternated and the means by which the alternated areas will be separated from other parts of the premises. TTB's proposed amendments require more specific information. TTB proposes similar amendments to with respect to alternation of an alcohol fuel plant at § 19.692.

Sections 19.74 and 19.143 are currently included in the collection of information assigned OMB control number 1513–0048; §§ 19.141 and 19.142 are being added to the collection of information assigned OMB control number 1513–0048 in revisions submitted to OMB (these sections were inadvertently not referenced in the supporting statement, but their burden has been accounted for); §§ 19.673, 19.675, and 19.676 are currently included in the collection of information assigned OMB control number 1513–0051; and the amended provisions of § 19.692 are currently included in the collection of information assigned OMB control number 1513–0051. TTB has submitted to OMB revisions of those information collections to account for the reduced burden of the proposed amendments. The information collected under § 19.643 is not subject to the Paperwork Reduction Act due to the limited number of respondents.

The TTB regulations generally require that, when there is a change in the information filed with TTB as part of an application for a permit or registration, the proprietor of the regulated business must notify TTB of the change. To extend deadlines for reporting certain changes in a permitted or registered business, TTB proposes amendments to 27 CFR 19.112, 19.114, 19.126, 19.127, 19.130, 19.644, 19.683, 19.684, 19.686, 19.687, 19.691, 20.56, 20.57, 22.57, 22.58, and 31.138. In each case, the deadline for reporting the specified change in the business is extended to 60 days, typically from 30 days (in some cases, current regulatory text required industry to inform TTB ''immediately'' of certain changes; see, *e.g.,* § 19.644). Sections 19.112 and 19.114 are currently included in the collection of information assigned OMB control number 1513–0048; §§ 19.126 and 19.130 are currently included in the collection of information assigned OMB control number 1513–0040; §§ 19.683, 19.684, and 19.686 are currently included in the collection of information assigned OMB control number 1513–0051; §§ 19.683, 19.687, and 19.691 are currently included in the collection of information assigned OMB control number 1513–0052 (additionally, the letterhead application provisions of § 19.686 are being added to this collection of information in revisions submitted to OMB); §§ 20.56 and 20.57 are currently included in the collection of information assigned OMB control number 1513–0061; §§ 22.57 and 22.58 are currently included in the collection of information assigned OMB control number 1513–0060; and § 31.138 is currently included in the collection of information assigned OMB control number 1513–0112. TTB has submitted to OMB revisions of those information collections to account for the reduced burden of the proposed amendments. The revision to number 1513–0040 also adds a reference to § 19.127. The information collected under § 19.644 is not subject to the Paperwork Reduction Act due to the limited number of respondents.

The TTB regulations generally require that changes to, or additions of, the trade names under which a permitted or registered business may operate be made by filing for an amended permit or registration. Such applications would need to be approved prior to the applicant beginning operations under the new trade name. To relax the requirements associated with altering the trade names available for use by a permitted or registered business, TTB proposes amendments to 27 CFR 1.40, 19.129, 20.61, 22.62, and 31.132. The amendments would allow changes to, or additions of, trade names to be accomplished by a letterhead notice. TTB also proposes an amendment to 27 CFR 19.94 to remove the requirement that an applicant for an original DSP operating permit submit supporting documentation for the trade names identified in the application. Section 1.40 is currently included in the collection of information assigned OMB control number 1513–0019; §§ 19.94 and 19.129 are currently included in the collection of information assigned OMB control number 1513–0040; § 20.61 is currently included in the collection of information assigned OMB control number 1513–0061; § 22.62 is currently included in the collection of information assigned OMB control number 1513–0060; and § 31.132 currently included in the collection of information assigned OMB control number 1513–0112. TTB has submitted to OMB revisions of those information collections to account for the reduced burden of the proposed amendments.

The current recordkeeping requirements applicable to specially denatured spirits dealers and users, tax-free alcohol users, manufacturers of nonbeverage products, importers, wholesalers, and alcohol beverage dealers do not allow records to be maintained at a location other than the premises covered by the permit or registration. As a result, such proprietors generally must submit a request for specific authorization to retain records at a central recordkeeping location rather than the premises covered by the permit or registration. To allow the maintenance of required records at locations other than the permitted or registered premises, TTB proposes amendments to 27 CFR 17.161, 17.171, 20.267, 22.164, 26.174, 26.275, 26.310, 27.136, 28.45, 31.152, 31.172, and 31.181. These amendments, as well as amendments to 27 CFR 19.574, also clarify that an industry member generally may satisfy a request for documents by providing copies of such documents, including electronic copies. Sections 17.161 and 17.171 are currently included in the collection of information assigned OMB control number 1513–0073; § 19.574 is currently included in the collection of information assigned OMB control number 1513–0041; the general record retention provisions of § 22.164 are currently included in the collection of information assigned OMB control number 1513–0059, while the proposed notice associated with off-premises records retention has been added to the collection of information assigned OMB control number 1513–0060 in revisions submitted to OMB. In addition, § 20.267 is currently included in OMB control number 1513–0062; §§ 26.174 and 26.310 are currently included in the collection of information assigned OMB control number 1513–0089; § 28.45 is currently included in the collection of information assigned OMB control number 1513–0075; §§ 31.152 and 31.172 are currently included in the collection of information assigned OMB control number 1513–0065; § 31.181 is currently included in the collection of information assigned OMB control number 1513–0066; and §§ 19.574, 26.174, 26.310, and 27.136 are currently

included in the collection of information assigned OMB control number 1513–0088. TTB has submitted to OMB revisions of those information collections as needed to account for the reduced burden of the proposed amendments. Additionally, the revision to OMB control number 1513–0088 adds references to §§ 26.275 and 28.45. TTB also submitted to OMB a revision of the information collection assigned OMB control number 1513–0061, to add a reference to § 20.267.

With respect to the collection of applicant background information, TTB proposes amendments to 27 CFR 19.93, 19.677, 20.45, 22.45, and 31.114 to clarify the individuals who are required to submit statements of financial interest in the applicant business. The above regulations generally require statements disclosing the identities of persons holding certain levels of ownership in a business applying for a distilled spirits-related registration or permit be submitted with such applications. The proposed amendments clarify that (1) Such statements of interest are required only from persons with an ownership interest in the applicant of 10 percent or greater; and (2) where a ''person'' holding such an interest is a legal entity other than an individual, an applicant must submit basic identifying information about a representative individual for that entity. Section 19.93 is currently included in the collection of information assigned OMB control number 1513–0040, and TTB has proposed revisions to also include it in the collection of information assigned OMB control number 1513–0048; § 19.677 is currently included in the collection of information assigned OMB control number 1513–0051; §§ 20.45 and 22.45 are currently included in the collection of information assigned OMB control number 1513–0028; and § 31.114 is currently included in the collection of information assigned OMB control number 1513–0112. TTB proposes conforming amendments to 27 CFR 1.27, 1.42, 1.44, 19.114, 19.127, 19.130, 19.684, and 19.687, each relating to reporting changes in the ownership of the applicant or permitted business, to update the description of ownership interests consistent with the amendments described above. Section 1.27 is currently included in the collection of information assigned OMB control number 1513–0018; § 1.42 is currently included in the collection of information assigned OMB control number 1513–0019; § 19.114 is currently included in the collection of information assigned OMB control number 1513–0048; § 19.130 is currently included in the collection of information assigned OMB control number 1513–0040; § 19.684 currently included in the collection of information assigned OMB control number 1513–0051; and § 19.687 is currently included in the collection of information assigned OMB control number 1513–0052. TTB has submitted to OMB revisions of the collections of information assigned OMB control numbers 1513–0019 and 1513–0040 to add references to §§ 1.44 and 19.127, respectively. The burden for these sections was already accounted for, but citations to these sections were left out in error.

As noted above, TTB has submitted the revised information collection requirements to OMB for review. Comments on these revised recordkeeping and reporting requirements should be sent to OMB at Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503 or by email to *OIRA_submissions@omb.eop.gov.* A copy should also be sent to TTB by any of the methods previously described. Comments on the information collections should be submitted no later than February 1, 2022. Comments are specifically requested concerning:

- Whether the collections of information submitted to OMB are necessary for the proper performance of the functions of the Alcohol and Tobacco Tax and Trade Bureau, including whether the information will have practical utility;
- The accuracy of the estimated burdens associated with the collections of information submitted to OMB;
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the proposed revisions of the collections of information, including the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

List of Subjects

27 CFR Part 1

Alcohol and alcoholic beverages, Application procedures, Distilled spirits plants, Importers, Permit requirements, Reporting and recordkeeping requirements, Trade names, Wholesalers.

27 CFR Part 17

Claims, Excise taxes, Liquors, Reporting and recordkeeping requirements.

27 CFR Part 19

Alcohol and alcoholic beverages, Alcohol fuel plants, Alternation, Application procedures, Distilled spirits plants, Permit requirements, Registration requirements, Reporting and recordkeeping requirements, Security requirements, Trade names, Vinegar plants.

27 CFR Part 20

Alcohol, Application procedures, Denatured spirits, Distilled spirits plants, Permit requirements, Reporting and recordkeeping requirements, Specially denatured spirits, Trade names.

27 CFR Part 22

Alcohol, Application procedures, Permit requirements, Reporting and recordkeeping requirements, Tax-free alcohol.

27 CFR Part 26

Alcohol and alcohol beverages, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

27 CFR Part 27

Alcohol and alcohol beverages, Importation, Importers, Reporting and recordkeeping requirements.

27 CFR Part 28

Alcohol and alcohol beverages, Exportation, Exporters, Reporting and recordkeeping requirements.

27 CFR Part 31

Alcohol and alcohol beverages, Reporting and recordkeeping requirements, Retail dealers, Trade names, Wholesale dealers.

Amendments to the Regulations

For the reasons discussed above in the preamble, TTB proposes to amend 27 CFR parts 1, 17, 19, 20, 22, 26, 27, 28, and 31 as follows:

PART 1—BASIC PERMIT REQUIREMENTS UNDER THE FEDERAL ALCOHOL ADMINISTRATION ACT, NONINDUSTRIAL USE OF DISTILLED SPIRITS AND WINE, BULK SALES AND BOTTLING OF DISTILLED SPIRITS

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

Authority: 27 U.S.C. 203, 204, 206, 211 unless otherwise noted.

■ 2. Section 1.24 is amended by revising paragraph (a) to read as follows:

§ 1.24 Qualifications of applicants.

* * * * *

(a) Such person (or in case of a limited liability entity, any of its officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the applicant) has not, within 5 years prior to the date of application, been convicted of a felony under Federal or State law, and has not, within 3 years prior to the date of application, been convicted of a misdemeanor under any Federal law relating to liquor, including the taxation thereof; and

* * * * *

■ 3. Section 1.27 is revised to read as follows:

§ 1.27 Change in ownership, management, or control of the applicant.

In the event of any change in the ownership, management, or control of the applicant (in case of a limited liability entity, any change in the officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the applicant), after the date of filing of any application for a basic permit and prior to final action on such application, the applicant must notify the appropriate TTB officer immediately of such change.

■ 4. Section 1.40 is revised to read as follows:

§ 1.40 Change in name.

(a) *Legal name.* In the event of any change in the name of the individual, firm, corporation, or other entity holding a basic permit, the permittee must file application form TTB F 5100.18 for an amended basic permit. The application must be approved and an amended permit issued before operations may be commenced under the new name.

(b) *Trade name.* In the event of any change in a trade name of a permittee, or, in the event a permittee desires to engage in operations under an additional trade name, the permittee must first file a letterhead notice with the appropriate TTB officer listing the new names and the offices where they are registered.

(Approved by the Office of Management and Budget under control number 1513–0019)

■ 5. Section 1.42 is revised to read as follows:

§ 1.42 Change in ownership, management, or control of business.

In the event of any change in the ownership, management, or control of any business operated pursuant to a basic permit (in case of a limited liability entity, any change in the officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the permittee) the permittee must within 30 days notify the appropriate TTB officer of such change, giving the names and addresses of all new persons participating in the ownership, management, or control of such business. Notice to the appropriate TTB officer of any such change must be accompanied or supplemented by such data in reference to the personal or business history of such persons as the appropriate TTB officer may require.

§ 1.44 [Amended]

■ 6. Section 1.44 is amended by removing the word ''stock'' in the second sentence.

PART 17—DRAWBACK ON TAXPAID DISTILLED SPIRITS USED IN MANUFACTURING NONBEVERAGE PRODUCTS

■ 7. The authority citation for part 17 continues to read as follows:

Authority: 26 U.S.C. 5010, 5111–5114, 5123, 5206, 5273, 6065, 6091, 6109, 7213, 7652, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 8. Section 17.161 is revised to read as follows:

§ 17.161 General.

Each person claiming drawback on taxpaid distilled spirits used in the manufacture of nonbeverage products must maintain records showing the information required in this subpart. No particular form is prescribed for these records, but the data required to be shown must be clearly recorded and organized to enable appropriate TTB officers to trace each operation or transaction, monitor compliance with law and regulations, and verify the accuracy of each claim. Ordinary business records, including invoices and cost accounting records, are acceptable if they show the required information or are annotated to show any such information that is lacking. The records must be kept complete and current at all times and must be retained by the manufacturer for the period prescribed in § 17.170 and at the place prescribed in § 17.171.

■ 9. Section 17.171 is amended by:

■ a. Designating the paragraph as paragraph (a);

■ b. Removing the word ''shall'' each place it appears and adding in its place the word ''must'' in newly designated paragraph (a);

■ c. Adding paragraph (b); and

■ d. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 17.171 Inspection of records.

* * * * *

(b) A manufacturer may keep the records required by this part at a location other than the premises where the distilled spirits are used in the manufacture or production of nonbeverage products, if he or she has first provided a letterhead notice to the appropriate TTB officer, identifying the location where the records are to be kept. A manufacturer keeping records at a location other than the premises where distilled spirits are used in the manufacture or production of nonbeverage products must make the records available at such premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the permittee to supply copies (including electronic copies) of such records instead of the originals.

PART 19—DISTILLED SPIRITS PLANTS

■ 10. The authority citation for part 19 continues to read as follows:

Authority: 19 U.S.C. 81c, 1311; 26 U.S.C. 5001, 5002, 5004–5006, 5008, 5010, 5041, 5061, 5062, 5066, 5081, 5101, 5111–5114, 5121–5124, 5142, 5143, 5146, 5148, 5171–5173, 5175, 5176, 5178–5181, 5201–5204, 5206, 5207, 5211–5215, 5221–5223, 5231, 5232, 5235, 5236, 5241–5243, 5271, 5273, 5301, 5311–5313, 5362, 5370, 5373, 5501–5505, 5551–5555, 5559, 5561, 5562, 5601, 5612, 5682, 6001, 6065, 6109, 6302, 6311, 6676, 6806, 7011, 7510, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 11. Section 19.73 is amended by:

■ a. Revising paragraphs (a)(12) and (13);

■ b. Removing paragraph (a)(14);

■ c. Redesignating paragraph (a)(15) as paragraph (a)(14) and revising newly redesignated paragraph (a)(14);

■ d. Redesignating paragraph (a)(16) as paragraph (a)(15); and

■ e. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 19.73 Information required in an application for registration.

(a) * * *

(12) A certification that the plant's security will be in compliance with § 19.192;

(13) If the applicant intends to operate as a distiller, a statement of the total proof gallons of spirits that can be produced daily;

(14) If the applicant intends to operate as a processor, a statement whether spirits will or will not be bottled, denatured, redistilled, and whether articles will be manufactured; and

* * * * *

■ 12. Section 19.74 is revised to read as follows:

§ 19.74 Description of the plant.

(a) As required by § 19.73(a)(8), the application for registration must include a description of the distilled spirits plant. The description may be in narrative form or diagram form, and must illustrate:

(1) The overall dimensions of the building(s) housing the distilled spirits plant;

(2) The dimensions of the bonded premises and any general premises;

(3) Any internal walls establishing the boundaries of the bonded premises and general premises;

(4) The external doors of the distilled spirits plant premises;

(5) Any portions of the plant premises that are outdoors, including the location of any outdoor tanks; and

(6) Any adjacent retail premises that are to be operated by the applicant.

(b) Photographs further illustrating any of the elements required in paragraph (a) of this section must be submitted upon request of the appropriate TTB officer.

■ 13. Section 19.75 is amended by:

■ a. Revising the first sentences of paragraphs (a) and (b);

■ b. Revising paragraph (c); and

■ c. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 19.75 Major equipment.

* * * * *

(a) The capacity of each tank in the plant. * * *

(b) The kind, capacity, and intended use of each still in the plant. * * *

(c) The number of condensers used in the plant.

§ 19.76 [Removed]

■ 14. Section 19.76 is removed.

§ 19.77 [Removed]

■ 15. Section 19.77 is removed.

■ 16. Section 19.80 is amended by:

■ a. Adding a sentence before the last sentence; and

■ b. Removing the parenthetical authority citation at the end of the section.

The addition reads as follows:

§ 19.80 Approved notice of registration.

* * * In a circumstance in which a proprietor of a distilled spirits plant is authorized to continue to operate under either an FAA Act permit or an operating permit under the IRC while a new permit application is pending, such as under 27 CFR 1.44 or 19.127, the proprietor's notice of registration will also remain valid until TTB takes final action upon the new application. * * *

■ 17. Section 19.93 is amended by:

■ a. Removing the citation to ''19.92(a)(4)'' and adding in its place ''19.92(b)(4)'' in the first sentence of paragraph (a) introductory text;

■ b. Adding the word ''ownership'' before the word ''interest'' the first time it appears in paragraph (b)(1);

■ c. Revising paragraphs (b)(2)(i) and (ii);

■ d. Adding paragraph (b)(3); and

■ e. Removing the parenthetical authority citation at the end of the section.

The revisions and addition read as follows:

§ 19.93 Applicant organization documents.

* * * * *

(b) * * *

(2) * * *

(i) The names and addresses of persons having a 10 percent or more ownership interest in each of the classes or types of ownership interest in the applicant, and the nature and amount of ownership interest of each person.

(ii) The name of the person in whose name the interest appears. If the limited liability entity is under actual or legal control of another limited liability entity, the appropriate TTB officer may request the same information regarding ownership for the parent limited liability entity.

(3) *Representative.* If any interested person named under paragraphs (b)(1) and (2) of this section is a legal entity other than an individual, the applicant must also provide the name, title, and city and state of residence of a representative individual for the entity. The representative individual must be the individual designated by the entity to represent the entity's interest in the applicant business or, in the absence of a designated individual, an owner, chief officer or manager, or person with similar authority within the entity.

§ 19.94 [Amended]

■ 18. Section 19.94 is amended by removing the final sentence in paragraph (a) and the parenthetical authority citation at the end of the section.

■ 19. Section 19.96 is amended by:

■ a. Revising paragraph (a); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.96 Denial of permit.

* * * * *

(a) The applicant (including, in the case of a limited liability entity, any of its officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the applicant) is, by reason of business experience, financial standing, or trade connections, not likely to maintain operations in compliance with 26 U.S.C. chapter 51, or the regulations in this chapter;

* * * * *

§ 19.112 [Amended]

■ 20. Section 19.112 is amended by:

■ a. Removing the phrase ''30 days'' and adding in its place ''60 days'' in the first sentence of the introductory text; and

■ b. Removing the parenthetical authority citation at the end of the section.

§ 19.114 [Amended]

■ 21. Section 19.114 is amended by:

■ a. Adding the words ''an ownership'' before the word ''interest'' in the first sentence of the introductory text;

■ b. Removing the phrase ''30 days'' each place it appears and adding in its place ''60 days''; and

■ c. Removing the parenthetical authority citation at the end of the section.

■ 22. Section 19.119 is amended by:

■ a. Designating the paragraph as paragraph (a);

■ b. Adding paragraph (b); and

■ c. Removing the parenthetical authority citation at the end of the section.

The addition reads as follows:

§ 19.119 Change in premises.

* * * * *

(b)(1) If the proprietor intends to make any change to the premises, other than those covered by paragraph (a) of this section or by §§ 19.142 and 19.143, that would render inaccurate the description submitted with the registration or submitted separately or previously by the proprietor with another reported change, the proprietor must first submit to TTB updated information meeting the requirements of § 19.74.

(2) The proprietor may make emergency changes to the premises described in paragraph (b)(1) of this section without first submitting updated information. However, the proprietor

must promptly report any emergency change to the appropriate TTB officer and submit updated information meeting the requirements of § 19.74 within 60 days of the emergency changes.

§ 19.121 [Removed]

■ 23. Section 19.121 is removed.

§ 19.122 [Removed]

■ 24. Section 19.122 is removed.

§ 19.123 [Removed]

■ 25. Section 19.123 is removed.

§ 19.126 [Amended]

■ 26. Section 19.126 is amended by:
■ a. Removing the phrase ''30 days'' and adding in its place ''60 days'' in paragraph (a); and
■ b. Removing the parenthetical authority citation at the end of the section.
■ 27. Section 19.127 is amended by:
■ a. Revising paragraph (a)(3); and
■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.127 Automatic termination of permits.

(a) * * *

(3) In the case of a limited liability entity (*i.e.,* a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity) holding a permit issued under subpart D of this part, if actual or legal control of such limited liability entity changes, directly or indirectly, whether by reason of a change in ownership or control (in the permittee limited liability entity or any other limited liability entity), by operation of law, or in any other manner, the permittee must file an application for a new permit within 60 days of the change. If an application for a new permit is not filed within 60 days of the change, the outstanding permit will automatically terminate. If an application for a new permit is filed within the 60-day period prescribed in the preceding sentences, the outstanding permit will remain in effect until TTB takes final action on the application. When TTB takes final action on the application, the outstanding permit will automatically terminate.

* * * * *

■ 28. Section 19.129 is revised to read as follows:

§ 19.129 Change in trade name.

In the event of any change in a trade name of a proprietor of a distilled spirits plant, or, in the event a proprietor desires to engage in operations under an additional trade name, the proprietor must first file a letterhead notice with the appropriate TTB officer listing the new names and the offices where they are registered.

§ 19.130 [Amended]

■ 29. Section 19.130 is amended by:
■ a. Adding the words ''an ownership'' before the word ''interest'' in the first sentence of the introductory text;
■ b. Removing the phrase ''30 days'' each place it appears and adding in its place ''60 days''; and
■ c. Removing the parenthetical authority citation at the end of the section.
■ 30. Section 19.141 is amended by:
■ a. Revising paragraph (a);
■ b. Removing the word ''diagrams'' and adding in its place ''description'' in paragraph (b)(4); and
■ c. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.141 Procedures for alternation of proprietors.

(a) *General.* A proprietor may alternate use of a distilled spirits plant or part of the plant with one or more other proprietors. In order to do so, each proprietor must separately file and receive approval of the necessary registration, applications and bonds that are required by subpart D of this part and this subpart. Each proprietor must also conduct operations and keep records in accordance with the regulations in this part. Where operations by alternating proprietors will be limited to parts of the plant, the descriptions required to be submitted with each proprietor's application for registration under § 19.73(a)(8) must additionally illustrate the following:

(1) The areas, rooms, or buildings, or combination of rooms and/or buildings, that will alternate between proprietors; and

(2) The means by which the alternated premises will be separated from any premises that will not be alternated.

* * * * *

■ 31. Section 19.142 is amended by:
■ a. Revising paragraph (b);
■ b. Removing the word ''diagrams'' and adding in its place ''description'' in paragraph (c)(3); and
■ c. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.142 Alternate use of premises and equipment for customs purposes.

* * * * *

(b) *Qualification.* Before alternating the plant premises for customs purposes, the proprietor must file and receive approval of the necessary registration, application and bonds as required by this part. The description required to be submitted with the proprietor's application for registration under § 19.73(a)(8) must additionally illustrate the following:

(1) The areas, rooms, or buildings, or combination of rooms and/or buildings, that will alternate between proprietors; and

(2) The means by which the alternated premises will be separated from any premises that will not be alternated.

* * * * *

■ 32. Section 19.143 is amended by:
■ a. Revising paragraph (b)(2); and
■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.143 Alternation for other purposes.

* * * * *

(b) * * *

(2) *Description.* For all alternate uses, the proprietor must provide additional versions of the description required under § 19.73(a)(8) describing or showing the premises as they will exist, both during extension and curtailment, and clearly depicting all buildings, floors, rooms, areas, equipment that are to be subject to alternation, in their relative operating sequence.

* * * * *

■ 33. Section 19.192 is amended by:
■ a. Revising paragraph (e);
■ b. Removing paragraph (f);
■ c. Redesignating paragraph (g) as paragraph (f); and
■ d. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.192 Security.

* * * * *

(e) *Locks.* Locks of a class and construction that is usual and customary in the industry to prevent unauthorized access to, and theft of, commercial property must be used to secure:

(1) Outdoor tanks used to store spirits, or an enclosure around such tanks;

(2) Indoor tanks used to store spirits, or the door from which access may be gained from the outside to the rooms or buildings in which such tanks are housed; and

(3) Any doors from which access may be gained from the outside to rooms or buildings containing spirits stored in portable bulk containers.

* * * * *

■ 34. Section 19.574 is revised to read as follows:

§ 19.574 Availability of records.

The records required by this part must be available for inspection by the appropriate TTB officer during normal business hours. Any proprietor keeping records at a location other than the distilled spirits plant where operations or transactions occur must make them available at the distilled spirits plant premises upon request of the appropriate TTB officer; however, the TTB officer may, in his or her discretion, allow the proprietor to supply copies (including electronic copies) of such records instead of the originals.

■ 35. Section 19.643 is revised to read as follows:

§ 19.643 Qualification requirements.

(a) *General.* Before beginning the business of manufacturing vinegar by the vaporizing process, a person must make written application to the appropriate TTB officer and receive approval of the application from TTB. The application must include:

(1) The applicant's name and principal business address (including the plant address if different from the applicant's principal business address);

(2) A description of the plant premises;

(3) A description of the operations to be conducted; and

(4) A description of each still, including the name and address of the owner, the kind of still and its capacity, and the purpose for which the still was set up.

(b) *Specifications of plant description.* (1) The description required by paragraph (a)(2) of this section may be in narrative form or diagram form, and must describe or illustrate the following:

(i) The overall dimensions of the building(s) housing the vinegar plant;

(ii) The dimensions of the bonded premises and any general premises;

(iii) Any internal walls establishing the boundaries of the bonded premises and general premises;

(iv) The external doors of the plant premises; and

(v) Any portions of the plant premises that are outdoors, including the location of any outdoor tanks.

(2) Photographs further illustrating the elements required under paragraph (b)(1) of this section must be submitted upon request of the appropriate TTB officer.

■ 36. Section 19.644 is amended by:

■ a. Revising the first sentence; and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.644 Changes after original qualification.

If there is any change in the information that was provided in an approved application, the proprietor of the vinegar plant must notify the appropriate TTB officer in writing within 60 days of the change. * * *

■ 37. Section 19.673 is amended by:

■ a. Revising paragraphs (b)(2) and (6);

■ b. Redesignating paragraphs (c) through (e) as paragraph (d) through (f);

■ c. Adding a new paragraph (c); and

■ d. Removing the parenthetical authority citation at the end of the section.

The revisions and addition read as follows:

§ 19.673 Small plant permit applications.

* * * * *

(b) * * *

(2) A description of the plant premises;

* * * * *

(6) A certification that the plant's construction and security will be in compliance with §§ 19.703 and 19.704.

(c) *Specifications of plant description.* (1) The description required by paragraph (b)(2) of this section may be in narrative form or diagram form, and must describe or illustrate the following:

(i) The overall dimensions of the building(s) housing the alcohol fuel plant;

(ii) The dimensions of the bonded premises and any general premises;

(iii) Any internal walls establishing the boundaries of the bonded and general premises;

(iv) The external doors of the plant premises; and

(v) Any portions of the plant premises that are outdoors, including the location of any outdoor tanks.

(2) Photographs further illustrating the elements required under paragraph (c)(1) of this section must be submitted upon request of the appropriate TTB officer.

* * * * *

■ 38. Section 19.675 is amended by:

■ a. Revising paragraphs (b)(2), (6), and (8);

■ b. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g);

■ c. Adding a new paragraph (c); and

■ d. Removing the parenthetical authority citation at the end of the section.

The revisions and addition read as follows:

§ 19.675 Medium plant permit applications.

* * * * *

(b) * * *

(2) A description of the plant premises;

* * * * *

(6) A certification that the plant's construction and security will be in compliance with §§ 19.703 and 19.704;

* * * * *

(8) Information identifying the principal persons involved in the management of the business. This identifying information must include each person's name, address, and title;

* * * * *

(c) *Specifications of plant description.* (1) The description required by paragraph (b)(2) of this section may be in narrative form or diagram form, and must describe or illustrate the following:

(i) The overall dimensions of the building(s) housing the alcohol fuel plant;

(ii) The dimensions of the bonded premises and any general premises;

(iii) Any internal walls establishing the boundaries of the bonded premises and general premises;

(iv) The external doors of the plant premises; and

(v) Any portions of the plant premises that are outdoors, including the location of any outdoor tanks.

(2) Photographs further illustrating the elements required under paragraph (c)(1) of this section must be submitted upon request of the appropriate TTB officer.

* * * * *

■ 39. Section 19.676 is amended by:

■ a. Revising paragraphs (b)(2), (6), and (8);

■ b. Redesignating paragraphs (c) through (g) as paragraph (d) through (h);

■ c. Adding a new paragraph (c); and

■ d. Removing the parenthetical authority citation at the end of the section.

The revisions and addition read as follows:

§ 19.676 Large plant permit applications.

* * * * *

(b) * * *

(2) A description of the plant premises;

* * * * *

(6) A certification that the plant's construction and security will be in compliance with §§ 19.703 and 19.704;

* * * * *

(8) Information identifying the principal persons involved in the management of the business. This identifying information must include each person's name, address, and title;

* * * * *

(c) *Specifications of plant description.* (1) The description required by

paragraph (b)(2) of this section may be in narrative form or diagram form, and must describe or illustrate the following:

(i) The overall dimensions of the building(s) housing the alcohol fuel plant;

(ii) The dimensions of the bonded premises and any general premises;

(iii) Any internal walls establishing the boundaries of the bonded premises and general premises;

(iv) The external doors of the plant premises; and

(v) Any portions of the plant premises that are outdoors, including the location of any outdoor tanks.

(2) Photographs further illustrating the elements required under paragraph (c)(1) of this section must be submitted upon request of the appropriate TTB officer.

* * * * *

■ 40. Section 19.677 is amended by:

■ a. Revising paragraphs (a)(2) and (d); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 19.677 Large plant applications—organizational documents.

* * * * *

(a) * * *

(2) A list of officers and directors with their names and addresses;

* * * * *

(d) *Statement of interest*—(1) *Sole proprietorships and general partnerships.* In the case of an individual owner or a general partnership, the applicant must provide the name and address of each person having an ownership interest in the business and a statement indicating whether the interest appears in the name of the interested person or in the name of another person.

(2) *Limited liability entities.* In the case of a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity, the applicant must provide the following information about persons having an ownership interest in the business:

(i) The names and addresses of persons having a 10 percent or more ownership interest in each of the classes or types of ownership interests in the applicant, and the nature and amount of ownership interest of each person.

(ii) The name of the person in whose name the interest appears. If the limited liability entity is under actual or legal control of another limited liability entity, the appropriate TTB officer may request the same information regarding ownership for the parent limited liability entity.

(3) *Representative.* If any interested person named under paragraphs (d)(1) and (2) of this section is a legal entity other than an individual, the applicant must also provide the name, title, and city and state of residence of a representative individual for the entity. The representative individual must be the individual designated by the entity to represent the entity's interest in the applicant business or, in the absence of a designated individual, an owner, chief officer or manager, or person with similar authority within the entity.

* * * * *

■ 41. Section 19.678 is amended by:

■ a. Revising paragraph (a); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.678 Criteria for issuance of permit.

* * * * *

(a) The applicant (including, in the case of a limited liability entity, any of its officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the applicant) is, by reason of business experience, financial standing, or trade connections, not likely to maintain operations in compliance with 26 U.S.C. chapter 51, or the regulations in this chapter;

* * * * *

§ 19.683 [Amended]

■ 42. Section 19.683 is amended by:

■ a. Removing the phrase ''30 days'' each place it appears and adding in its place ''60 days''; and

■ b. Removing the parenthetical authority citation at the end of the section.

■ 43. Section 19.684 is amended by:

■ a. Revising paragraph (b); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.684 Automatic termination of permits.

* * * * *

(b) *Limited liability entities.* In the case of a limited liability entity (*i.e.,* a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity) holding a permit issued under this subpart, if actual or legal control of such limited liability entity changes, directly or indirectly, whether by reason of a change in ownership or control (in the permittee limited liability entity or any other limited liability entity), by operation of law, or in any other manner, the permittee must file an application for a new permit within 60 days of the change. If an application for a new permit is not filed within 60 days of the change, the outstanding permit will automatically terminate. If an application for a new permit is filed within the 60-day period prescribed in the preceding sentences, the outstanding permit will remain in effect until TTB takes final action on the application. When TTB takes final action on the application, the outstanding permit will automatically terminate.

§ 19.686 [Amended]

■ 44. Section 19.686 is amended by:

■ a. Removing the phrase ''30 days'' and adding in its place ''60 days'' in the first sentence; and

■ b. Removing the parenthetical authority citation at the end of the section.

■ 45. Section 19.687 is revised to read as follows:

§ 19.687 Changes in officers, directors, members, managers, or principal persons.

If there is a change in the list of officers, directors, members, managers, or other principal persons furnished under the provisions of § 19.675, § 19.676, or § 19.677, the proprietor must submit a letterhead notice to the appropriate TTB officer within 60 days of the change. The letterhead notice must identify each change and must include the identifying information for each new officer, director, member, manager, or other principal person required by § 19.675, § 19.676, or § 19.677.

§ 19.691 [Amended]

■ 46. Section 19.691 is amended by:

■ a. Removing the phrase ''30 days'' and adding in its place ''60 days''; and

■ b. Removing the parenthetical authority citation at the end of the section.

■ 47. Section 19.692 is amended by:

■ a. Revising paragraph (b)(2); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 19.692 Qualifying for alternating proprietorship.

* * * * *

(b) * * *

(2) Additional versions of the description required under § 19.673(b)(2), § 19.675(b)(2), or § 19.676(b)(2) describing or illustrating the arrangement for the alternation of

the premises. Where operations by alternating proprietors are limited to parts of an alcohol fuel plant, the description or illustration must include the areas, rooms, or buildings, or combination of rooms and/or buildings, that will alternate between proprietors. The description or illustration must also include the means by which the alternated premises will be separated from any premises that will not be alternated. A description or illustration must be submitted for each arrangement under which the premises will be operated;

* * * * *

§ 19.761 [Amended]

■ 48. Section 19.761 is amended by removing the entries for §§ 19.76, 19.77, 19.121, 19.122, and 19.123 from the table in paragraph (b).

PART 20—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

■ 49. The authority citation for part 20 continues to read as follows:

Authority: 26 U.S.C. 5001, 5206, 5214, 5271–5275, 5311, 5552, 5555, 5607, 6065, 7805.

§ 20.42 [Amended]

■ 50. Section 20.42 is amended by removing the phrase ''serial number,'' in paragraph (a)(8).

■ 51. Section 20.45 is amended by revising paragraph (c) to read as follows:

§ 20.45 Organizational documents.

* * * * *

(c) *Statement of interest*—(1) *Sole proprietorships and general partnerships.* In the case of an individual owner or a general partnership, the applicant must provide the name and address of each person having an ownership interest in the business and a statement indicating whether the interest appears in the name of the interested person or in the name of another person.

(2) *Limited liability entities.* In the case of a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity, the applicant must provide the following information about persons having an interest in the business:

(i) The names and addresses of persons having a 10 percent or more ownership interest in each of the classes or types of ownership interest of the applicant, and the nature and amount of ownership interest of each person.

(ii) The name of the person in whose name the interest appears. If the limited liability entity is under actual or legal control of another limited liability entity, the appropriate TTB officer may request the same information regarding ownership for the parent limited liability entity.

(3) *Representative.* If any interested person named under paragraphs (c)(1) and (2) of this section is a legal entity other than an individual, the applicant must also provide the name, title, and city and state of residence of a representative individual for the entity. The representative individual must be the individual designated by the entity to represent the entity's interest in the applicant business or, in the absence of a designated individual, an owner, chief officer or manager, or person with similar authority within the entity.

■ 52. Section 20.56 is amended by:

■ a. Removing the phrase ''30 days'' and adding in its place ''60 days'' in paragraph (a)(1); and

■ b. Revising paragraphs (c) heading and (c)(3).

The revisions read as follows:

§ 20.56 Changes affecting applications and permits.

* * * * *

(c) *Changes in officers, directors, and ownership interests.* * * *

(3) *Ownership interests.* In lieu of reporting all changes, within 60 days, to the list of persons with an ownership interest furnished under the provisions of § 20.45(c), a permittee may, upon filing written notice to the appropriate TTB officer and establishing a reporting date, file an annual notice of changes. The notice of changes in ownership interest holders does not apply if the sale or transfer of ownership interest(s) results in a change in ownership or control which is required to be reported under § 20.57.

* * * * *

■ 53. Section 20.57 is amended by revising paragraph (b) to read as follows:

§ 20.57 Automatic termination of permits.

* * * * *

(b) *Limited liability entities.* In the case of a limited liability entity (*i.e.,* a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity) holding a permit issued under this part, if actual or legal control of such limited liability entity changes, directly or indirectly, whether by reason of a change in ownership or control (in the permittee limited liability entity or any other limited liability entity), by operation of law, or in any other manner, the permittee must file an application for a new permit within 60 days of the change. If an application for a new permit is not filed within 60 days of the change, the outstanding permit will automatically terminate. If an application for a new permit is filed within the 60-day period prescribed above, the outstanding permit will remain in effect until TTB takes final action on the application. When TTB takes final action on the application, the outstanding permit will automatically terminate.

* * * * *

■ 54. Section 20.61 is revised to read as follows:

§ 20.61 Change in trade name.

In the event of any change in a trade name of a permittee, or, in the event a permittee desires to engage in operations under an additional trade name, the permittee must first file a letterhead notice with the appropriate TTB officer listing the names and the offices where they are registered.

(Approved by the Office of Management and Budget under control number 1513–0061)

■ 55. Section 20.267 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

§ 20.267 Filing and retention of records.

* * * * *

(b) File all records and copies of reports at the premises where the operations are conducted. A permittee may keep the required records at a location other than the permitted premises, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept.

(c) Make the files of records and copies of reports available for inspection by the appropriate TTB officer during regular business hours. Any permittee keeping records at a location other than the premises where operations are conducted must make them available at such premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the permittee to supply copies (including electronic copies) of such records instead of the originals.

PART 22—DISTRIBUTION AND USE OF TAX-FREE ALCOHOL

■ 56. The authority citation for part 22 continues to read as follows:

Authority: 26 U.S.C. 5001, 5121, 5123, 5206, 5214, 5271–5275, 5311, 5552, 5555, 6056, 6061, 6065, 6109, 6151, 6806, 7805; 31 U.S.C. 9304, 9306.

§ 22.42 [Amended]

■ 57. Section 22.42 is amended by removing the phrase ''serial number,'' in paragraph (a)(8).

■ 58. Section 22.45 is amended by revising paragraph (c) to read as follows:

§ 22.45 Organizational documents.

* * * * *

(c) *Statement of interest*—(1) *Sole proprietorships and general partnerships.* In the case of an individual owner or a general partnership, the applicant must provide the name and address of each person having an ownership interest in the business and a statement indicating whether the interest appears in the name of the interested person or in the name of another person.

(2) *Limited liability entities.* In the case of a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity, the applicant must provide the following information about persons having an interest in the business:

(i) The names and addresses of persons having a 10 percent or more ownership interest in each of the classes or types of ownership interest of the applicant, and the nature and amount of ownership interest of each person.

(ii) The name of the person in whose name the interest appears. If the limited liability entity is under actual or legal control of another limited liability entity, the appropriate TTB officer may request the same information regarding ownership for the parent limited liability entity.

(3) *Representative.* If any interested person named under paragraphs (c)(1) and (2) of this section is a legal entity other than an individual, the applicant must also provide the name, title, and city and state of residence of a representative individual for the entity. The representative individual must be the individual designated by the entity to represent the entity's interest in the applicant business or, in the absence of a designated individual, an owner, chief officer or manager, or person with similar authority within the entity.

■ 59. Section 22.57 is amended by:

■ a. Removing the phrase ''30 days'' and adding in its place ''60 days'' each place it appears in paragraph (a)(1).

■ b. Revising paragraphs (c) heading and (c)(3).

The revisions read as follows:

§ 22.57 Changes affecting applications and permits.

* * * * *

(c) *Changes in officers, directors, and ownership interests.* * * *

(3) *Ownership interests.* In lieu of reporting all changes, within 60 days, to the list of persons with an ownership interest furnished under the provisions of § 22.45(c), a permittee may, upon filing written notice to the appropriate TTB officer and establishing a reporting date, file an annual notice of changes. The notice of changes in ownership interest holders does not apply if the sale or transfer of ownership interest(s) results in a change in ownership or control which is required to be reported under § 22.58.

* * * * *

■ 60. Section 22.58 is amended by revising paragraph (b) and the parenthetical Office of Management and Budget control number statement to read as follows:

§ 22.58 Automatic termination of permits.

* * * * *

(b) *Limited liability entities.* In the case of a limited liability entity (*i.e.,* a corporation, limited liability partnership, limited liability company, or other legal entity in which some or all of the owners have limited personal liability for the activities of the entity) holding a permit issued under this part, if actual or legal control of such limited liability entity changes, directly or indirectly, whether by reason of a change in ownership or control (in the permittee limited liability entity or any other limited liability entity), by operation of law, or in any other manner, the permittee must file an application for a new permit within 60 days of the change. If an application for a new permit is not filed within 60 days of the change, the outstanding permit will automatically terminate. If an application for a new permit is filed within the 60-day period prescribed above, the outstanding permit will remain in effect until TTB takes final action on the application. When TTB takes final action on the application, the outstanding permit will automatically terminate.

* * * * *

(Approved by the Office of Management and Budget under control number 1513–0060)

■ 61. Section 22.62 is revised to read as follows:

§ 22.62 Change in trade name.

In the event of any change in a trade name of a permittee, or, in the event a permittee desires to engage in operations under an additional trade name, the permittee must first file a letterhead notice with the appropriate TTB officer listing the new names and the offices where they are registered.

(Approved by the Office of Management and Budget under control number 1513–0060)

■ 62. Section 22.164 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 22.164 Filing and retention of records.

* * * * *

(b) Maintain all records at the permitted premises. A permittee may keep the required records at a location other than the permitted premises, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept.

(c) Make the files of records and copies of claims available for inspection by the appropriate TTB officer during regular business hours. Any permittee keeping records at a location other than the permitted premises must make them available at the permitted premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the permittee to supply copies (including electronic copies) of such records instead of the originals.

PART 26—LIQUORS AND ARTICLES FROM PUERTO RICO AND THE VIRGIN ISLANDS

■ 63. The authority citation for part 26 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5061, 5111–5114, 5121, 5122–5124, 5131–5132, 5207, 5232, 5271, 5275, 5301, 5314, 5555, 6001, 6109, 6301, 6302, 6804, 7101, 7102, 7651, 7652, 7805; 27 U.S.C. 203, 205; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 64. Section 26.174 is amended by revising paragraphs (a) and (e) and the parenthetical Office of Management and Budget control number statement to read as follows:

§ 26.174 Records.

(a) *General.* Every person intending to file a claim for drawback on eligible articles brought into the United States from Puerto Rico must keep permanent records of the data elements required by this section.

* * * * *

(e) *Retention and availability of records.* (1) Each drawback claimant must retain for a period of not less than three years all records required by this subpart, all commercial invoices or shipping documents, and all bills of lading received evidencing receipt and tax determination of the spirits. In addition, a copy of each approved formula returned to the manufacturer of eligible articles must be retained for not less than three years from the date the

claimant files their last claim for drawback under the formula.

(2) The records required under this subpart must be maintained at the business premises for which the claim is filed, or at any other location provided that the claimant first provides a letterhead notice to the appropriate TTB officer of the location where the records are to be kept. Records must be available for inspection by any appropriate TTB officer during business hours. If the records are stored at a location other than the business premises for which the claim is filed, they must be made available at such premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow copies (including electronic copies) of such records to be provided instead of the originals.

(Approved by the Office of Management and Budget under control number 1513–0089)

■ 65. Section 26.275 is amended by:

■ a. Revising paragraph (a); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 26.275 Filing.

(a) All records and reports required by this part will be maintained separately, by transaction or reporting date, at the importer's place of business. An importer may keep the required records and reports at an alternative location other than his or her place of business, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. Any importer keeping records at a location other than the importer's place of business must make them available at the importer's place of business upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the importer to supply copies (including electronic copies) of such records instead of the originals. The appropriate TTB officer may require an importer to maintain the required records and reports at his or her place of business if the alternative location is found to cause undue inconvenience to appropriate TTB or Customs officers desiring to examine the files or cause delay in the timely submission of documents.

* * * * *

■ 66. Section 26.310 is amended by revising paragraphs (a) and (e) and the parenthetical Office of Management and Budget control number statement to read as follows:

§ 26.310 Records.

(a) *General.* Every person intending to file claim for drawback on eligible articles brought into the United States from the Virgin Islands must keep permanent records of the data elements required by this section.

* * * * *

(e) *Retention and availability of records.* (1) Each drawback claimant must retain for a period of not less than three years all records required by this subpart, all commercial invoices or shipping documents, and all bills of lading received evidencing receipt and tax determination of the spirits. In addition, a copy of each approved formula returned to the manufacturer of eligible articles must be retained for not less than three years from the date the claimant files their last claim for drawback under the formula.

(2) The records required under this subpart must be maintained at the business premises for which the claim is filed, or at any other location provided that the claimant first provides a letterhead notice to the appropriate TTB officer of the location where the records are to be kept. Records must be available for inspection by any appropriate TTB officer during business hours. If the records are stored at a location other than the business premises for which the claim is filed, they must be made available at such premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow copies (including electronic copies) of such records to be provided instead of the originals.

(Approved by the Office of Management and Budget under control number 1513–0089)

PART 27—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

■ 67. The authority citation for part 27 continues to read as follows:

Authority: 5 U.S.C. 552(a), 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5054, 5061, 5121, 5122–5124, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5382, 5555, 6109, 6302, 7805.

■ 68. Section 27.136 is amended by:

■ a. Revising paragraph (a) and the parenthetical Office of Management and Budget control number statement; and

■ b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 27.136 Filing.

(a) All records and reports required by this part will be maintained separately, by transaction or reporting date, at the importer's place of business. An importer may keep the required records and reports at an alternative location other than his or her place of business, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. Any importer keeping records at a location other than the importer's place of business must make them available at the importer's place of business upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the importer to supply copies (including electronic copies) of such records instead of the originals. The appropriate TTB officer may require an importer to maintain the required records and reports at his or her place of business if the alternative location is found to cause undue inconvenience to appropriate TTB or Customs officers desiring to examine the files or cause delay in the timely submission of documents.

* * * * *

(Approved by the Office of Management and Budget under control number 1513–0088)

PART 28—EXPORTATION OF ALCOHOL

■ 69. The authority citation for part 28 continues to read as follows:

Authority: 5 U.S.C. 552(a); 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5041, 5051, 5054, 5061, 5121, 5122, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5555, 6109, 6302, 7805; 27 U.S.C. 203, 205; 44 U.S.C. 3504(h).

■ 70. Section 28.45 is revised to read as follows:

§ 28.45 Retention of records.

File copies of forms required by this part to be retained by any proprietor or claimant, and all records, documents, or copies of records and documents supporting such forms, must be preserved by such proprietor or claimant for a period of not less than two years, and during such period must be available for inspection by any appropriate TTB officer at the proprietor or claimant's place of business. A proprietor or claimant may keep the required records at a location other than his or her place of business if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. The proprietor or claimant must nonetheless make the records available at the permitted premises upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the proprietor or claimant to supply copies (including

electronic copies) of such records instead of the originals.

(Approved by the Office of Management and Budget under control number 1513–0075)

PART 31—ALCOHOL BEVERAGE DEALERS

■ 71. The authority citation for part 31 continues to read as follows:

Authority: 26 U.S.C. 5001, 5002, 5121, 5122–5124, 5131, 5132, 5206, 5207, 5273, 5301, 5352, 5555, 5603, 5613, 5681, 5687, 6061, 6065, 6071, 6091, 6103, 6109, 6723, 6724, 7805.

■ 72. Section 31.114 is amended by:

■ a. Removing the word ''true'' and adding in its place ''legal'' in paragraph (b)(1);

■ b. Revising paragraph (b)(8); and

■ c. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 31.114 Completion of registration form.

* * * * *

(b) * * *

(8) Ownership and control information. This consists of the name, position, and residence address of every owner of the business and of every person having power to control its management and policies with respect to the activity subject to registration. ''Owner of the business'' includes every partner if the dealer is a partnership and, in the case of a limited liability entity, any of its officers, directors, or persons holding a 10 percent or more ownership interest in any of the classes or types of ownership of the applicant. However, the ownership and control information required by this paragraph (b)(8) need not be stated if the same information has been previously provided to TTB and that previously provided information is still current.

* * * * *

■ 73. Section 31.132 is revised to read as follows:

§ 31.132 Change in name.

(a) *Legal name.* In the event of any change in the name of the individual, firm, corporation, or other entity registered as a dealer at a given location, the dealer must complete an amended registration and submit it on or before the next July 1.

(b) *Trade name.* In the event of any change in a trade name of a dealer registered at a given location, or in the event a dealer desires to engage in operations under an additional trade name at a given location, the dealer must first file a letterhead notice with the appropriate TTB officer listing the new names and the offices where they are registered.

§ 31.138 [Amended]

■ 74. Section 31.138 is amended by removing the phrase ''30 days'' and adding ''60 days'' in its place.

■ 75. Section 31.152 is revised to read as follows:

§ 31.152 Requirements as to wines and beer.

(a) *General.* Every wholesale dealer in liquors who receives wines, or wines and beer, and every wholesale dealer in beer must keep a complete record showing the quantities of wine and beer received, from whom the wine and beer were received, and the dates of receipt. This record, which must be kept for a period of not less than three years as prescribed in § 31.191, must consist of all purchase invoices or bills covering wines and beer received or, at the option of the dealer, a book record containing all of the required information. Wholesale dealers are not required to prepare or submit reports to the appropriate TTB officer of transactions relating to wines and beer.

(b) *Availability of records.* The records required under this subpart must be kept at the dealer's place of business. A dealer may keep the required records at a location other than his or her place of business premises, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. The dealer must make the files of records and copies of reports available for inspection by the appropriate TTB officer during regular business hours. Any dealer keeping records at a location other than his or her place of business must make them available at the his or her place of business upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the dealer to supply copies (including electronic copies) of such records instead of the originals.

(Approved by the Office of Management and Budget under control number 1513–0065.)

■ 76. Section 31.172 is revised to read as follows:

§ 31.172 Place of filing.

Records of receipt and disposition and monthly summary reports required by §§ 31.155, 31.156, and 31.160 must be maintained at the dealer's place of business. A dealer may keep the required records at a location other than his or her place of business premises, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. Any dealer keeping records at a location other than his or her place of business must make them available at his or her place of business upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the dealer to supply copies (including electronic copies) of such records instead of the originals.

■ 77. Section 31.181 is amended by:

■ a. Revising paragraph (a); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 31.181 Requirements for retail dealers.

(a) *Records of receipt.* All retail dealers must keep at their place of business complete records showing the quantities of all distilled spirits, wines, and beer received, from whom the distilled spirits, wines, and beer were received, and the dates of receipt. Records of receipts must consist of all purchase invoices or bills covering distilled spirits, wines, and beer received, or, at the option of the retail dealer, a book record containing all of the required information. A retail dealer may keep the required records at a location other than his or her place of business premises, if he or she has first provided a letterhead notice to the appropriate TTB officer identifying the location where the records are to be kept. Any retailer dealer keeping records at a location other than his or her place of business must make them available at the his or her place of business upon request of the appropriate TTB officer; however, the TTB officer may, at his or her discretion, allow the dealer to supply copies (including electronic copies) of such records instead of the originals.

* * * * *

Signed: November 19, 2021.

Mary G. Ryan,

Administrator.

Approved: November 19, 2021.

Timothy E. Skud,

Deputy Assistant Secretary, Tax, Trade and Tariff Policy.

[FR Doc. 2021–25721 Filed 12–2–21; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

[Docket No. OSHA–2021–0009]

RIN 1218–AD39

Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings; Extension of Comment Period

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Advance notice of proposed rulemaking (ANPRM); extension of comment period.

SUMMARY: OSHA is extending the period for submitting comments by 30 days to allow stakeholders interested in the ANPRM on Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings additional time to review the ANPRM and collect information and data necessary for comment.

DATES: The comment period for the ANPRM that was published at 86 FR 59309 on October 27, 2021, is extended. Comments on any aspect of the ANPRM must be submitted by January 26, 2022.

ADDRESSES:

Written comments: You may submit comments and attachments, identified by Docket No. OSHA–2021–0009, electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the online instructions for making electronic submissions. The Federal e-Rulemaking Portal at *www.regulations.gov* is the only way to submit comments on this ANPRM.

Instructions: All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2021–0009). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA–2021–0009 at *www.regulations.gov.* All comments and submissions are listed in the *www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code. OSHA is identifying supporting information in this ANPRM by author name and publication year, when appropriate. This information can be used to search for a supporting document in the docket at *http://www.regulations.gov.* Contact the OSHA Docket Office at 202–693–2350 (TTY number: 877–889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Contact Frank Meilinger, Director, Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Andrew Levinson, Directorate of Standards and Guidance, U.S. Department of Labor; telephone: (202) 693–1950.

SUPPLEMENTARY INFORMATION: On October 27, 2021, OSHA issued an ANPRM to initiate rulemaking to protect indoor and outdoor workers from hazardous heat and to obtain additional information about the extent and nature of hazardous heat in the workplace and the nature and effectiveness of interventions and controls used to prevent heat-related injury and illness.

The public comment period for the ANPRM was to close on December 27, 2021, 60 days after publication of the ANPRM. However, OSHA received requests from stakeholders to extend the comment period by an additional 30 days (Document ID 0145) or 60 days (Document ID 0101, 0133, 0141, 0143, 0144, 0148, 0152, 0159). These stakeholders explained that they need additional time to carefully review the questions in the ANPRM, obtain input from members, and provide comments (see, *e.g.,* Document ID 0101).

OSHA agrees to an extension of the public comment period and believes a 30-day extension is sufficient and appropriate in order to balance the agency's need for timely input to inform how the agency will proceed with the rulemaking with these stakeholder requests. Therefore, OSHA is extending the public comment period until January 26, 2022.

Authority and Signature

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this document pursuant to the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8–2020 (85 FR 58393 (Sept. 18, 2020)); 29 CFR part 1911; and 5 U.S.C. 553.

Signed at Washington, DC, on November 24, 2021.

Douglas L. Parker,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–26269 Filed 12–2–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–3409–NC]

RIN 0938–AU55

Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information solicits public comments on potential changes to the requirements that transplant programs, organ procurement organizations, and end-stage renal disease facilities must meet in order to participate in the Medicare and Medicaid programs. These providers and suppliers are integral to the transplant ecosystem in the United States and to the health of patients across the Nation. We are seeking public comment that will help to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 1, 2022.

ADDRESSES: In commenting, refer to file code CMS–3409–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3409–NC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3409–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786–8486; James Cowher, (410) 786–1948; Jeannine Cramer, (410) 786–5664; Lauren Oviatt, (410) 786–4683; or Alpha-Banu Wilson, (410) 786–8687.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

The organ donation and transplantation system (known and referred to herein as the transplant ecosystem) in the United States comprises a vast network of institutions dedicated to ensuring that patients are evaluated and, if appropriate, placed onto the organ transplant waitlist, and that those on the organ transplant waitlists receive lifesaving organ transplants. These entities include organ procurement organizations (OPOs), charged with identifying eligible donors and procuring organs from deceased donors; transplant programs, located within transplant hospitals, that perform transplantation procedures from living and deceased donors; and donor hospitals that notify OPOs of the imminent death of potential donors and assist the OPO in the management of the donor and the procurement of the donor's organs. OPOs, donor hospitals, and transplant programs rely on a close collaborative relationship to ensure that organs are successfully procured and appropriately placed with transplant programs. Further, OPOs rely on families or next-of-kin, or the deceased donor themselves (if they made the decision to donate prior to death), who voluntarily make the choice to save lives and become donors. OPOs also have the role of compassionately discussing donation issues with donor families and educating the public on organ donation. In calendar year 2020, there were a total of 39,034 transplants.[1] These transplants resulted from 12,587 deceased donors and 5,725 living donors. For deceased donors, this represents about a 6 percent increase over 2019.[2] However, there continues to be a chronic substantial unmet need for transplantable organs as the number of people who need an organ transplant increases in the United States. As of November 2, 2021, there are 106,712 patients waiting for organ transplants.

On the other side of the care spectrum and prior to transplantation, end-stage renal disease (ESRD) facilities, also known as dialysis facilities, are charged with delivering safe, adequate dialysis to patients with ESRD. ESRD facilities also educate patients on their treatment options, including kidney transplantation, and ultimately refer patients to transplant programs for evaluation and potential kidney transplantation. ESRD is complete kidney impairment that is irreversible, permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. In the United States, approximately 37 million patients suffer from chronic kidney disease (CKD)[3] and more than 785,000 have ESRD.[4]

We have made changes to the existing CMS regulations with the goal of making impactful changes to the transplantation ecosystem and improving patient health, safety, and outcomes in transplant programs, OPOs, and ESRD facilities. On September 30, 2019, we published the final rule, ''Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732) and finalized changes to the transplant program regulations by eliminating the data, clinical experience, and outcome requirements for re-approval of transplant programs. This action removed disincentives to transplantation by encouraging the use of organs that may be perceived as being less than ideal, but could still be used for transplantation with improved outcomes over traditional therapies such as dialysis. On December 2, 2020, in response to Executive Order 13879, which aimed to increase the utilization of available organs, we published a final rule entitled, ''Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations (85 FR 77898),'' which revised the OPO conditions for coverage (CfCs) by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures. While these regulatory changes recently went into effect with the goal of creating improvements in the performance of these entities and the delivery of care to patients additional system-wide improvements may be necessary to further improve patient health and safety and outcomes in transplant programs, OPOs, and ESRD facilities. In

[1] U.S. Health Resources and Services Administration. Organ Procurement and Transplantation Network—DATA. *https://optn.transplant.hrsa.gov/data/.* Accessed January 13, 2021. *https://optn.transplant.hrsa.gov/data/.* Accessed January 13, 2021.

[2] U.S. Health Resources and Services Administration. Annual record trend continues for deceased organ donation, deceased donor transplants. *https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/.* Published January 11, 2021. Accessed January 13, 2021. *https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/.* Published January 11, 2021. Accessed January 13, 2021.

[3] Chronic Kidney Disease Initiative. *https://www.cdc.gov/kidneydisease/basics.html#:~:text=About%2037%20million%20US%20adults,dialysis%20treatment%20for%20kidney%20failure.* Accessed November 4, 2021.

[4] Kidney Disease: The Basics. National Kidney Foundation. *https://www.kidney.org/news/newsroom/fsindex.*

addition, CMS is actively working to identify and address disparities and inequities across these programs. We discuss the inequities that exist in organ donation, transplantation, and dialysis and ask questions regarding how the CoPs/CfCs can address and improve these issues later in this RFI. We are soliciting comments on ways to:

1. Continue to improve systems of care for all patients in need of a transplant;
2. Increase the number of organs available for transplant for all solid organ types;
3. Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous;
4. Ensure that the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) policies appropriately incentivize the creation and use of future new treatments and technologies; and
5. Harmonize requirements across government agencies to facilitate these objectives and improve quality across the organ donation and transplantation ecosystem.

In addition, we are soliciting information related to opportunities, inefficiencies, and inequities in the transplant ecosystem and what can be done to ensure all segments of our healthcare systems are invested and accountable in ensuring improvements to organ donation and transplantation rates.

II. Solicitation of Public Comments

A. Transplant Programs

1. Background

Transplant programs, located within a hospital that has a Medicare provider agreement, provide transplantation services for one or more specific organs. Transplant programs must comply with the Medicare transplant program conditions of participation (CoPs) regulations at 42 CFR 482.68 through 482.104, and with the hospital CoPs at §§ 482.1 through 482.58. There are several types of CMS-approved transplant programs including heart, lung, liver, kidney, intestine, pancreas, and multi-organ. The transplant program CoPs were finalized and effective in 2007 and updated again in 2019 (84 FR 51732).

While we have made refinements to the transplant program CoPs over the years, more work is still necessary to improve the transplantation ecosystem. As evidenced through several studies and Organ Procurement and Transplantation Network (OPTN) data, the number of organs discarded continues to be high and we believe that this number could be significantly reduced. For example, in 2018, there were 37,852 organs recovered from deceased donors. Of these, 5,085 organs were discarded, with 3,755 of those organs being kidneys, 278 being pancreata, 707 livers, 3 intestines, 23 hearts, and 319 lungs.[5] Transplant programs must play an important role in reducing the organ discard rate and can do so by accepting and utilizing more organs that are deemed ''marginal'', thus ensuring that more patients on the waitlist receive lifesaving transplants. Research indicates that many of the organs deemed as ''marginal'' that are denied are later transplanted successfully into patients at other transplant centers or they are discarded despite having similar or better quality characteristics to organs that are successfully transplanted elsewhere (see discussion in section II.C.5).[6] [7] We are requesting the public's input on issues pertaining to potential changes to the transplant program CoPs, transplant recipient patient's rights, and equity in organ transplantation, in order to achieve these goals.

2. Transplant Program CoPs

We are seeking public comments on the following questions:

1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received? Specifically, what type of information are you receiving from your transplant program or transplant surgeon?

2. Do transplant programs adequately protect the health and safety of living donors and transplant patients? Please provide data, research, studies, or firsthand accounts that would be illustrative of how transplant programs are performing with regards to adequately protecting patient health and safety.

3. How can the current transplant program CoPs be improved in order to incentivize and ensure performance quality in organ transplantation?

4. Do the initial approval requirements at § 482.80 create barriers to the establishment of new transplant programs? Do they require an excessive amount of hospital resources at program launch, resulting in hospitals retaining lower performing transplant programs? What alternatives for ensuring quality and oversight should be considered?

5. We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies? [8] What are the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency?

6. Are there additional requirements that CMS could implement that would improve the manner, effectiveness and timeliness of communication between OPOs, donor hospitals, and transplant programs?

7. Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS' decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval?

8. The industry as a whole has acknowledged that changes cannot be made solely to one part of the transplantation system. Similar to the outcome requirements that OPOs must meet, should CMS again consider additional metrics of performance in relation to the organ transplantation rate, considering that the number of organs discarded remains high? What should these metrics be? Are there additional quality measures that CMS should consider to measure a transplant program's performance? For a meaningful evaluation of transplant program outcomes from the recipient point of view, please comment on meaningful outcome measures that should be included in the transplant outcomes evaluations.

9. In the context of organ shortage and expanded use of marginal, suboptimal quality organs, and transplantation into

[5] OPTN/SRTR 2018 Annual Data Report: Deceased Organ Donation.

[6] Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. JAMA Network Open. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: JAMA Network Open. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

[7] Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. JAMA Network Open. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: JAMA Network Open. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

[8] Organ Procurement and Transplantation Network website. *https://optn.transplant.hrsa.gov/governance/*

standard and high-risk recipients, we are seeking public comments from the recipient perspective and expectations on meaningful measures including but not limited to graft survival benefit, shorter waiting list time, frailty improvement and quality of life after transplant, and other transplant benefits.

10. How can CMS meaningfully measure transplant outcomes without dis-incentivizing transplantation of marginal organs or dis-incentivizing performing transplants on higher risk patients?

3. Transplant Recipient Patient Rights

Section 482.102 ''Patient and living donor rights'' provides specific rights for the patients on the waiting lists and transplant recipients. However, these enumerated rights do not address transparency regarding organ offers made for the patient on a transplant program's waiting list. There is no requirement for the transplant center or surgeon to notify a patient on the waiting list that there has been an organ offered for them.

Research has shown that less than 16 percent of deceased donor kidneys are accepted without being declined at least once.[9] In addition, as discussed later in this RFI, there are concerns that kidneys may be declined for reasons other than organ quality. We believe that there should be some degree of transparency between the transplant program or surgeon and the patient on the waiting list. Although we believe there should be some degree of transparency and accountability, we want to avoid causing the patient undue anxiety. Therefore, we are seeking comments on the degree of transparency that we should require of programs to ensure that transplant patients on the wait list receive the information they need to make decisions about their care and ensure that transplant programs and surgeons are accountable and transparent in their decisions to decline organs.

Specifically, we are seeking public comments on the following question:

1. How can transplant programs facilitate greater communication and transparency with patients on their waiting list regarding organ selection while limiting undue delays or undue anxiety to their patients?

We are also requesting feedback from individuals who are on a waiting list or who have received a transplant, their families, advocates, and caregivers regarding patient education, support, and information on transplantation. We are interested in understanding how the CoPs/CfCs, in particular the patient and transplant recipient rights requirements, could be revised to ensure that transplant programs, ESRD facilities, and OPOs are providing appropriate education and information to patients and their families on organ transplantation. This would ensure that patients, particularly those in underserved communities, are aware of their ability to access a lifesaving organ transplant, which will lead to better long-term health outcomes. While we use the term ''transplant program,'' please include any communication or information that you have received from other health care providers such as physicians or hospitals in your responses.

Specifically, we are seeking public comments on the following questions:

1. Did the transplant program provide you with information specific to your unique needs, medical situation, and potential transplant outcomes?

2. Did the transplant program provide you with any information about waiting times specific to your type of organ transplant? If so, what was the waiting time estimate that the transplant program gave you?

3. Did the transplant program or transplant surgeon provide you with any information on organ offers that were made for you and were declined by the transplant program or surgeon? If so, was the reason for a decline explained to you?

4. What is/was the most helpful information about organ transplantation you received? From which source did you receive this information? Did you receive other helpful information from other sources? If so, what were those sources?

5. Are you satisfied with the communication and support you have received from your transplant program? What information from your transplant program did you find helpful in making your decision?

6. For patients who are or were on dialysis, what information did you receive on organ transplantation from your dialysis center? Do you believe the dialysis center supported organ transplantation? Why or why not?

4. Equity in Organ Transplantation and Organ Donation

On January 20 through January 21, 2021, President Biden issued three executive orders addressing issues of health equity:

- Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, 86 FR 7009, January 20, 2021);
- Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (E.O. 13988, 86 FR 7023, January 25, 2021); and
- Executive Order or Ensuring an Equitable Pandemic Response and Recovery (E.O. 13995, 86 FR 7193, January 26, 2021).

We are committed to supporting the President's Executive Orders by ''advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality''.[10] Such efforts extend to ensuring equity within the organ transplantation and donation system for all populations, including racial and ethnic minorities and people with disabilities. Organ transplantation and donation in the United States remains highly inequitable amongst racial and ethnic minorities as compared to White Americans. As one study notes regarding kidney transplants, ''racial disparities were observed in access to referral, transplant evaluation, waitlisting and organ receipt'' and ''SES [socioeconomic status] explained almost one-third of the lower rate of transplant among black versus white patients, but even after adjustment for demographic, clinical and SES factors, blacks had a 59 percent lower rate of transplant than whites''.[11] In addition, Black/African Americans, Hispanics/Latinos, Asian Americans, and other minorities are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[12] ''Black/African Americans are almost 4 times more likely and Hispanics or Latinos are 1.3 times more likely to have kidney failure as compared to White Americans.'' [13] Yet those Black/African American and Hispanic/Latinos patients on dialysis are less likely to be placed on the transplant waitlist and also have a lower likelihood of transplantation.[14] In particular, Black/African Americans make up the largest group of minorities in need of an organ transplant and yet the number of organ transplants performed on Black/African Americans

[9] Mohan S, ''Kidney Transplantation: Good intentions and missed opportunities leave patients behind.'' Centers for Medicare & Medicaid Grand Rounds. June 13, 2019.

[10] Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, January 20, 2021.

[11] Patzer, RE, Perryman, JP et. al. The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. American Journal Tranplant. *https://pubmed.ncbi.nlm.nih.gov/22233181/.*

[12] *https://www.kidney.org/atoz/content/minorities-KD,* Race, Ethnicity, & Kidney Disease.

[13] *https://www.kidney.org/atoz/content/minorities-KD.* Race, Ethnicity, & Kidney Disease.

[14] Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. *https://journals.lww.com/transplantjournal/Fulltext/2020/07000/Social_Determinants_of_Health__Going_Beyond_the.9.aspx.* Access.

in 2020 was 28.5 percent of the number of Black/African Americans currently waiting for a transplant. The number of transplants performed on White Americans, however, was 40.4 percent of the number currently waiting.[15]

U.S. TRANSPLANT WAITING LIST—CANDIDATES BY RACE/ETHNICITY

Organ	All candidates	Number of Black candidates	Black percent of all candidates	Number of White candidates	White percent of all candidates
All Organs	106,666	30,421	28.5	43,054	40.4
Kidney	90,235	28,365	31.4	32,377	35.9
Liver	11,704	836	7.1	7,865	67.2
Heart	3,531	990	28.0	2,004	56.8
Lung	922	118	11.9	661	66.6

TRANSPLANTS PERFORMED IN THE U.S. BY RECIPIENT ETHNICITY, 2020

	Number	Percentage of total 2020 transplants
Black	8,414	21.6
White	20,997	53.8
Total Transplants	39,036	100

Source: HRSA. U.S. Organ Procurement and Transplantation Network (OPTN). Based on OPTN data as of August 23, 2021. *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.* Tables from *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27.*

There are many theories that have been posited as to why these racial and ethnic inequities in transplantation exist. A person's social determinants of health (those additional social and economic factors that are driven by systemic racism and social policies) affect a wide range of health and quality of life risks and outcomes.[16] These can therefore be contributing factors that lead to inequities in transplantation and impact a patient's access to dialysis and placement on the waitlist. In addition, low health literacy, lack of healthcare coverage, and lack of economic, environmental, and other social opportunities can contribute to poorer health outcomes in general. However, studies have also shown that medical practices can contribute to inequities in transplantation. Delays in referrals to kidney transplantation, in particular, may be due ''. . . in part, to clinicians' implicit or explicit biases, including physician misperceptions about the benefits of transplants for Black individuals or discordant and inaccurate beliefs regarding causes or prevalence of these disparities''.[17] Another contributing factor to inequities in transplantation could also be due to the widespread use of the Chronic Kidney Disease Epidemiology (CKD–EPI) equation used by kidney transplant programs, which measures kidney function and includes an adjustment for race (Black/African American) that often under-identifies chronic kidney disease in Black/African Americans and denies them equitable appropriate intervention, which in turn could have an impact on the time a patient waits for a kidney transplant. The use of race in the calculation of the estimated glomerular filtration rate (eGFR) has been questioned recently and the OPTN has solicited public feedback on reassessing the inclusion of race in eGFR equations.[18]

In addition, inequity exists for people with disabilities who similarly need access to organ transplantation. A 2019 National Council on Disability report found that people with disabilities are frequently denied equal access to receive organ transplants based solely on their disability status.[19] Providers and transplant centers also often assume that people with disabilities, especially those with intellectual disabilities, will have worse outcomes after transplantation. A survey conducted in 2008 of pediatric transplant centers determined that ''43 percent always or usually consider intellectual disabilities an absolute or relative contraindication to transplant due to assumptions about quality of life, concerns regarding 'compliance or long-term self-care' 'financial concerns', and 'the functional prognosis of the delay itself' ''.[20] However, individuals with disabilities can have equally positive outcomes, and the disability should have very limited impact on the individual's ability to adhere to post-transplant care, if they receive adequate support.[21] These individuals must be afforded equal access to transplantation services in accordance with federal civil rights laws, and the value of their lives are no less than those individuals who are without disabilities. This inequity exists despite numerous federal and state prohibitions on discrimination on the basis of race, color, national origin, and disability.

As the discussion on inequity for racial and ethnic minorities and people with disabilities demonstrates, there remain outstanding issues, including those that lead to inequities in transplantation. It is imperative that racial and ethnic minorities as well as those with disabilities are afforded the same opportunities to receive a life-

[15] Organ Donation and African Americans—The Office of Minority Health (*hhs.gov*). Accessed June 10, 2021.

[16] *https://www.cdc.gov/socialdeterminants/index.htm.*

[17] Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations | Health Disparities | JAMA Network Open | JAMA Network. January 14, 2021.

[18] Reassess Inclusion of Race in Estimated Blomerular Filtration Rate (eGFR) Equation. *https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/.*

[19] Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. *https://ncd.gov/publications/2019/bioethics-report-series.*

[20] Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. *https://ncd.gov/publications/2019/bioethics-report-series.*

[21] Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series, National Council on Disability, September 25, 2019. *https://ncd.gov/publications/2019/bioethics-report-series.*

saving organ transplant as their non-disabled, white counterparts. Further, addressing these issues in transplantation will have intersectional impacts for individuals that belong to more than one group.

We acknowledge that this and other critical improvements cannot, and will not, be achieved only through revisions to the transplant CoPs, OPO CfCs alone, or the ESRD facility CfCs. Thus, we are asking the public for specific ideas on advancing equity within the organ transplantation ecosystem, as they pertain to changes to the health and safety standards for transplant programs and OPOs. Specifically, we are seeking public comments on the following questions:

1. Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?

2. Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights? Social determinants of health are those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes.[22] Obtaining consent for donation is vital to increasing the number of organs available for transplantation. However, studies have demonstrated that African Americans are half as likely as Whites to agree to donate a loved one's organs.[23] In addition, studies have shown a ''lower donation rate among racial/ethnic minorities, specifically including Blacks, Hispanics, and Asians''.[24] There are many factors that contribute to these differences, including medical mistrust and differing opinions on organ donation and transplantation. OPOs have a key role in educating the public on organ donation and reaching out to those in underserved populations to address concerns or misconceptions regarding organ donation. They must also obtain consent from families in underserved communities with cultural sensitivity, awareness, and empathy. In order to ensure that more organs are available for transplant to those in underserved populations that need them the most, we are therefore asking what role CMS can play to ensure that OPOs can better build trust and awareness in historically underserved populations and communities (including racial and ethnic minorities).

3. How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation? This would include ways that CMS can hold OPOs accountable for their outreach and communication to those underrepresented communities while maintaining cultural competency, such as awareness of various religious beliefs surrounding organ donation. Comments should include considerations of how to address issues pertaining to medical mistrust, disadvantageous social and economic factors, and the effects of systemic racism and discrimination on underserved populations.

4. How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?

5. What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?

6. What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?

B. Kidney Health and End-Stage Renal Disease Facilities

1. Background

On September 29, 2020, we published a final rule entitled, ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), hereinafter referred to as the Specialty Care Models final rule. Among other things, the Specialty Care Models final rule finalized the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, which is designed to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to beneficiaries with ESRD. As described in the Specialty Care Models final rule, both of these modalities have support among health care providers and patients as preferable alternatives to in-center hemodialysis, but utilization has been less than in other developed nations (85 FR 61263).

Interventions that can slow progression of CKD include early identification of the disease, controlling blood pressure, controlling blood glucose, reducing albuminuria, eating a healthy diet, and maintaining a healthy lifestyle. We would like to learn what patient, clinician and system factors would help patients maintain or improve their health. We are also interested in knowing various approaches to identifying those at risk of developing CKD and ways to improve CKD detection rates. Additionally, we are interested in actions that aim to close health equity gaps in CKD detection, education and care and would like to learn about these and other health equity concerns among this patient population. Feedback on ways to increase interventions and awareness of health inequities may further improve patient centered ESRD health and safety CfCs, or may impact future CfCs for health equity. To that end, we request the public's help in answering the following questions:

1. How can CMS increase the use of nutritional, lifestyle, and medical management interventions to improve health care and decrease the progression of CKD?

2. What are the barriers to access for routine and preventive health care? To what extent does low health literacy and cultural and attitudinal beliefs impact access to care?

3. How can we better educate patients about behaviors (such as diet and exercise) that may affect CKD progression? What is working? What is not working? How can pre-dialysis education and prevention programs be improved?

4. How can we increase awareness of known racial, ethnic, gender, sexual orientation, and economic disparities in care for CKD?

5. How can primary care providers (PCPs) better support their patients in prevention and slowing progression of CKD? What can be done to increase screening of at-risk individuals and how can we ensure that PCPs provide timely referrals to nephrologists for individuals with poor or declining kidney function?

6. How can we improve health literacy among the general population, and individuals at higher risk about the prevention of CKD?

7. How can individuals facing complete kidney failure be informed and empowered to make choices about their care?

Transition to dialysis is too often a surprise, with as many as half of all new dialysis patients having never previously seen a nephrologist. We are interested in learning about how patients with CKD receive appropriate information on kidney health and modality options, including transplantation. Transitional care units are specialized programs offered by dialysis facilities that provide medical and psychosocial support during the peridialysis initiation period. The goal of these units is to improve awareness of all aspects of renal replacement therapy, including modalities, access, transplantation options, and nutritional and psychosocial aspects of the disease enabling patients to make informed decisions regarding their care. In addition, we would like more information on transitional units.

[22] Social Determinants of Health. Know What Affects Health. *https://www.cdc.gov/socialdeterminants/index.htm.*

[23] Goldberg, David, et al. Rejecting Bias: The case against race adjustment for OPO performance in communities of Color. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1831604/.* March 17, 2020.

[24] Siminoff, Laura, et al. Racial Disparities in Preferences and Perceptions Regarding Organ Donation. *https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15865.* September 21, 2006.

1. To improve long-term outcomes and quality of life, how can we support and promote transplantation prior to the need for dialysis (preemptive transplantation)?
2. For people beginning dialysis, how can CMS support a safe transition?
3. Are there concerns regarding the location or quality of care of the transitional care units?
4. How can these care transitions be equitably provided?

2. Home Dialysis

Under the current CfCs at 42 CFR 494.70(a)(7) the patient has the right to be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. Once they are stable on a specific modality, patients are infrequently aware that they are able to change modalities. In 2018, 72 percent of Black or African-American patients with ERSD received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that more White ESRD patients receive home dialysis than Black or African-American patients.[25] We would like information on the following questions:

1. What are patient barriers to dialysis modality choice? How can we overcome barriers to ensure patients understand their options and have the freedom to choose their treatment modality?
2. What are reasons for differing rates of home dialysis by race/ethnicity? How can we address any barriers in access to home dialysis to improve equity in access to home dialysis?
3. With regard to home dialysis, how can CMS ensure adequate safety standards such as appropriate infection control behaviors and techniques are enforced?
4. What can CMS do to increase availability and use of home support resources with regard to home dialysis as described in 42 CFR 494.100(a)((3)(iv)? Given the increase in home dialysis patients, is there a need to revise the current standards § 494.100, including but not limited to updating and revising training and care delivery requirements?
5. If more patients choose home dialysis, would there be systems and infrastructure in place to support this? Were more patients to choose home dialysis, what other supports, systems or infrastructure might be necessary?
6. To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection of and uptake of home dialysis as a modality? What are best practices in this area that would facilitate the delivery of safe and quality care?

3. Dialysis in Alternative Settings

a. Dialysis in Nursing Homes

There are several means by which dialysis services are currently provided to nursing home residents, including transporting a resident to a local dialysis facility, dialysis facilities located on the campus of a nursing home, qualified dialysis facility staff that comes to the nursing home, or trained nursing home staff that provides dialysis services. The population of dialysis patients who receive home dialysis care in nursing homes is small, but it is an especially high-risk population. Our internal analysis shows that the percentage of dialysis patients in a nursing home was approximately 17 percent (89,568) in 2018. Most dialysis facilities (93 percent) had at least one patient in a nursing home. Only a small fraction of these dialysis patients (<1 percent) appear to receive dialysis treatment in a nursing home setting annually. There are no limitations to the number of agreements a dialysis facility may have with nursing homes to provide home dialysis services. We have received reports where some nursing homes are over 100 miles away or across the state from the dialysis facility where the agreement to provide care exists. We are concerned that this poses concerns for oversight of the dialysis care and services in providing timely support services and patient assessments as well as necessary equipment & supplies. We must ensure that these patients are receiving safe and appropriate dialysis care. We seek answers to the following questions:

1. Should dialysis facilities have geographical limitations for distance between the certified dialysis facility and nursing homes where they provide home dialysis services? Would health and safety issues be mitigated if there were some type of geographical limitation? Are there areas where placing a geographical limitation could create access issues where there are no dialysis facilities near the nursing home? If so, why, and how could these issues be mitigated?
2. Should there be a limit to the number of agreements that a given dialysis facility can have to provide home dialysis services in nursing homes? Why or why not?
3. Should CMS enhance protections for dialysis in institutional settings in the CfCs, such as including a written agreement to outline the roles and responsibilities of the dialysis facility and nursing home when home dialysis services are provided to residents, have protections for residents incapable of self-care, including clarifying staff roles, responsibilities, safety, and supervision when the home dialysis services are not administered by the dialysis facility staff?

b. Alternative Types of Dialysis Treatment Facilities Including Mobile Dialysis

We are also seeking information on the potential certification and safe use of alternate types of facilities that can provide dialysis treatments outside of an individual's home or resident care facility, such as mobile units. Mobile dialysis units are not currently defined or certified by CMS.

1. Should the use of mobile dialysis be limited to emergency circumstances and enrollment as a Special Purpose Renal Dialysis Facility?
2. How can mobile dialysis be used? Should these units be independently certified or used as an extension to an existing facility if approved outside of emergency circumstances?
3. What are the oversight considerations of these mobile dialysis units if units do not have a brick and mortar location and are moving among various locations? If used outside of an emergency circumstance, should there be geographical limitations?
4. Should mobile units have separate/different physical environment requirements compared to a brick and mortar building?
5. What health and safety standards are necessary to ensure a safe physical environment in mobile units?
6. What are the concerns related to equipment handling and maintenance related to mobile units that are different from brick and mortar facilities?
7. How can CMS ensure appropriate staffing roles, responsibilities and oversight of patient's dialysis care and needs by interdisciplinary team members for mobile units? Would these units require different staffing mix or requirements than a stationary dialysis unit?
8. What other alternative types of dialysis treatment facilities should we consider?
9. What should be the appropriate use of alternative types of facilities, such as only for emergency situations?
10. How should CMS certify these alternative types of facilities?
11. Are these facilities able to meet current patient safety and equipment standards?
12. Given the importance of water quality for dialysis, how do we ensure safe water standards with facilities that do not have water treatment centers?
13. Do patients in Medicare Advantage plans have a choice whether or not to dialyze at one of these alternative facilities?
14. What kind of emergency plans would be appropriate for mobile units or other alternative settings?

c. Alternate Models of Care

We have received significant public interest and questions related to staff-assisted home dialysis, which is not a separately paid service, but is covered as part of the ESRD Prospective Payment System (PPS) bundled

[25] National Kidney Foundation. *https://www.kidney.org/news/newsroom/fsindex.* Accessed 11/15/2021.

payment. A dialysis facility may provide qualified staff members in the patient's home to assist them in performing their home dialysis treatments as long as the facility provides Home Training and Support services specified at (42 CFR 494.100(a)). The dialysis staff member functions in the role of the patient's caregiver and monitors the patient throughout the dialysis treatment. The dialysis facility maintains overall responsibility and oversight to ensure appropriate, qualified staff are assigned and trained and provides supervision of staff members as indicated. Employees performing staff assisted dialysis must meet the personnel qualification requirements at § 494.140. In addition, staff who provide staff-assisted home dialysis must meet any state scope of practice requirements and any other applicable state laws.

1. Should there be two sets of guidelines for staff-assisted home dialysis in residential homes and staff-assisted home dialysis in alternative settings; and if so, how should they differ?

2. What factors should be taken into consideration for establishing different guidelines?

C. Organ Procurement Organizations (OPOs)

1. OPO Assessment and Recertification and Competition

CMS recently revised the OPO performance metrics that will be implemented in the 2022 through 2026 recertification cycle (85 FR 77898). The changes were made to improve upon the current measures by using objective and reliable data that will incentivize OPOs to ensure all viable organs are transplanted, apply greater oversight to OPOs while driving higher performance, and as a result, save more lives. We implemented a tiered approach based on thresholds set prior to the performance period using a previous year's data, while also using a median rate for assessing OPOs. We will assign OPOs to tiers based on whether performance exceeded these thresholds. OPOs assigned to tier 1 are those OPOs with performance rates for both measures (donation rate and transplantation rate) that are not statistically below the lowest rates among the highest 25 percent of all OPOs. These OPOs are automatically recertified after successfully complying with the remaining Conditions for Coverage and can compete for other open areas (provided they meet all other requirements). OPOs assigned to tier 2 are those whose performance for both measures statistically meet or exceed the median rates for all OPOs but do not meet tier 1 requirements for both measures. The designated service areas (DSAs) for these OPOs will be opened for competition and these OPOs must compete to retain their DSA. Additionally, these OPOs can compete for other open areas (provided they meet all other requirements). OPOs assigned to tier 3 are OPOs whose performance rate for either measure is statistically below the respective median rate for all OPOs. These OPOs will be decertified and their areas opened for competition. If no OPO applies to compete for the area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area.

Although we believe our new assessment approach will incentivize OPO performance, resulting in clustering of rates close to the highest performers, eventually the margin between the top 25 percent and the median will begin to narrow. Once OPO performance on the outcome measures reaches this level, CMS will need to consider other factors that differentiate highly functioning OPOs from those that are less highly functioning. We are interested in exploring what factors CMS may consider in this regard and ways to measure performance in these areas.

1. Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO?

2. What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes?

3. Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation, and how should this be measured?

4. Are there ways to scale, or rate, performance of other (new) factors that CMS may consider in assessing OPO performance?

We are interested in ensuring our processes for the assessment of OPO performance are continually evolving and reflective of current industry standards and technological capabilities while providing the necessary incentives and rewards based on the dynamics within the OPO community and organ donation–transplantation ecosystem. We seek public comment to facilitate fair and equitable oversight of OPOs while ensuring we continually drive performance to ensure more lifesaving organs are available to individuals on transplant waitlists.

In addition, we are assessing ways that we can improve the current recertification and competition processes. We ask the public for specific information on how these CfCs can be modified to ensure that OPOs are recertified and competition occurs in such a manner that would allow for the seamless determination of recertification for an OPO at the end of the recertification cycle, or the assignment of a new OPO to an open DSA. Therefore, we are asking the following questions:

1. Are there additional factors or criteria that CMS should consider when determining which OPO should be selected for an open service area?

2. Should CMS consider other performance measures when selecting an OPO for an open DSA? Such measures could include performance on converting donor referrals to potential donors or the number of ''zero organ donors'' or the number of organ discards (see section C.5. for additional information), reflected in the discard rate, or improvement, over time.

3. Should CMS continue to consider the contiguity of an OPO to an open DSA?

4. What are the challenges that an OPO would face if taking over an open DSA? Are there specific disincentives within the current regulatory requirements to taking over an open DSA?

5. Are the current CMS requirements for a governing body and advisory board adequate for OPO governance? Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations? What structure best serves accountability, and efficient and effective organ procurement?

6. What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?

7. Any other helpful information that could inform potential changes to the current recertification and competition processes.

2. Organ Transport and Tracking

While many organs are transported to recipients with organ recovery teams, some organs need to be transported independently via common or commercial carrier in order to reach the intended recipient at a transplant hospital. A recent media report of organs being lost or delayed in transport, mainly through commercial airlines, have raised concern regarding the risks associated with unaccompanied organ transport. The tracking of these organs during transport is often subpar, using outdated methods.[26] Lost or delayed organs lead to the unnecessary discards and missed opportunities for those waiting for a lifesaving organ transplant. Ensuring

[26] Kaiser Health News. How Lifesaving Organs for Transplant Go Missing In Transit. *https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/.*

that organs arrive at the transplant hospital in a timely manner is of the utmost importance.

Recovered organs that are ready for transplant must first be preserved, packed, stored, and transported to the transplant hospital. The OPTN has specific policies for the transport of organs including requirements for packaging, labeling, shipping and storage of organs and vessels.[27] Such processes are extremely important in reducing errors and help ensure that donated organs are matched correctly and efficiently with the identified recipient. However, there are currently no specific requirements, such as real-time tracking, for OPOs that utilize organ transport via common or commercial carriers. An OPO may choose a transport and tracking method that it believes is most appropriate based on the particular circumstances; however, these choices sometimes have resulted in lost opportunities for transplantation. Therefore, we are asking the public the following questions:

1. Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program?
2. How can the tracking of organs during transport be improved? Should specific requirements be implemented to facilitate real-time tracking of organs? What additional factors should be considered to ensure organs undergoing real-time tracking arrive at their intended destination timely?
3. Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?
4. Are there other ways HHS can incentivize creation or use of additional mechanisms to reduce the likelihood organs will be lost or damaged after procurement but before transplantation?

3. Donor Referral Process

Under the OPO CfCs, OPOs are required to have agreements with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its DSA that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regards to organ donation. Hence, the first step in the organ donation process is for the donor hospital to timely notify the appropriate OPO of all deaths and imminent deaths in the hospital (42 CFR 482.45(a)(1)).

The notification and timing of referrals to OPOs is critical to ensure the identification of potential donors and availability of organs for transplantation. The failure to make this referral is a significant reason a potential donor who is medically suitable for organ donation does not become a donor.[28] This should be done as soon as possible to give the OPO time to evaluate the person to determine if he or she is a potential donor and, if so, obtain consent and begin managing the potential donor's care to maximize the chances of organ recovery. CMS does not define ''imminent death'' or ''timely referral'' but requires that these terms be defined in the agreement between the OPO and the hospital (42 CFR 486.322(a)).

Some members of the OPO community have advocated for invasive mechanical ventilation to be a clinical trigger that would require a referral to the OPO. Most of the potential donors will be on invasive mechanical ventilation. A person being assessed for brain death criteria will be on invasive mechanical ventilation due to their inability to breathe. In addition, potential donation after cardiac death (DCD) donors will most likely be on invasive mechanical ventilation prior to any decision to discontinue life support due to devastating injuries. If the decision has been made to withdraw life support, it is critical that the OPO know of these individuals before invasive mechanical ventilation is withdrawn to give the OPO time to evaluate the potential donor and obtain consent for donation.

Since CMS does not specifically define ''imminent death'' or ''timely referral,'' it has been suggested that this may result in variable performance in this requirement due to lack of any national standards. Some have indicated that reporting timelines vary from hospital to hospital and the demands of patient care can cause unintended delays in this process. One recommendation to reduce the variation in timeliness of reporting is automating real time donor referral thereby removing the subjective element of identifying potential organ donors and reducing the variation in timeliness of reporting.[29]

CMS is interested in learning more about the capabilities hospitals and OPOs may currently have for transmitting and receiving automated referrals. We are particularly interested in the experience of OPOs and donor hospitals that have successfully piloted or implemented the use of automated donor referral systems.

1. What specific patient events, clinical triggers, or subsets of clinical information are used to send notifications to OPOs?
2. Should a patient being placed on invasive mechanical ventilation, except for a planned medical or surgical procedure, be one of the triggers for a referral to the OPO? Should these triggers exclude certain patient populations (for example, should the reason for placement on invasive mechanical ventilation be considered for a potential exclusion from the trigger or should the trigger be automatic for all patients)?
3. Could the referral to the OPO be made by someone other than a doctor or nurse, such as a respiratory therapist?
4. What is the minimum information necessary to facilitate notification to the OPO and what additional clinical information, if any, may also be beneficial?
5. Do donor hospitals that are making electronic referrals leverage the existing admission, discharge, and transfer elements in electronic medical record systems to transfer information to OPOs, and if so, how is this information utilized? We are interested to learn if there is any standardization in the industry for transmitting and receiving this information as well as any common data sets that are currently collected.
6. Are there aspects to donor referral processes or how referrals are made that help to engender trust or potentially worsen mistrust among underserved populations, including racial, ethnic, and religious minorities?
7. Are there clinical decision support protocols or algorithms that can reduce the cognitive burden and thereby assist clinicians in identifying potential donor candidates? If so, are there concerns regarding potential bias in clinical decision support protocols or algorithms that can introduce or exacerbate inequities, and how can those biases be addressed?
8. Are there opportunities for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate key information transfer between the hospital and OPO?

We welcome comments from staff in the electronic medical record (EMR) and EHR industries on ways to automate reporting requirements in a cost-effective manner, as well as how such an approach may be implemented on a national scale. We would like to better understand what technical requirements are necessary and how any changes can be duplicated across hospital EHR systems nationally with minimal burden to the industry.

Finally, we are also interested in challenges OPOs may have in gaining access to donor hospital EHRs for organ procurement activities once referrals are received. Since OPOs have agreements with a large number of hospitals within its DSA, and timely access to potential

[27] UNOS. *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.*

[28] Dominguez-Gil, B, et al. The critical pathway for deceased donation: Reportable uniformity in the approach to deceased donation. Transplant International. 24 (2011): 373–378.

[29] *https://unos.org/news/media-resources/5-ways/automate-real-time-donor-referral/.*

donor information facilitates donation, we are interested to learn of any potential barriers to accessing information via EMRs and how CMS may facilitate better access to information through its requirements.

4. Organ Recovery Facilities

Organs from deceased donors are nearly always recovered in donor hospitals. However, OPOs have pointed out that there can be numerous challenges in recovering organs in this setting, and the overall process of organ procurement is often time consuming and logistically challenging. Unless an organ(s) is going to be recovered and transplanted in the same hospital, transplant surgeons must often travel to the donor hospital to surgically recover the organ(s). This procedure is complex and time-sensitive, especially for extra-renal organs. Depending upon the organs intended to be procured from the donor, multiple teams of recovery surgeons may need to travel to the donor hospital. Due to competing priorities in a donor hospital, donors often receive lower priority for operating room time and may experience delays in special tests, such as echocardiograms, biopsies, or cardiac catheterizations. These delays may result in increased costs for procurement of the organ(s) or in not being able to procure organs from a donor due to medical complications during a protracted timeframe while on mechanical ventilation. Additionally, OPOs are responsible for all costs for donor evaluation and medical management once declaration of death and consent for donation occurs. These costs are reimbursed by transplant hospitals, other OPOs and Medicare for Medicare beneficiaries. Donor evaluation and management tasks can include a range of laboratory, imaging, and diagnostic procedures that OPOs report they may complete at a fraction of the cost they pay for these services at donor hospitals.

CMS is aware of at least 10 OPOs that have developed dedicated facilities to recover organs from donors. These facilities are independent of the donor hospital location from which the donor was referred. These facilities do not provide routine medical care but they may provide a range of services to facilitate donor evaluation and management and organ recovery. In addition, the only potential donors who would be transferred to these facilities would have been declared dead by brain death criteria and the OPO would have already received appropriate consent for organ donation.

There are few published studies evaluating the effectiveness of organ recovery facilities.[30] [31] While these studies highlight the potential benefits, the practice has not been universally adopted by OPOs and growth of these facilities is relatively slow. Federal oversight of tissue collection is provided under the Public Health Service Act (PHS Act) and FDA regulations on human cells, tissue, and cellular and tissue-based products, or HCT/Ps (21 CFR part 1271). However, organ recovery facilities are not specifically addressed in the OPO CfCs and Medicare does not currently compensate OPOs for some activities associated with operation of these facilities, such as transportation of the donor to the OPO's facility.

CMS is interested in learning about the potential benefits and concerns for the use of organ recovery facilities in greater detail and determining whether it would be appropriate or beneficial to establish specific health and safety requirements that would apply to these facilities. Specifically, CMS would like to explore aspects related to the effectiveness, operations, donor families, and impacts to other stakeholders. Since this is an emerging model of practice, there is limited information currently available. We are requesting public comments that provide evidence-based conclusions, such as additional peer-reviewed literature, that we should consider to inform any future rulemaking. Additionally, we are requesting that commenters share any experiences in operating or interacting with staff from OPOs with organ recovery facilities. Finally, we are particularly interested in the experience of donor families and patient advocates and seek comments from these individuals and any organizations representing donor families. While much of the information reviewed by CMS highlights the benefits of organ recovery facilities, we are also interested in learning of specific risks or adverse outcomes associated with these facilities.

Effectiveness:

1. What benefits and risks may OPOs experience in regards to cost-effectiveness, organ yield, and organ quality from operating an organ recovery facility?

2. Are there particular benefits to securing organs from marginal or extended criteria donors while at an organ recovery facility?

3. Are OPOs able to achieve better placement of these organs relative to organs recovered at donor hospitals?

Operations:

1. What medical evaluation diagnostic procedures are commonly performed in these organ recovery facilities?

2. What special equipment needs, such as laboratory and imaging, are necessary?

3. What supplies, such as pharmaceuticals, should be considered?

4. Which professional staff are needed and what are their qualifications for operating an organ recovery facility?

5. What specific risks may be associated with operating a facility for the recovery of organs outside a donor hospital?

6. What state or local requirements apply to the currently existing facilities, including health and safety and fire?

Impacts on other stakeholders:

1. Are there any negative impacts or disincentives to donor hospitals or transplant centers?

2. How does having an organ recovery facility impact tissue recovery and the relationships with tissue banks in the DSA? [32]

Impacts on Donor Families:

1. Were you satisfied with the request for donation discussion by the OPO representative and how did this affection your decision for donation?

2. How does organ donation at organ recovery facilities impact donor families?

3. Does the process for transfer to organ recovery facility make the process more difficult for the donor family if the facility is remote from the donor hospital? How are distance challenges addressed to ensure family involvement in the donation process?

4. What are the reasons why donor families reject transfer from the donor hospital to an organ recovery facility? If you have personal experience with this issue, what reasons led you and your family to the decision to reject transfer?

5. Have there been any studies specifically focused on evaluating donor family satisfaction when utilizing an OPO operated organ recovery facility versus traditional organ recovery in donor hospitals?

[30] Doyle, M., et al. Organ Donor Recovery Performed at an OPO-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield.'' Journal of the American College of Surgeons, April 2016 (Vol. 222, Issue 4, pp. 591–600).

[31] Marslais, P., et al. The First 2 Years of Activity of a Specialized Organ Procurement Center: Report of an Innovative Approach to Improve Organ Donation. American Journal of Transplantation 2017; 17: 1613–1619.

[32] Establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under section 361 of the PHS Act are commonly referred to as ''tissue establishments'' within FDA terminology but are commonly referred to as ''tissue banks'' within the CMS regulations.

6. What aspects do donor families find particularly beneficial and which are challenging for them?

5. ''Zero Organ Donors'' and Discarded Organs

In response to our recent rulemaking (85 FR 77898), some commenters raised concerns about the new definition of ''donor,'' which excludes ''zero organ donors.'' While there is no commonly accepted definition of a ''zero organ donor,'' it is generally interpreted to mean a situation where the donation process was initiated but no organ was transplanted. Our internal analysis during this rulemaking indicated that in 2018, there were 1,255 organs procured from 593 ''zero organ donors,'' but never transplanted. Commenters claimed that excluding ''zero organ donors'' from the donation rate may discourage OPOs from pursuing extended criteria or marginal and complex donors, which is inconsistent with our goal of increasing organ donation.

More recent data indicates that the number of ''zero organ donors'' is increasing significantly. A recent internal analysis indicates that ''zero organ donors'' increased by 31 percent between 2019 and 2020 (746 to 977) and 76 percent from 2017 through 2020 (555 to 977). In 2017, these donors represented 5 percent (555) of all deceased donors and 25 percent (1,215) of all discarded organs. In 2020, ''zero organ donors'' increased to 8 percent (977) of all deceased donors and 31 percent (2,051) of all discarded organs. During the past decade, the rate of ''zero organ donors'' ranged from a low of 5.3 percent to a high of 8.5 percent in 2020 with an average annual rate of 6.0 percent.

In addition to ''zero organ donors'' where no organs from a donor are transplanted, there are many donors that have organs recovered and transplanted while other organs from the same donor are discarded. The number of all organ discards (including organs from zero organ donors) has increased steadily over the past 15 years. There were 3,553 discarded organs (including kidney, liver, heart, pancreas, lung, and intestine) in 2005, 3,878 discarded organs in 2010 (increase of 9.1 percent), 4,439 discarded organs in 2015 (increase of 14.5 percent), and 6,512 discarded organs in 2020 (increase of 31.8 percent). Overall, there were a total of 71,335 discarded organs in the 16-year period inclusive of the years 2005 to 2020. The rate of organ discards increased from 10.5 percent to 13.4 percent during this same period highlighting the increased frequency of discarding organs. Historically, kidney discards represent the largest number of discarded organs accounting for 77.6 percent (5,051) of all organ discards in 2020 despite over 91,000 candidates registered on the waitlist for a kidney transplant.[33] The Scientific Registry of Transplant Recipients (SRTR) data indicate that many organs that are not recovered or are discarded are a result of failure to locate a recipient for the organs. Additionally, many of these organs have a disposition reason code of ''other'' despite a range of options for categorizing the organs.[34] While there may be many medically appropriate reasons for organ discards or non-recovery, such as infection, organ trauma, poor organ function and anatomical abnormalities, we are concerned with the increasing number of organs that go unused and are subsequently discarded. We are interested in ways to better understand and identify these issues and incentivize a reduction in these numbers through policy options.

The elimination of outcome measures for recertification of transplant programs was intended to eliminate provider disincentives for performing transplantations, improve organ procurement for transplantation, and increase organ utilization through increased acceptance of organs that previously may have been declined. Since the change in the transplant program outcome measures was only implemented in 2019, we only have 1 year of data to assess at this time. However, data from 2020 demonstrates a continued increase in the number of ''zero organ donors'' and discarded organs suggesting the policy change may not be achieving the desired outcome indicating other factors may be impacting placement of organs. While we acknowledge the complexity that is involved in the placement of organs, we are seeking information on additional factors to consider and methods that may facilitate improvements in this area through OPO and transplant center collaboration.

Recent research indicates that factors beyond organ quality impact acceptance behavior by transplant centers. These factors may include donor characteristics, geographic area, characteristics of the organ donation-transplantation environment within a DSA, and timing such as interruptions caused by weekends and holidays.[35] This often results in missed opportunities for many patients on the waitlist and frequently leads to organ discards. Some of these organs are initially rejected only to later be accepted at other centers and successfully transplanted in patients lower on the waitlist. Recent studies have found that many kidneys that were discarded had similar or better quality characteristics to those that had been successfully transplanted.[36] [37] Additionally, candidates for transplantation are frequently not aware of organs being declined on their behalf and may not be informed of the reason for the decline. Center-level organ acceptance practices eliminate a patient-centered approach to involvement in decision making on the advantages and disadvantages to organ acceptance versus continuation of existing care while remaining on a waitlist.[38] This may result in significant negative quality of life impacts for potential organ recipients, and even death, while waiting for a better organ after many potentially acceptable offers were declined on behalf of the patient. The net effect is the discard of lifesaving organs, frequently without potential recipient involvement in the decision-making process, while there is a shortage of organs for over 106,000 individuals.[39]

Given the impact from reducing the number of organ discards, CMS is interested in exploring policy options that may assist in this effort. We are seeking information that we can act upon to strengthen requirements as well

[33] OPTN National Data. Accessed 2/18/2021.

[34] SRTR/OPTN 2018 Annual Data Report; Deceased Organ Donors: *https://srtr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx.*

[35] Mohan S, Foley K, Chiles MC, Dube GK, Patzer RE, Pastan SO, Crew RJ, Cohen DJ, Ratner LE. The weekend effect alters the procurement and discard rates of deceased donor kidneys in the United States. Kidney Int. 2016 Jul; 90(1):157–63. doi: 10.1016/j.kint.2016.03.007. Epub 2016 May 12. PMID: 27182001; PMCID: PMC4912390.

[36] Aubert O, Reese PP, Audry B, Bouatou Y, Raynaud M, Viglietti D, Legendre C, Glotz D, Empana JP, Jouven X, Lefaucheur C, Jacqueline C. Loupy A. Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. JAMA Intern Med. 2019 Aug 26;179(10):1365–74. doi: 10.1001/jamainternmed.2019.2322. Epub ahead of print. PMID: 31449299; PMCID: PMC6714020.

[37] Mohan S, Chiles MC, Patzer RE, Pastan SO, Husain SA, Carpenter DJ, Dube GK, Crew RJ, Ratner LE, Cohen DJ. Factors leading to the discard of deceased donor kidneys in the United States. Kidney Int. 2018 Jul;94(1):187–198. doi: 10.1016/j.kint.2018.02.016. Epub 2018 May 5. PMID: 29735310; PMCID: PMC6015528.

[38] Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. JAMA Network Open. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312. Erratum in: JAMA Netw Open. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID: PMC6724162.

[39] Organ Procurement and Transplantation Network (OPTN) website. Accessed 10/27/2021.

as information where additional burden reduction may facilitate improvement. We are seeking input on areas where our policies may create additional burdens or conflict with policies of the OPTN. We are particularly interested in ways to facilitate better communication and collaboration between OPOs and transplant centers and how this information can be incorporated into our requirements.

1. How has the sharing of information on organ offer and acceptance data impacted practice, including information on root causes for failure to place organs as well as organs that were declined but later successfully transplanted at another center?

2. What is the impact to these types of information sharing in practice, and if they have been productive, how can CMS build requirements around OPO—transplant center collaboration to support best practices in reducing the number of organ discards?

3. Should this type of collaboration between OPOs and transplant programs be incorporated into quality assurance performance improvement (QAPI) requirements for OPOs and transplant centers?

There are many quality improvement tools and initiatives available to OPOs and transplant centers through the OPTN, and potentially within the industry itself that may foster improvements in reducing the number of ''zero organ donors'' and organ discards. OPOs and transplant programs that do not take full advantage of the resources available to improve performance may continue to unnecessarily waste these lifesaving organs.

Patient rights and patient-centered care are a vitally important aspect of organ donation and transplantation. Ensuring individuals have the information needed to make informed decisions about their care is essential and transparency is an important component of this process. We believe that patients and their families should have increased awareness of practices at OPOs and transplant centers. OPOs that have a high discard rate and transplant centers that have a high rate of declining organs are a concern in that many potentially life-savings organs are wasted and patients are at greater risk for dying while waiting for a transplant.

1. We are interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes.

2. We are also interested in ways in which it may be possible to determine an ''acceptable'' baseline rate of organ discards based on medically disqualifying factors and how this should be assessed.

6. Donation After Cardiac Death (DCD)

In the May 31, 2006 final rule entitled, ''Conditions for Coverage for Organ Procurement Organizations (OPOs)'' (71 FR 30982), we noted that commenters expressed concern that we did not include specific requirements related to Donation after Cardiac Death (DCD) (71 FR 30985). In this rulemaking, our intention was not to avoid addressing the issue of DCD, nor did we specifically encourage OPOs to recover organs from cardiac death donors. Rather, we stated that we believed DCD donation was addressed in three separate sections of the CFCs, specifically 42 CFR 486.322, Relationships with hospitals, critical access hospitals, and tissue banks; § 486.324, Administration and governing body; and § 486.344, Evaluation and management of potential donors and organ replacement and recovery. Therefore, we finalized the requirements to facilitate our oversight of donation after cardiac death and not disadvantage OPOs that did not pursue these donors. We indicated that we understood donation after cardiac death was an evolving practice and was not yet accepted in every area of the country. Some donor hospitals were reluctant to permit donation after cardiac death in their facilities and some transplant surgeons were unwilling to transplant organs from such donors into their patients. Thus, some OPOs were hesitant to advocate donation after cardiac death in their service areas.

CMS is interested in better understanding both the successes and the challenges that OPOs face in implementing DCD organ donation. We are interested in learning whether and to what extent the clinical, scientific, and general environment for DCD donation has changed in recent years and if commenters have specific recommendations in regards to policy options related to DCD donation that may be beneficial.

1. What has contributed to the recent rapid increase in DCD organ donation?

2. What challenges do OPOs face from stakeholders regarding DCD donation and how have some OPOs overcome these challenges?

3. How are OPOs sharing information related to best practices in DCD donation and what barriers limit progress in this area?

4. Are there ways to better align the CfCs with the current environment for DCD donation?

5. How well do the CfCs complement requirements from the OPTN related to DCD donation?

6. Are there requirements that CMS should establish that may facilitate greater acceptance of DCD donation while ensuring patient rights and protections?

7. OPO Tissue Banking Activity and Relationships With Other Tissue Banking Organizations

CMS is interested in exploring the relationship between hospitals, OPOs, and tissue banks and how these relationships may have evolved over time, particularly since publication of the OPO final rule in 2006. Currently, hospitals are required to have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, to assure that all usable tissues and eyes are obtained from potential donors provided these activities do not interfere with organ donation.

Additionally, regulations at § 486.322(c) require that OPOs have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. These regulations include cooperating on a range of potential activities to ensure that all usable tissues are obtained from potential donors. These activities may include screening and referrals; obtaining informed consent; managing tissue retrieval, processing, preservation, storage, and distribution; and providing designated requestor training. CMS does not regulate tissue banks, also known as tissue establishments. Instead, oversight over such establishments is primarily provided by FDA.

In drafting requirements for OPOs with respect to such agreements with tissue banks, in 2006, CMS considered three factors including (1) an OPO's role as the agency that receives most referrals of deaths and imminent deaths from the hospitals in its service area (unless referrals are screened by a third-party designated by the OPO); (2) the need to show sensitivity toward the circumstances of potential organ and tissue donor families (such as ensuring that potential donor families are not approached by more than one agency unnecessarily); and (3) the statutory requirement that an OPO have arrangements to cooperate with tissue banks to assure that all useable tissues are obtained. The CfCs were intended to ensure OPOs maintain a collaborative relationship with tissue banks in their area but OPOs are only required to have agreements with those tissue banks that have agreements with hospitals in their DSA.

We noted in our 2006 final rule ''Medicare and Medicaid Programs;

Conditions for Coverage for Organ Procurement Organizations (OPOs)'' (71 FR 31007), that many OPOs were beginning to establish tissue banking services. We seek input on the changes that have occurred since then to better understand how this service has evolved and if changes to the existing requirements are necessary.

1. To what level have OPOs developed their own tissue banks and is this currently standard practice across OPOs?
2. How has the increase in OPOs participating in tissue banking impacted the collection of useable tissues from donors?
3. Are there areas for improvement in the relationship between OPOs, hospitals, and tissue banks that would facilitate increasing the collection of useable tissue?
4. For OPOs that do have active tissue banks, how does this service impact or intersect with the OPOs primary mission of recovering and distributing organs?

8. Organs for Research

While the primary mission of an OPO is to maximize the number of viable organs it recovers for transplantation, OPOs also serve a role in providing organs to the research community. Currently, OPOs are assessed on both these aspects of organ donation as a requirement of the outcome measures at § 486.318. During recent rulemaking revising these measures (85 FR 77898), CMS eliminated the assessment of organs for research focusing the measures on the primary mission of OPOs in providing organs for transplantation. This change is scheduled to be implemented during the next OPO certification period beginning in 2022. The one exception to this change was the inclusion of pancreata procured for islet cell transplantation or research that was included in the outcome measures in order to comply with the Pancreatic Islet Cell Transplantation Act of 2004. While this recent rulemaking accomplished our goal of developing more transparent, reliable, and objective outcome measures that will drive higher performance, it also leaves some areas that CMS may consider in future rulemaking. Specifically, CMS is interested in exploring the need for continued support for obtaining organs for research as well as possible alternative approaches to address the requirements of the Pancreatic Islet Cell Transplantation Act. Additionally, we are seeking information on approaches that align with our efforts to have transparent, reliable, and easily verifiable information while minimizing burdens associated with any potential future changes.

Providing organs for research is an important aspect for assisting researchers in discovering new treatments for debilitating and fatal diseases. The Department of Health & Human Services defines research at 45 CFR 46.102(l). For our purpose of assessing OPO performance, we consider three categories of organs including: organs transplanted into patients with no research interventions (conventional transplants); organs that have had a research intervention that are transplanted into patients; and organs used exclusively for research purposes. In recent rulemaking (85 FR 77902), we indicated the transplant and research communities commonly described the transplantation of organs into humans using research protocols (for example, deceased donor intervention research) as both transplants and research. Generally, such research involves the transplantation of organs into transplant candidates that is generally considered clinical care while simultaneously qualifying as human subject research. Therefore, in establishing the new OPO performance measures, we consider organs used for research as applying to organs procured and used only for research purposes whereas organs transplanted into human subjects are counted as part of clinical care and included in the outcome measures. For example, in regards to assessing OPO performance in providing organs for research purposes as relating to organs that have been manipulated for research purposes but are not transplanted into a human recipient. This interpretation, used only for assessing OPOs on performance outcome measures, provides a level of demarcation for counting organs transplanted into human subjects (including those as part of a research protocol) versus those that are utilized strictly for research purposes, and aligns with our assessment of an OPO's primary mission with data that is independently verifiable. As previously noted, pancreata procured for research are also counted in the performance measures based on statutory requirement.

Given the importance of research to continued innovation in transplant medicine, CMS is interested in exploring the issue of incentivizing the placement of organs with researchers without detracting from the OPOs primary mission of providing organs for transplantation.

1. We are interested to know if there are currently sufficient incentives to provide organs for research absent a metric or process measure for this purpose. If an incentive is needed in this area, how should OPOs be assessed on this aspect of its operations?
2. Data on organs submitted for research is self-reported by OPOs and there is currently no method to independently verify this information on a regular basis limiting utility in annual performance measures. Are there other methods CMS should consider that would be effective?
3. How can CMS implement an approach that both incentivizes OPOs and is not excessively burdensome through enforcement?
4. Given the decline in islet transplantation research, are there other methods CMS should consider to assess pancreata procured for islet transplantation and research that can be used for certification and recertification purposes?

9. Vascular Composite Allografts

The use of vascular composite allografts (VCAs) is an evolving area of practice that involves the transplantation of multiple tissue types that may include skin, bone, muscles, blood vessels, nerves, and connective tissue. It includes body structures such as a face, limb (for example, arms, hands, fingers, legs, toes), bone, soft tissue (for example, larynges and abdominal wall), and/or reproductive organs. According to data from the OPTN, there have been approximately 110 VCA transplantations in the United States. While VCA transplantations are relatively infrequent and the goals of surgery are restorative and life-enhancing, versus lifesaving, they can provide profound quality of life benefits for the recipient. FDA regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) under 21 CFR part 1271. Prior to 2014, VCAs were not explicitly excluded from the definition of HCT/Ps under FDA's regulations and therefore were subject to FDA oversight, while HRSA regulated vascularized human organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs, at regulations under 42 CFR part 121 (the ''OPTN final rule''). In enacting the National Organ Transplant Act (NOTA) in 1984, the Congress gave the Secretary the authority to expand the definition of organ in regulation. Prior to 2013, VCAs were not included in the definition of organ and the classification of VCAs as HCT/Ps previously excluded them from regulation by HRSA. However, in 2013 the Secretary changed the definition of ''organ'' in the OPTN final rule to include VCAs shifting oversight responsibilities to HRSA (78 FR 40033, July 3, 2013). By including VCAs within the OPTN final rule's definition of ''organs'', transplants involving VCA are subject to the requirements of the OPTN final rule and explicitly excluded from the definition of HCT/Ps under FDA

regulations. This change became effective on July 3, 2014. The rule established specific criteria for body parts to qualify as VCAs.

In establishing the regulatory requirements for the oversight of VCAs through the OPTN, HRSA requires the body part to have specific characteristics to be considered a VCA. The characteristics include a body part that is: (1) Vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; (2) containing multiple tissue types; (3) recovered from a human donor as an anatomical/structural unit; (4) transplanted into a human recipient as an anatomical/structural unit; (5) minimally manipulated (that is, processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement; (6) for homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor; (7) not combined with another article such as a device; (8) susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and (9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Despite the change in the definition of organ by HRSA, CMS has not made changes to its definition of ''organ'' in oversight of solid organ transplantation through the CoPs at 42 CFR part 482 subpart E. However, we are seeking comment on whether or not we should revise its definition of organ to correspond to that of HRSA. We seek comment on ways to support this evolving area of practice while providing necessary health and safety oversight for transplant recipients.

1. CMS would like to determine if it is equitable to count VCAs as organs for OPO performance measures. Would certain OPOs be disproportionately advantaged or disadvantaged from such a change?

2. Given the low volume of VCA transplantation, should CMS establish specific survey and certification requirements for centers that transplant VCAs? If so, what health and safety aspects specific to VCA transplantation should be considered?

D. Nephrology Joint Ventures

The Medicare Payment Advisory Commission (MedPAC) has stated that many dialysis facilities are operated as a joint venture between a dialysis organization and physicians. Joint ventures allow participating partners to share in the management, profits, and losses of an entity.[40] MedPAC has noted concerns raised in the literature that joint ventures between dialysis organizations and physicians create financial incentives for participating physicians that could inappropriately influence decisions about patient.[41]

The health care industry is increasingly interested in identifying Medicare-enrolled providers and suppliers and their associations with other health care groups/organizations. CMS has been working on improving provider and supplier enrollment transparency by making data available for use by the healthcare community for research and to increase awareness in the provider and supplier community about enrollment information on file with CMS.[42] [43] Recently, CMS has received requests from the research community for data to study the business practices of dialysis facilities and the effect of joint ventures between nephrologists and dialysis facilities. These researchers have reported difficulty in performing the research due to the lack of information on these financial arrangements collected by CMS.

When a provider enrolls in Medicare, CMS collects information that is self-reported by the provider on individuals and organizations with 5 percent or greater direct or indirect ownership of, a partnership interest in, and/or managing control of the provider.[44] Institutional providers, such as dialysis facilities, may self-report whether their affiliation with a Chain Home Office is a joint-venture or partnership on their enrollment application.

In addition to efforts to increase transparency of Medicare enrollment information and in order to learn more about the impact of nephrology joint ventures for the purpose of these efforts, CMS is seeking information on the following questions:

1. Would it be helpful for CMS to collect information on joint venture arrangements as part of Medicare enrollment in order to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries?

2. Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients for improved transparency?

3. Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so, please describe how joint venture arrangements affect resource use, patient care, or choice of modality.

III. Collection of Information Requirements

This is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will consider all input as we develop future regulatory proposals or future subregulatory policy guidance.

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[40] March 2021 Report to the Congress: Medicare Payment Policy *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar18_medpac_entirereport_sec_rev_0518-pdf/* (cut and paste into browser, page 205).

[41] MedPAC 2021 report citing Berns, J.S., A. Glickman, and M.S. McCoy. 2018. Dialysis facility joint-venture ownership—Hidden conflicts of interest. New England Journal of Medicine 379, no. 14 (October 4): 1295–1297.

[42] Medicare Fee-For-Service Public Provider Enrollment. *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-fee-for-service-public-provider-enrollment.*

[43] Public Provider and Supplier Enrollment Files. *https://www.cms.gov/newsroom/fact-sheets/public-provider-and-supplier-enrollment-files.*

[44] Medicare Enrollment Application. Institutional Providers. *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855a.pdf.*

We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this RFI are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 4, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–26146 Filed 12–1–21; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No.: 21123–0243; RTID 0648–XY119]

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands; Proposed 2022 and 2023 Harvest Specifications for Groundfish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; harvest specifications and request for comments.

SUMMARY: NMFS proposes 2022 and 2023 harvest specifications, apportionments, and prohibited species catch allowances for the groundfish fisheries of the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to establish harvest limits for groundfish during the 2022 and 2023 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The 2022 harvest specifications supersede those previously set in the final 2021 and 2022 harvest specifications, and the 2023 harvest specifications will be superseded in early 2023 when the final 2023 and 2024 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the BSAI in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Comments must be received by January 3, 2022.

ADDRESSES: Submit your comments, identified by NOAA–NMFS–2020–0141, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter 211123–0243 in the Search box. Click on the ''Comment'' icon, complete the required fields and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record, and NMFS will post the comments for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD) for the Final EIS, and the annual Supplementary Information Reports (SIRs) to the Final EIS prepared for this action are available from *https://www.regulations.gov.* An updated 2022 SIR for the final 2022 and 2023 harvest specifications will be available from the same source. The final 2020 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the BSAI, dated November 2020, is available from the North Pacific Fishery Management Council (Council) at 605 West 4th Avenue, Suite 306, Anchorage, AK 99501–2252, phone 907–271–2809, or from the Council's website at *https://www.npfmc.org/.* The 2021 SAFE report for the BSAI will be available from the same source.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR part 679 implement the FMP and govern the groundfish fisheries in the BSAI. The Council prepared the FMP, and NMFS approved it, under the Magnuson-Stevens Act. General regulations governing U.S. fisheries also appear at 50 CFR part 600.

The FMP and its implementing regulations require that NMFS, after consultation with the Council, specify annually the total allowable catch (TAC) for each target species category. The sum of TACs for all groundfish species in the BSAI must be within the optimum yield (OY) range of 1.4 million to 2.0 million metric tons (mt) (see § 679.20(a)(1)(i)(A)). Section 679.20(c)(1) further requires that NMFS publish proposed harvest specifications in the **Federal Register** and solicit public comments on proposed annual TACs and apportionments thereof; prohibited species catch (PSC) allowances; prohibited species quota (PSQ) reserves established by § 679.21; seasonal allowances of pollock, Pacific cod, and Atka mackerel TAC; American Fisheries Act allocations; Amendment 80 allocations; Community Development Quota (CDQ) reserve amounts established by § 679.20(b)(1)(ii); and acceptable biological catch (ABC) surpluses and reserves for CDQ groups and Amendment 80 cooperatives for flathead sole, rock sole, and yellowfin sole. The proposed harvest specifications set forth in Tables 1 through 15 of this action satisfy these requirements.

Under § 679.20(c)(3), NMFS will publish the final 2022 and 2023 harvest specifications after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2021 meeting, (3) considering information presented in the 2022 SIR to the Final EIS that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**), and (4) considering information presented in the final 2021 SAFE report prepared for the 2022 and 2023 groundfish fisheries.

Other Actions Affecting or Potentially Affecting the 2022 and 2023 Harvest Specifications

State of Alaska Guideline Harvest Levels

For 2022 and 2023, the Board of Fisheries (BOF) for the State of Alaska (State) established the guideline harvest level (GHL) for vessels using pot gear in State waters in the Bering Sea subarea (BS). The 2021 BS GHL was set at 10 percent of the 2021 BS ABC (86 FR 11449, February 25, 2021). The State's pot gear BS GHL will increase one percent annually up to 15 percent of the BS ABC, if at least 90 percent of the GHL is harvested by November 15 of the preceding year. In 2021, 90 percent of the GHL was harvested by November 15, 2021, which triggers a 1 percent increase in the GHL in 2022 and results in a 2022 GHL of 11 percent of the proposed Pacific cod BS ABC. If at least 90 percent of the 2022 BS GHL is not harvested by November 15, 2022, then the 2023 BS GHL will remain at the same percent (11 percent) as the 2022 BS GHL. If 90 percent of the 2022 BS GHL is harvested by November 15, 2022, then the 2023 BS GHL will increase by 1 percent and the 2023 BS TAC will be set to account for the increased BS GHL. Also, for 2022 and 2023, the BOF established an additional GHL for vessels using jig gear in State waters in the BS equal to 45 mt of Pacific cod. The Council and its BSAI Groundfish Plan Team (Plan Team), Scientific and Statistical Committee (SSC), and Advisory Panel (AP) recommended that the sum of all State and Federal water Pacific cod removals from the BS not exceed the proposed ABC recommendations for Pacific cod in the BS. Accordingly, the Council recommended, and NMFS proposes, that the 2022 and 2023 Pacific cod TACs in the BS account for the State's GHLs for Pacific cod caught in State waters.

For 2022 and 2023, the BOF for the State established the GHL in State waters in the Aleutian Islands subarea (AI). In 2021, 90 percent of the GHL has been harvested by November 15, 2021, and results in a 2022 GHL of 39 percent of the proposed Pacific cod AI ABC. The AI GHL may not exceed 39 percent of the AI ABC or 15 million pounds (6,804 mt). In 2022, 39 percent of the proposed 2022 and 2023 AI ABC is 8,034 mt, which exceeds the AI GHL limit of 6,804 mt. The Council and its Plan Team, SSC, and AP recommended that the sum of all State and Federal water Pacific cod removals from the AI not exceed the proposed ABC recommendations for Pacific cod in the AI. Accordingly, the Council recommended, and NMFS proposes, that the 2022 and 2023 Pacific cod TACs in the AI account for the State's GHL of 6,804 mt for Pacific cod caught in State waters.

Proposed ABC and TAC Harvest Specifications

In October 2021, the Council's SSC, its AP, and the Council reviewed the most recent biological and harvest information on the condition of the BSAI groundfish stocks. The Plan Team compiled and presented this information in the final 2020 SAFE report for the BSAI groundfish fisheries, dated November 2020 (see **ADDRESSES**). The final 2021 SAFE report will be available from the same source.

The proposed 2022 and 2023 harvest specifications are based on the final 2022 harvest specifications published in February 2021 (86 FR 11449, February 25, 2021), which were set after consideration of the most recent 2020 SAFE report, and are based on the initial survey data that were presented at the September 2021 Plan Team meeting. The proposed 2022 and 2023 harvest specifications in this action are subject to change in the final harvest specifications to be published by NMFS following the Council's December 2021 meeting.

In November 2021, the Plan Team will update the 2020 SAFE report to include new information collected during 2021, such as NMFS stock surveys, revised stock assessments, and catch data. The Plan Team will compile this information and present the draft 2021 SAFE report at the December 2021 Council meeting. At that meeting, the SSC and the Council will review the 2021 SAFE report, and the Council will approve the 2021 SAFE report. The Council will consider information in the 2021 SAFE report, recommendations from the November 2021 Plan Team meeting and December 2021 SSC and AP meetings, public testimony, and relevant written comments in making its recommendations for the final 2022 and 2023 harvest specifications.

Potential Changes Between Proposed and Final Specifications

In previous years, the most significant changes (relative to the amount of assessed tonnage of fish) to the Overfishing Levels (OFLs) and ABCs from the proposed to the final harvest specifications have been based on the most recent NMFS stock surveys. These surveys provide updated estimates of stock biomass and spatial distribution, and inform changes to the models or the models' results used for producing stock assessments. Any changes to models used in stock assessments will be recommended by the Plan Team in November 2021, reviewed by the SSC in December 2021, and then included in the final 2021 SAFE report. Model changes can result in changes to final OFLs, ABCs, and TACs. The final 2021 SAFE report will include the most recent information, such as catch data.

The final harvest specification amounts for these stocks are not expected to vary greatly from these proposed harvest specification amounts. If the 2021 SAFE report indicates that the stock biomass trend is increasing for a species, then the final 2022 and 2023 harvest specifications may reflect an increase from the proposed harvest specifications. Conversely, if the 2021 SAFE report indicates that the stock biomass trend is decreasing for a species, then the final 2022 and 2023 harvest specifications may reflect a decrease from the proposed harvest specifications. In addition to changes driven by biomass trends, there may be changes in TACs due to the sum of ABCs exceeding 2 million mt. Since the regulations require TACs to be set to an OY between 1.4 and 2 million mt, the Council may be required to recommend TACs that are lower than the ABCs recommended by the Plan Team and the SSC, if setting all TACs equal to ABCs would cause the sum of TACs to exceed an OY of 2 million mt. Generally, total ABCs greatly exceed 2 million mt in years with a large pollock biomass. For both 2022 and 2023, NMFS anticipates that the sum of the final ABCs will exceed 2 million mt. NMFS expects that the final TACs for the BSAI for both 2022 and 2023 will equal 2 million mt each year.

The proposed 2022 and 2023 OFLs and ABCs are based on the best available biological and scientific information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods used to calculate stock biomass. The FMP specifies a series of six tiers to define OFLs and ABCs based on the level of reliable information available to fishery scientists. Tier 1 represents the highest level of information quality available, while Tier 6 represents the lowest. The proposed 2022 and 2023 TACs are based on the best available biological and socioeconomic information.

In October 2021, the SSC adopted the proposed 2022 and 2023 OFLs and ABCs recommended by the Plan Team for all groundfish. The Council adopted the SSC's OFL and ABC recommendations. The OFL and ABC amounts are unchanged from the final 2022 harvest specifications published in the **Federal Register** on February 25,

2021 (86 FR 11449). The sum of the proposed 2022 and 2023 ABCs for all assessed groundfish is 2,682,318 mt. The sum of the proposed TACs is 2,000,000 mt.

Specification and Apportionment of TAC Amounts

The Council recommended proposed 2022 and 2023 TACs that are equal to the proposed ABCs for 2022 and 2023 BS sablefish, Central AI Atka mackerel, BS and Eastern AI Atka mackerel, BS Pacific ocean perch, Central AI Pacific ocean perch, Eastern AI Pacific ocean perch, Central AI and Western AI blackspotted and rougheye rockfish, and AI ''other rockfish.'' The Council recommended proposed TACs less than the respective proposed ABCs for all other species. Section 679.20(a)(5)(iii)(B)(*1*) requires the AI pollock TAC to be set at 19,000 mt when the AI pollock ABC equals or exceeds 19,000 mt. The Bogoslof pollock TAC is set to accommodate incidental catch amounts. TACs are set so that the sum of the overall TAC does not exceed the BSAI OY.

The proposed groundfish OFLs, ABCs, and TACs are subject to change pending the completion of the final 2021 SAFE report, public comment, and the Council's recommendations for the final 2022 and 2023 harvest specifications during its December 2021 meeting. These proposed amounts are consistent with the biological condition of groundfish stocks as described in the 2020 SAFE report. The proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs have been adjusted for other biological information and socioeconomic considerations, including maintaining the entire TAC within the required OY range. Pursuant to Section 3.2.3.4.1 of the FMP, the Council could recommend adjusting the final TACs ''if warranted on the basis of bycatch considerations, management uncertainty, or socioeconomic considerations; or if required in order to cause the sum of the TACs to fall within the OY range.'' Table 1 lists the proposed 2022 and 2023 OFL, ABC, TAC, initial TAC (ITAC), and CDQ amounts for groundfish for the BSAI. The proposed apportionment of TAC amounts among fisheries and seasons is discussed below.

TABLE 1—PROPOSED 2022 AND 2023 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), AND CDQ RESERVE ALLOCATION OF GROUNDFISH IN THE BSAI [1]

[Amounts are in metric tons]

Species	Area	Proposed 2022 and 2023					
		OFL	ABC	TAC	ITAC [2]	CDQ [3 4]	Nonspecified reserves
Pollock [4]	BS	2,366,000	1,484,000	1,400,000	1,260,000	140,000	
	AI	61,308	50,789	19,000	17,100	1,900	
	Bogoslof	113,479	85,109	100	100		
Pacific cod [5]	BS	128,340	106,852	95,053	84,882	10,171	
	AI	27,400	20,600	13,796	12,320	1,476	
Sablefish	Alaska-wide	70,710	36,995	n/a	n/a	n/a	
	BS	n/a	4,863	4,863	2,067	182	2,614
	AI	n/a	6,860	5,061	1,075	95	3,891
Yellowfin sole	BSAI	374,982	344,140	200,000	178,600	21,400	
Greenland turbot	BSAI	7,181	6,139	6,025	5,121	n/a	
	BS	n/a	5,175	5,125	4,356	548	220
	AI	n/a	964	900	765		135
Arrowtooth flounder	BSAI	94,368	80,323	15,000	12,750	1,605	645
Kamchatka flounder	BSAI	10,843	9,163	8,982	7,635		1,347
Rock sole [6]	BSAI	213,783	206,605	54,500	48,669	5,832	
Flathead sole [7]	BSAI	77,763	64,119	25,000	22,325	2,675	
Alaska plaice	BSAI	36,928	30,815	22,500	19,125		3,375
Other flatfish [8]	BSAI	22,919	17,189	6,500	5,525		975
Pacific Ocean perch	BSAI	42,384	35,503	34,758	30,596	n/a	
	BS	n/a	10,298	10,298	8,753		1,545
	EAI	n/a	8,041	8,041	7,181	860	
	CAI	n/a	5,919	5,919	5,286	633	
	WAI	n/a	11,245	10,500	9,377	1,124	
Northern rockfish	BSAI	18,221	14,984	13,000	11,050		1,950
Blackspotted/Rougheye rockfish [9].	BSAI	595	500	326	277		49
	BS/EAI	n/a	324	150	128		23
	CAI/WAI	n/a	176	176	150		26
Shortraker rockfish	BSAI	722	541	225	191		34
Other rockfish [10]	BSAI	1,751	1,313	694	590		104
	BS	n/a	919	300	255		45
	AI	n/a	394	394	335		59
Atka mackerel	BSAI	79,660	68,220	57,717	51,541	6,176	
	EAI/BS	n/a	23,880	23,880	21,325	2,555	
	CAI	n/a	14,330	14,330	12,797	1,533	
	WAI	n/a	30,010	19,507	17,420	2,087	
Skates	BSAI	47,372	39,598	16,000	13,600		2,400
Sharks	BSAI	689	517	200	170		30
Octopuses	BSAI	4,769	3,576	700	595		105

TABLE 1—PROPOSED 2022 AND 2023 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), AND CDQ RESERVE ALLOCATION OF GROUNDFISH IN THE BSAI [1]—Continued

[Amounts are in metric tons]

Species	Area	Proposed 2022 and 2023					
		OFL	ABC	TAC	ITAC [2]	CDQ [3 4]	Nonspecified reserves
Total		3,802,167	2,707,590	2,000,000	1,785,904	194,677	19,419

[1] These amounts apply to the entire BSAI management area unless otherwise specified. With the exception of pollock, and for the purpose of these harvest specifications, the Bering Sea subarea (BS) includes the Bogoslof District.

[2] Except for pollock, the portion of the sablefish TAC allocated to hook-and-line and pot gear, and the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 15 percent of each TAC is put into a nonspecified reserve. The ITAC for these species is the remainder of the TAC after subtraction of the reserves. For pollock and Amendment 80 species, ITAC is the non-CDQ allocation of TAC (see footnote 3 and 4).

[3] For the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 10.7 percent of the TAC is reserved for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C) and 679.31). Twenty percent of the sablefish TAC allocated to hook-and-line gear or pot gear, 7.5 percent of the sablefish TAC allocated to trawl gear, and 10.7 percent of the TACs for Bering Sea Greenland turbot and BSAI arrowtooth flounder are reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(B) and (D)). The 2022 hook-and-line or pot gear portion of the sablefish ITAC and CDQ reserve will not be specified until the final 2022 and 2023 harvest specifications. Aleutian Islands Greenland turbot, ''other flatfish,'' Alaska plaice, Bering Sea Pacific ocean perch, Kamchatka flounder, northern rockfish, shortraker rockfish, blackspotted and rougheye rockfish, ''other rockfish,'' skates, sharks, and octopuses are not allocated to the CDQ Program.

[4] Under § 679.20(a)(5)(i)(A), the annual BS pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (4 percent), is further allocated by sector for a pollock directed fishery as follows: Inshore–50 percent; catcher/processor–40 percent; and motherships–10 percent. Under § 679.20(a)(5)(iii)(B)(*2*), the annual Aleutian Islands (AI) pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (2,500 mt), is allocated to the Aleut Corporation for a pollock directed fishery.

[5] The proposed BS Pacific cod TAC is set to account for the 11 percent, plus 45 mt, of the BS ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS. The proposed AI Pacific cod TAC is set to account for 39 percent of the AI ABC for the State guideline harvest level in State waters of the AI, unless the State guideline harvest level would exceed 15 million pounds (6,804 mt), in which case the TAC is set to account for the maximum authorized State guideline harvest level of 6,804 mt.

[6] ''Rock sole'' includes *Lepidopsetta polyxystra* (Northern rock sole) and *Lepidopsetta bilineata* (Southern rock sole).

[7] ''Flathead sole'' includes *Hippoglossoides elassodon* (flathead sole) and *Hippoglossoides robustus* (Bering flounder).

[8] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.

[9] ''Blackspotted/Rougheye rockfish'' includes *Sebastes melanostictus* (blackspotted) and *Sebastes aleutianus* (rougheye).

[10] ''Other rockfish'' includes all *Sebastes* and *Sebastolobus* species except for Pacific ocean perch, dark rockfish, northern rockfish, shortraker rockfish, and blackspotted/rougheye rockfish.

Note: Regulatory areas and districts are defined at § 679.2 (BSAI = Bering Sea and Aleutian Islands management area, BS = Bering Sea subarea, AI = Aleutian Islands subarea, EAI = Eastern Aleutian district, CAI = Central Aleutian district, WAI = Western Aleutian district.)

Groundfish Reserves and the Incidental Catch Allowance (ICA) for Pollock, Atka Mackerel, Flathead Sole, Rock Sole, Yellowfin Sole, and AI Pacific Ocean Perch

Section 679.20(b)(1)(i) requires NMFS to reserve 15 percent of the TAC for each target species category (except for pollock, hook-and-line and pot gear allocation of sablefish, and Amendment 80 species) in a nonspecified reserve. Section 679.20(b)(1)(ii)(B) requires that NMFS allocate 20 percent of the hook-and-line or pot gear allocation of sablefish to the fixed gear sablefish CDQ reserve for each subarea. Section 679.20(b)(1)(ii)(D) requires that NMFS allocate 7.5 percent of the trawl gear allocation of sablefish and 10.7 percent of BS Greenland turbot and BSAI arrowtooth flounder TACs to the respective CDQ reserves. Section 679.20(b)(1)(ii)(C) requires that NMFS allocate 10.7 percent of the TACs for Atka mackerel, AI Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod to the respective CDQ reserves. Sections 679.20(a)(5)(i)(A) and 679.31(a) require allocation of 10 percent of the BS pollock TAC to the pollock CDQ directed fishing allowance (DFA). Sections 679.20(a)(5)(iii)(B)(*2*)(*i*) and 679.31(a) require 10 percent of the AI pollock TAC be allocated to the pollock CDQ DFA. The entire Bogoslof District pollock TAC is allocated as an ICA pursuant to § 679.20(a)(5)(ii) because the Bogoslof District is closed to directed fishing for pollock by regulation (§ 679.22(a)(7)(B)). With the exception of the hook-and-line or pot gear sablefish CDQ reserve, the regulations do not further apportion the CDQ reserves by gear.

Pursuant to § 679.20(a)(5)(i)(A)(*1*), NMFS proposes a pollock ICA of 4 percent of the BS pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidentally retained and discarded catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2000 through 2021. During this 22-year period, the pollock incidental catch ranged from a low of 2.2 percent in 2006 to a high of 4.6 percent in 2014, with a 22-year average of 3 percent. Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), NMFS proposes a pollock ICA of 15 percent or 2,500 mt of the AI pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidental catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2003 through 2021. During this 19-year period, the incidental catch of pollock ranged from a low of 5 percent in 2006 to a high of 17 percent in 2014, with a 19-year average of 9 percent.

Pursuant to § 679.20(a)(8) and (10), NMFS proposes ICAs of 3,000 mt of flathead sole, 6,000 mt of rock sole, 4,000 mt of yellowfin sole, 10 mt of Western Aleutian District Pacific ocean perch, 60 mt of Central Aleutian District Pacific ocean perch, 100 mt of Eastern Aleutian District Pacific ocean perch, 20 mt of Western Aleutian District Atka mackerel, 75 mt of Central Aleutian District Atka mackerel, and 800 mt of Eastern Aleutian District and BS Atka mackerel, after subtracting the 10.7 percent CDQ reserves. These ICAs are based on NMFS's examination of the incidental catch in other target fisheries from 2003 through 2021.

The regulations do not designate the remainder of the nonspecified reserve by species or species group. Any amount of the reserve may be apportioned to a target species that contributed to the nonspecified reserve during the year, provided that such apportionments are consistent with § 679.20(a)(3) and do not result in overfishing (see § 679.20(b)(1)(i)).

Allocations of Pollock TAC Under the American Fisheries Act (AFA)

Section 679.20(a)(5)(i)(A) requires that BS pollock TAC be apportioned as a DFA, after subtracting 10 percent for the CDQ Program and 4 percent for the ICA, as follows: 50 percent to the inshore sector, 40 percent to the catcher/processor (CP) sector, and 10 percent to the mothership sector. In the BS, 45 percent of the DFA is allocated to the A season (January 20 to June 10), and 55 percent of the DFA is allocated to the B season (June 10 to November 1) (§§ 679.20(a)(5)(i)(B)(*1*) and 679.23(e)(2)). The AI directed pollock fishery allocation to the Aleut Corporation is the amount of pollock TAC remaining in the AI after subtracting 1,900 mt for the CDQ DFA (10 percent), and 2,500 mt for the ICA (§ 679.20(a)(5)(iii)(B)(*2*)). In the AI, the total A season apportionment of the pollock TAC (including the AI directed fishery allocation, the CDQ DFA, and the ICA) may equal up to 40 percent of the ABC for AI pollock, and the remainder of the pollock TAC is allocated to the B season (§ 679.20(a)(5)(iii)(B)(*3*)). Table 2 lists these proposed 2022 and 2023 amounts.

Section 679.20(a)(5)(iii)(B)(*6*) sets harvest limits for pollock in the A season (January 20 to June 10) in Areas 543, 542, and 541. In Area 543, the A season pollock harvest limit is no more than 5 percent of the AI pollock ABC. In Area 542, the A season pollock harvest limit is no more than 15 percent of the AI pollock ABC. In Area 541, the A season pollock harvest limit is no more than 30 percent of the AI pollock ABC.

Section 679.20(a)(5)(i)(A)(*4*) includes several specific requirements regarding BS pollock allocations. First, it requires that 8.5 percent of the pollock allocated to the CP sector be available for harvest by AFA catcher vessels (CVs) with CP sector endorsements, unless the Regional Administrator receives a cooperative contract that allows the distribution of harvest among AFA CPs and AFA CVs in a manner agreed to by all members. Second, AFA CPs not listed in the AFA are limited to harvesting not more than 0.5 percent of the pollock allocated to the CP sector. Table 2 lists the proposed 2022 and 2023 allocations of pollock TAC. Tables 13, 14, and 15 list the AFA CP and CV harvesting sideboard limits. The BS inshore pollock cooperative and open access sector allocations are based on the submission of AFA inshore cooperative applications due to NMFS on December 1 of each calendar year. Because AFA inshore cooperative applications for 2022 have not been submitted to NMFS, and NMFS therefore cannot calculate 2022 allocations, NMFS has not included inshore cooperative tables in these proposed harvest specifications. NMFS will post the 2022 AFA inshore pollock cooperative and open access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports* prior to the start of the fishing year on January 1, 2022, based on the harvest specifications effective on that date.

Table 2 also lists proposed seasonal apportionments of pollock and harvest limits within the Steller Sea Lion Conservation Area (SCA). The harvest of pollock within the SCA, as defined at § 679.22(a)(7)(vii), is limited to no more than 28 percent of the annual pollock DFA before 12:00 noon, April 1, as provided in § 679.20(a)(5)(i)(C). The A season pollock SCA harvest limit will be apportioned to each sector in proportion to each sector's allocated percentage of the DFA.

TABLE 2—PROPOSED 2022 AND 2023 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2022 and 2023 Allocations	A season [1]		B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea TAC	1,400,000	n/a	n/a	n/a
CDQ DFA	140,000	63,000	39,200	77,000
ICA [1]	50,400	n/a	n/a	n/a
Total Bering Sea DFA (non-CDQ)	1,209,600	544,320	338,688	665,280
AFA Inshore	604,800	272,160	169,344	332,640
AFA Catcher/Processors [3]	483,840	217,728	135,475	266,112
Catch by CPs	442,714	199,221	n/a	243,492
Catch by CVs [3]	41,126	18,507	n/a	22,620
Unlisted CP Limit [4]	2,419	1,089	n/a	1,331
AFA Motherships	120,960	54,432	33,869	66,528
Excessive Harvesting Limit [5]	211,680	n/a	n/a	n/a
Excessive Processing Limit [6]	362,880	n/a	n/a	n/a
Aleutian Islands subarea ABC	50,789	n/a	n/a	n/a
Aleutian Islands subarea TAC	19,000	n/a	n/a	n/a
CDQ DFA	1,900	760	n/a	1,140
ICA	2,500	1,250	n/a	1,250
Aleut Corporation	14,600	14,600	n/a	.....
Area harvest limit [7]	n/a	n/a	n/a	n/a
541	15,237	n/a	n/a	n/a
542	7,618	n/a	n/a	n/a
543	2,539	n/a	n/a	n/a

TABLE 2—PROPOSED 2022 AND 2023 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]—Continued

[Amounts are in metric tons]

Area and sector	2022 and 2023 Allocations	A season [1]		B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bogoslof District ICA [8]	100	n/a	n/a	n/a

[1] Pursuant to § 679.20(a)(5)(i)(A), the annual Bering Sea subarea pollock TAC, after subtracting the CDQ DFA (10 percent) and the ICA (4 percent), is allocated as a DFA as follows: Inshore sector–50 percent, catcher/processor sector (CPs)–40 percent, and mothership sector–10 percent. In the Bering Sea subarea, 45 percent of the DFA is allocated to the A season (January 20–June 10) and 55 percent of the DFA is allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(i) through (iii), the annual AI pollock TAC, after subtracting first for the CDQ DFA (10 percent) and second for the ICA (2,400 mt), is allocated to the Aleut Corporation for a directed pollock fishery. In the AI subarea, the A season is allocated up to 40 percent of the AI pollock ABC.

[2] In the Bering Sea subarea, pursuant to § 679.20(a)(5)(i)(C), no more than 28 percent of each sector's annual DFA may be taken from the SCA before noon, April 1.

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), 8.5 percent of the DFA allocated to listed CPs shall be available for harvest only by eligible catcher vessels with a CP endorsement delivering to listed CPs, unless there is a CP sector cooperative for the year.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted CPs are limited to harvesting not more than 0.5 percent of the C/P sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30 percent of the sum of the non-CDQ pollock DFAs.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 no more than 30 percent, in Area 542 no more than 15 percent, and in Area 543 no more than 5 percent of the Aleutian Islands pollock ABC.

[8] Pursuant to § 679.22(a)(7)(B), the Bogoslof District is closed to directed fishing for pollock. The amounts specified are for incidental catch only and are not apportioned by season or sector.

Allocation of the Atka Mackerel TACs

Section 679.20(a)(8) allocates the Atka mackerel TACs to the Amendment 80 and BSAI trawl limited access sectors, after subtracting the CDQ reserves, ICAs for the BSAI trawl limited access sector and non-trawl gear sectors, and the jig gear allocation (Table 3). The percentage of the ITAC for Atka mackerel allocated to the Amendment 80 and BSAI trawl limited access sectors is listed in Table 33 to 50 CFR part 679 and in § 679.91. Pursuant to § 679.20(a)(8)(i), up to 2 percent of the Eastern Aleutian District and Bering Sea subarea Atka mackerel TAC may be allocated to vessels using jig gear. The percent of this allocation is recommended annually by the Council based on several criteria, including the anticipated harvest capacity of the jig gear fleet. The Council recommended, and NMFS proposes, a 0.5 percent allocation of the Atka mackerel TAC in the Eastern Aleutian District and Bering Sea subarea to jig gear in 2022 and 2023.

Section 679.20(a)(8)(ii)(A) apportions the Atka mackerel TAC into two equal seasonal allowances. Section 679.23(e)(3) sets the first seasonal allowance for directed fishing with trawl gear from January 20 through June 10 (A season), and the second seasonal allowance from June 10 through December 31 (B season). Section 679.23(e)(4)(iii) applies Atka mackerel seasons to trawl CDQ Atka mackerel fishing. The ICA and jig gear allocations are not apportioned by season.

Sections 679.20(a)(8)(ii)(C)(*1*)(*i*) and (*ii*) limit Atka mackerel catch within waters 0 nautical miles (nmi) to 20 nmi of Steller sea lion sites listed in Table 6 to 50 CFR part 679 and located west of 178° W longitude to no more than 60 percent of the annual TACs in Areas 542 and 543, and equally divides the annual TAC between the A and B seasons as defined at § 679.23(e)(3). Section 679.20(a)(8)(ii)(C)(*2*) requires that the annual TAC in Area 543 will be no more than 65 percent of the ABC in Area 543. Section 679.20(a)(8)(ii)(D) requires that any unharvested Atka mackerel A season allowance that is added to the B season be prohibited from being harvested within waters 0 nm to 20 nmi of Steller sea lion sites listed in Table 6 to 50 CFR part 679 and located in Areas 541, 542, and 543.

Table 3 lists the proposed 2022 and 2023 Atka mackerel season allowances, area allowances, and the sector allocations. One Amendment 80 cooperative has formed for the 2022 fishing year. Because all Amendment 80 vessels are part of the cooperative, no allocation to the Amendment 80 limited access sector is required for 2022. The 2023 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022. NMFS will post the 2023 Amendment 80 cooperatives and Amendment 80 limited access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year on January 1, 2023, based on the harvest specifications effective on that date.

TABLE 3—PROPOSED 2022 AND 2023 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE (ICA), AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2022 and 2023 allocation by area		
		Eastern Aleutian District/ Bering Sea	Central Aleutian District [5]	Western Aleutian District [5]
TAC	n/a	23,880	14,330	19,507

TABLE 3—PROPOSED 2022 AND 2023 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE (ICA), AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC—Continued

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2022 and 2023 allocation by area		
		Eastern Aleutian District/ Bering Sea	Central Aleutian District [5]	Western Aleutian District [5]
CDQ reserve	Total	2,555	1,533	2,087
	A	1,278	767	1,044
	Critical habitat [5]	n/a	460	626
	B	1,278	767	1,044
	Critical habitat [5]	n/a	460	626
non-CDQ TAC	n/a	21,325	12,797	17,420
ICA	Total	800	75	20
Jig [6]	Total	103	.....	.....
BSAI trawl limited access	Total	2,042	1,272	.....
	A	1,021	636	.....
	Critical habitat [5]	n/a	382	.....
	B	1,021	636	.....
	Critical habitat [5]	n/a	382	.....
Amendment 80 [7]	Total	18,380	11,450	17,400
	A	9,190	5,725	8,700
	Critical habitat [5]	n/a	3,435	5,220
	B	9,190	5,725	8,700
	Critical habitat [5]	n/a	3,435	5,220

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, ICAs, and the jig gear allocation, to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in Table 33 to 50 CFR part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C) and 679.31).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10, and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of Steller sea lion critical habitat; § 679.20(a)(8)(ii)(C)(*1*)(*ii*) equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3); and § 679.20(a)(8)(ii)(C)(*2*) requires that the TAC in Area 543 shall be no more than 65 percent of ABC in Area 543.

[6] Sections 679.2 and 679.20(a)(8)(i) requires that up to 2 percent of the Eastern Aleutian District and Bering Sea subarea TAC be allocated to jig gear after subtraction of the CDQ reserves and ICAs. The proposed amount of this allocation is 0.5 percent. The jig gear allocation is not apportioned by season.

[7] The 2023 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022.

Allocation of the Pacific Cod TAC

The Council separated BS and AI subarea OFLs, ABCs, and TACs for Pacific cod in 2014 (79 FR 12108, March 4, 2014). Section 679.20(b)(1)(ii)(C) allocates 10.7 percent of the BS TAC and the AI TAC to the CDQ Program. After CDQ allocations have been deducted from the respective BS and AI Pacific cod TACs, the remaining BS and AI Pacific cod TACs are combined for calculating further BSAI Pacific cod sector allocations. If the non-CDQ Pacific cod TAC is or will be reached in either the BS or the AI subareas, NMFS will prohibit directed fishing for non-CDQ Pacific cod in that subarea, as provided in § 679.20(d)(1)(iii).

Section 679.20(a)(7)(i) and (ii) allocate to the non-CDQ sectors the combined BSAI Pacific cod TAC, after subtracting 10.7 percent for the CDQ Program, as follows: 1.4 percent to vessels using jig gear, 2.0 percent to hook-and-line or pot CVs less than 60 ft (18.3 m) length overall (LOA), 0.2 percent to hook-and-line CVs greater than or equal to 60 ft (18.3 m) LOA, 48.7 percent to hook-and-line CPs, 8.4 percent to pot CVs greater than or equal to 60 ft (18.3 m) LOA, 1.5 percent to pot CPs, 2.3 percent to AFA trawl CPs, 13.4 percent to the Amendment 80 sector, and 22.1 percent to trawl CVs. The BSAI ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of BSAI Pacific cod TAC allocated to the hook-and-line and pot sectors. For 2022 and 2023, the Regional Administrator proposes a BSAI ICA of 400 mt, based on anticipated incidental catch by these sectors in other fisheries.

The BSAI ITAC allocation of Pacific cod to the Amendment 80 sector is established in Table 33 to 50 CFR part 679 and § 679.91. One Amendment 80 cooperative has formed for the 2022 fishing year. Because all Amendment 80 vessels are part of the cooperative, no allocation to the Amendment 80 limited access sector is required for 2022. The 2023 allocations for Pacific cod between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022. NMFS will post the 2023 Amendment 80 cooperatives and Amendment 80 limited access allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year on January 1, 2023, based on the harvest specifications effective on that date.

The sector allocations of Pacific cod are apportioned into seasonal allowances to disperse the Pacific cod fisheries over the fishing year (see §§ 679.20(a)(7)(i)(B), 679.20 (a)(7)(iv)(A), and 679.23(e)(5)). In accordance with § 679.20(a)(7)(iv)(B) and (C), any unused portion of a Pacific cod seasonal allowance for any sector, except the jig sector, will become available at the

beginning of that sector's next seasonal allowance.

Section 679.20(a)(7)(vii) requires that the Regional Administrator establish an Area 543 Pacific cod harvest limit based on Pacific cod abundance in Area 543 as determined by the annual stock assessment process. Based on the 2020 stock assessment, the Regional Administrator has preliminarily determined for 2022 and 2023 that the estimated amount of Pacific cod abundance in Area 543 is 15.7 percent of total AI abundance. NMFS will first subtract the State GHL Pacific cod amount from the AI Pacific cod ABC. Then NMFS will determine the harvest limit in Area 543 by multiplying the percentage of Pacific cod estimated in Area 543 (15.7 percent) by the remaining ABC for AI Pacific cod. Based on these calculations, which rely on the 2020 stock assessment, the proposed Area 543 harvest limit is 2,166 mt. However, the final Area 543 harvest limit could change if the Pacific cod abundance in Area 543 changes based on the stock assessment in the final 2021 SAFE report.

On March 21, 2019, the final rule adopting Amendment 113 to the FMP (81 FR 84434, November 23, 2016) was vacated by the U.S. District Court for the District of Columbia (*Groundfish Forum* v. *Ross, No. 16–2495* (D.D.C. March 21, 2019)), and the corresponding regulations implementing Amendment 113 are no longer in effect. Therefore, this proposed rule is not specifying amounts for the AI Pacific Cod Catcher Vessel Harvest Set-Aside Program (see § 679.20(a)(7)(viii)).

Table 4 lists the CDQ and non-CDQ seasonal allowances by gear based on the proposed 2022 and 2023 Pacific cod TACs; the sector allocations of Pacific cod; and the seasons set forth at § 679.23(e)(5).

TABLE 4—PROPOSED 2022 AND 2023 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI [1] PACIFIC COD TAC

[Amounts are in metric tons]

Sector	Percent	2022 and 2023 share of gear sector total	2022 and 2023 share of sector total	2022 and 2023 seasonal apportionment	
				Season	Amount
Total Bering Sea TAC	n/a	95,053	n/a	n/a	n/a
Bering Sea CDQ	n/a	10,171	n/a	See § 679.20(a)(7)(i)(B)	n/a
Bering Sea non-CDQ TAC	n/a	84,882	n/a	n/a	n/a
Total Aleutian Islands TAC	n/a	13,796	n/a	n/a	n/a
Aleutian Islands CDQ	n/a	1,476	n/a	See § 679.20(a)(7)(i)(B)	n/a
Aleutian Islands non-CDQ TAC	n/a	12,320	n/a	n/a	n/a
Western Aleutians Islands Limit	n/a	2,166	n/a	n/a	n/a
Total BSAI non-CDQ TAC [1]	100.0	97,202	n/a	n/a	n/a
Total hook-and-line/pot gear	60.8	59,099	n/a	n/a	n/a
Hook-and-line/pot ICA [2]	n/a	n/a	400	n/a	n/a
Hook-and-line/pot sub-total	n/a	58,699	n/a	n/a	n/a
Hook-and-line catcher/processors	48.7	n/a	47,017	Jan-1–Jun 10	23,979
				Jun 10–Dec 31	23,038
Hook-and-line catcher vessels ≥60 ft LOA	0.2	n/a	193	Jan 1–Jun 10	98
				Jun 10–Dec 31	95
Pot catcher/processors	1.5	n/a	1,448	Jan 1–Jun 10	739
				Sept 1–Dec 31	710
Pot catcher vessels ≥60 ft LOA	8.4	n/a	8,110	Jan 1–Jun 10	4,136
				Sept-1–Dec 31	3,974
Catcher vessels <60 ft LOA using hook-and-line or pot gear.	2.0	n/a	1,931	n/a	n/a
Trawl catcher vessels	22.1	21,482	n/a	Jan 20–Apr 1	15,896
				Apr 1–Jun 10	2,363
				Jun 10–Nov 1	3,222
AFA trawl catcher/processors	2.3	2,236	n/a	Jan 20–Apr 1	1,677
				Apr 1–Jun 10	559
				Jun 10–Nov 1	
Amendment 80	13.4	13,025	n/a	Jan 20–Apr 1	9,769
				Apr 1–Jun 10	3,256
				Jun 10–Dec 31	
Jig	1.4	1,361	n/a	Jan 1–Apr 30	816
				Apr 30–Aug 31	272
				Aug 31–Dec 31	272

[1] The sector allocations and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs, after subtraction of the reserve for the CDQ Program. If the TAC for Pacific cod in either the BS or AI is or will be reached, then directed fishing will be prohibited for non-CDQ Pacific cod in that subarea, even if a BSAI allowance remains (§ 679.20(d)(1)(iii)).

[2] The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator proposes an ICA of 400 mt based on anticipated incidental catch by these sectors in other fisheries.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Sablefish Gear Allocation

Section 679.20(a)(4)(iii) and (iv) require allocation of sablefish TAC for the BS and AI between trawl gear and hook-and-line or pot gear. Gear allocations of the sablefish TAC for the BS are 50 percent for trawl gear and 50 percent for hook-and-line or pot gear. Gear allocations of the TAC for the AI are 25 percent for trawl gear and 75 percent for hook-and-line or pot gear. Section 679.20(b)(1)(ii)(B) requires that NMFS apportion 20 percent of the hook-and-line or pot gear allocation of sablefish TAC to the CDQ reserve for each subarea. Also, § 679.20(b)(1)(ii)(D)(*1*) requires that 7.5 percent of the trawl gear allocation of

sablefish TAC from the nonspecified reserve, established under § 679.20(b)(1)(i), be apportioned to the CDQ reserve. The Council recommended that only trawl sablefish TAC be established biennially. The harvest specifications for the hook-and-line or pot gear sablefish Individual Fishing Quota (IFQ) fisheries are limited to the 2022 fishing year to ensure those fisheries are conducted concurrently with the halibut IFQ fishery. Concurrent sablefish and halibut IFQ fisheries reduce the potential for discards of halibut and sablefish in those fisheries. The sablefish IFQ fisheries remain closed at the beginning of each fishing year until the final harvest specifications for the sablefish IFQ fisheries are in effect. Table 5 lists the proposed 2022 and 2023 gear allocations of the sablefish TAC and CDQ reserve amounts.

TABLE 5—PROPOSED 2022 AND 2023 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2022 Share of TAC	2022 ITAC [1]	2022 CDQ reserve	2023 Share of TAC	2023 ITAC	2023 CDQ reserve
Bering Sea:							
Trawl	50	2,432	2,067	182	2,432	2,067	182
Hook-and-line gear/pot [2]	50	2,432	n/a	486	n/a	n/a	n/a
Total	100	4,863	2,067	669	2,432	2,067	182
Aleutian Islands:							
Trawl	25	1,265	1,075	95	1,265	1,075	95
Hook-and-line gear/pot [2]	75	3,796	n/a	759	n/a	n/a	n/a
Total	100	5,061	1,075	854	1,265	1,075	95

[1] For the sablefish TAC allocated to vessels using trawl gear, 15 percent of TAC is apportioned to the nonspecified reserve (§ 679.20(b)(1)(i)). The ITAC is the remainder of the TAC after the subtraction of this reserve. In the BS and AI, 7.5 percent of the trawl gear allocation of TAC is assigned from the nonspecified reserve to the CDQ reserve (§ 679.20(b)(1)(ii)(D)(*1*)).

[2] For the sablefish TAC allocated to vessels using hook-and-line or pot gear, 20 percent of the allocated TAC is reserved for use by CDQ participants (§ 679.20(b)(1)(ii)(B)). The Council recommended that specifications for the hook-and-line and pot gear sablefish IFQ fisheries be limited to one year.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Allocation of the AI Pacific Ocean Perch, and BSAI Flathead Sole, Rock Sole, and Yellowfin Sole TACs

Section 679.20(a)(10)(i) and (ii) require that NMFS allocate AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs between the Amendment 80 sector and the BSAI trawl limited access sector, after subtracting 10.7 percent for the CDQ reserves and amounts for ICAs for the BSAI trawl limited access sector and vessels using non-trawl gear. The allocation of the ITAC for AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole to the Amendment 80 sector is established in Tables 33 and 34 to 50 CFR part 679 and in § 679.91.

One Amendment 80 cooperative has formed for the 2022 fishing year. Because all Amendment 80 vessels are part of the cooperative, no allocation to the Amendment 80 limited access sector is required for 2022. The 2023 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022. NMFS will post the 2023 Amendment 80 cooperatives and Amendment 80 limited access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year on January 1, 2023, based on the harvest specifications effective on that date. Table 6 lists the proposed 2022 and 2023 allocations of the AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs.

TABLE 6—PROPOSED 2022 AND 2023 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	2022 and 2023 allocations					
	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
TAC	8,041	5,919	10,500	25,000	54,500	200,000
CDQ	860	633	1,124	2,675	5,832	21,400
ICA	100	60	10	3,000	6,000	4,000
BSAI trawl limited access sector	708	523	187	.....	.....	34,782
Amendment 80 [1]	6,373	4,703	9,179	19,325	42,669	139,818

[1] The 2023 allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022.

Section 679.2 defines the ABC surplus for flathead sole, rock sole, and yellowfin sole as the difference between the annual ABC and TAC for each species. Section 679.20(b)(1)(iii) establishes ABC reserves for flathead sole, rock sole, and yellowfin sole. The ABC surpluses and the ABC reserves are necessary to mitigate the operational

variability, environmental conditions, and economic factors that may constrain the CDQ groups and the Amendment 80 cooperatives from achieving, on a continuing basis, the optimum yield in the BSAI groundfish fisheries. NMFS, after consultation with the Council, may set the ABC reserve at or below the ABC surplus for each species, thus maintaining the TAC below ABC limits. An amount equal to 10.7 percent of the ABC reserves will be allocated as CDQ ABC reserves for flathead sole, rock sole, and yellowfin sole. Section 679.31(b)(4) establishes the annual allocations of CDQ ABC reserves among the CDQ groups. The Amendment 80 ABC reserves are the ABC reserves minus the CDQ ABC reserves and are allocated to each Amendment 80 cooperative pursuant to § 679.91(i)(2), which establishes each Amendment 80 cooperative ABC reserve to be the ratio of each cooperatives' quota share units and the total Amendment 80 quota share units, multiplied by the Amendment 80 ABC reserve for each respective species. Table 7 lists the proposed 2022 and 2023 ABC surplus and ABC reserves for BSAI flathead sole, rock sole, and yellowfin sole.

TABLE 7—PROPOSED 2022 AND 2023 ABC SURPLUS, ABC RESERVES, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	Flathead sole [1]	Rock sole [1]	Yellowfin sole [1]
ABC	64,119	206,605	344,140
TAC	25,000	54,500	200,000
ABC surplus	39,119	152,105	144,140
ABC reserve	39,119	152,105	144,140
CDQ ABC reserve	4,186	16,275	15,423
Amendment 80 ABC reserve	34,933	135,830	128,717

[1] The 2023 allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022.

Proposed PSC Limits for Halibut, Salmon, Crab, and Herring

Section 679.21(b), (e), (f), and (g) set forth the BSAI PSC limits. Pursuant to § 679.21(b)(1), the annual BSAI halibut PSC limits total 3,515 mt. Section 679.21(b)(1) allocates 315 mt of the halibut PSC limit as the PSQ reserve for use by the groundfish CDQ Program, 1,745 mt of the halibut PSC limit for the Amendment 80 sector, 745 mt of the halibut PSC limit for the BSAI trawl limited access sector, and 710 mt of the halibut PSC limit for the BSAI non-trawl sector.

Section 679.21(b)(1)(iii)(A) and (B) authorize apportionment of the BSAI non-trawl halibut PSC limit into PSC allowances among six fishery categories, and § 679.21(b)(1)(ii)(A) and (B), (e)(3)(i)(B), and (e)(3)(iv) require apportionment of the BSAI trawl limited access sector's halibut and crab PSC limits into PSC allowances among seven fishery categories. Table 10 lists the proposed fishery PSC allowances for the BSAI trawl limited access sector fisheries, and Table 11 lists the proposed fishery PSC allowances for the non-trawl fisheries.

Pursuant to Section 3.6 of the FMP, the Council recommends, and NMFS proposes, that certain specified non-trawl fisheries be exempt from the halibut PSC limit. As in past years, after consultation with the Council, NMFS proposes to exempt the pot gear fishery, the jig gear fishery, and the sablefish IFQ hook-and-line gear fishery categories from halibut bycatch restrictions for the following reasons: (1) The pot gear fisheries have low halibut bycatch mortality; (2) NMFS estimates halibut mortality for the jig gear fleet to be negligible because of the small size of the fishery and the selectivity of the gear; and (3) the sablefish and halibut IFQ fisheries have low halibut bycatch mortality because the IFQ Program requires legal-size halibut to be retained by vessels using fixed gear if a halibut IFQ permit holder or a hired master is aboard and is holding unused halibut IFQ for that vessel category and the IFQ regulatory area in which the vessel is operating (§ 679.7(f)(11)).

As of October 18, 2021, total groundfish catch for the pot gear fishery in the BSAI was 32,658 mt, with an associated halibut bycatch mortality of 7 mt. The 2021 jig gear fishery harvested about 20 mt of groundfish. Most vessels in the jig gear fleet are exempt from observer coverage requirements. As a result, observer data are not available on halibut bycatch in the jig gear fishery. As mentioned above, NMFS estimates a negligible amount of halibut bycatch mortality because of the selective nature of jig gear and the low mortality rate of halibut caught with jig gear and released.

Under § 679.21(f)(2), NMFS annually allocates portions of either 33,318, 45,000, 47,591, or 60,000 Chinook salmon PSC limits among the AFA sectors, depending on past bycatch performance, on whether Chinook salmon bycatch incentive plan agreements (IPAs) are formed, and on whether NMFS determines it is a low Chinook salmon abundance year. NMFS will determine that it is a low Chinook salmon abundance year when abundance of Chinook salmon in western Alaska is less than or equal to 250,000 Chinook salmon. The State provides to NMFS an estimate of Chinook salmon abundance using the 3-System Index for western Alaska, based on the Kuskokwim, Unalakleet, and Upper Yukon aggregate stock grouping.

If an AFA sector participates in an approved IPA and has not exceeded its performance standard under § 679.21(f)(6), and if it is not a low Chinook salmon abundance year, then NMFS will allocate a portion of the 60,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(A). If no IPA is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), and if it is not a low abundance year, then NMFS will allocate a portion of the 47,591 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(C). If an AFA sector participates in an approved IPA and has not exceeded its performance standard under § 679.21(f)(6) in a low abundance year, then NMFS will allocate a portion of the 45,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(B). If no IPA is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), and if in a low abundance year, then NMFS will allocate a portion of the 33,318 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(D).

NMFS has determined that 2021 was a low Chinook salmon abundance year, based on the State's estimate that Chinook salmon abundance in western Alaska is less than 250,000 Chinook salmon. Therefore, in 2022, the Chinook salmon PSC limit is 45,000 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(B). The AFA sector Chinook salmon allocations are also seasonally apportioned with 70 percent of the allocation for the A season pollock fishery, and 30 percent of the allocation for the B season pollock fishery (§§ 679.21(f)(3)(i) and 679.23(e)(2)). In 2022, the Chinook salmon bycatch performance standard under § 679.21(f)(6) is 33,318 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(D). NMFS publishes the approved IPAs, allocations, and reports at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska.*

Section 679.21(g)(2)(i) specifies 700 fish as the 2022 and 2023 Chinook salmon PSC limit for the AI pollock fishery. Section 679.21(g)(2)(ii) allocates 7.5 percent, or 53 Chinook salmon, as the AI PSQ reserve for the CDQ Program, and allocates the remaining 647 Chinook salmon to the non-CDQ fisheries.

Section 679.21(f)(14)(i) specifies 42,000 fish as the 2022 and 2023 non-Chinook salmon PSC limit for vessels using trawl gear from August 15 through October 14 in the Catcher Vessel Operational Area (CVOA). Section 679.21(f)(14)(ii) allocates 10.7 percent, or 4,494 non-Chinook salmon, in the CVOA as the PSQ reserve for the CDQ Program, and allocates the remaining 37,506 non-Chinook salmon in the CVOA to the non-CDQ fisheries.

PSC limits for crab and herring are specified annually based on abundance and spawning biomass. Due to the lack of new information as of October 2021 regarding herring PSC limits and apportionments, the Council recommended, and NMFS proposes, basing the proposed herring 2022 and 2023 PSC limits and apportionments on the 2020 survey data. The Council will reconsider these amounts in December 2021. Section 679.21(e)(3)(i)(A)(*1*) allocates 10.7 percent of each trawl gear PSC limit specified for crab as a PSQ reserve for use by the groundfish CDQ Program.

Based on the most recent (2021) survey data, the red king crab mature female abundance is estimated at 6.432 million red king crabs, and the effective spawning biomass is estimated at 20,862 million lbs (9,463 mt). Based on the criteria set out at § 679.21(e)(1)(i), the proposed 2022 and 2023 PSC limit of red king crab in Zone 1 for trawl gear is 32,000 animals. This limit derives from the mature female abundance estimate below 8.4 million red king crab.

Section 679.21(e)(3)(ii)(B)(*2*) establishes criteria under which NMFS must specify an annual red king crab bycatch limit for the Red King Crab Savings Subarea (RKCSS) if the State has established a GHL fishery for red king crab in the Bristol Bay area in the previous year. The State's Department of Fish and Game (ADF&G) and NMFS have reviewed the final 2021 NMFS trawl survey data for the Bristol Bay red king crab stock. The stock is estimated to be below the regulatory threshold for opening a fishery. Therefore, the State did not establish a GHL for the Bristol Bay red king crab fishery, and the fishery will remain closed for the 2021/2022 crab season. Also, NMFS and the Council will not specify an amount of the red king crab bycatch limit, annually established under § 679.21(e)(1)(i), for the RKCSS. Therefore, NMFS will close directed fishing for vessels using non-pelagic trawl gear in the RKCSS for 2022. NMFS and the Council will assess the RKCSS closure for 2023 if the State's ADF&G establishes a GHL for the 2022/2023 red king crab fishery in the Bristol Bay area.

Based on the most recent (2021) survey data from the NMFS annual bottom trawl survey, Tanner crab (*Chionoecetes bairdi*) abundance is estimated at 385 million animals. Pursuant to criteria set out at § 679.21(e)(1)(ii), the calculated 2022 and 2023 *C. bairdi* crab PSC limit for trawl gear is 830,000 animals in Zone 1, and 2,520,000 animals in Zone 2. The limit in Zone 1 is based on the abundance of *C. bairdi* (estimated at 385 million animals), which is over 270 million to 400 million animals. The limit in Zone 2 is based on the abundance of *C. bairdi* (estimated at 385 million animals), which is over 290 million to 400 million animals.

Pursuant to § 679.21(e)(1)(iii), the PSC limit for trawl gear for snow crab (*C. opilio*) is based on total abundance as indicated by the NMFS annual bottom trawl survey. The *C. opilio* crab PSC limit in the *C. opilio* bycatch limitation zone (COBLZ) is set at 0.1133 percent of the Bering Sea abundance index minus 150,000 crabs, unless a minimum or maximum PSC limit applies. Based on the most recent (2021) survey estimate of 1.42 billion animals, the calculated *C. opilio* crab PSC limit is 1,608,860 animals. Because 0.1133 percent multiplied by the total abundance is less than 4.5 million, the minimum PSC limit applies and the PSC limit will be 4.350 million animals.

Pursuant to § 679.21(e)(1)(v), the PSC limit of Pacific herring caught while conducting any trawl operation for BSAI groundfish is 1 percent of the annual eastern Bering Sea herring biomass. The best estimate of 2022 and 2023 herring biomass is 272,281 mt. This amount was developed by the Alaska Department of Fish and Game based on biomass for spawning aggregations. Therefore, the herring PSC limit proposed for 2022 and 2023 is 2,723 mt for all trawl gear as listed in Tables 8 and 9.

Section 679.21(e)(3)(i)(A) requires that PSQ reserves be subtracted from the total trawl PSC limits. The 2022 crab and halibut PSC limits assigned to the Amendment 80 and BSAI trawl limited access sectors are listed in Table 35 to 50 CFR part 679. The resulting proposed allocations of crab and halibut PSC limits to CDQ PSQ, the Amendment 80 sector, and the BSAI trawl limited access sector are listed in Table 8. Pursuant to §§ 679.21(b)(1)(i), 679.21(e)(3)(vi), and 679.91(d) through (f), crab and halibut trawl PSC limits assigned to the Amendment 80 sector are then further allocated to Amendment 80 cooperatives as cooperative quotas. Crab and halibut PSC cooperative quotas assigned to Amendment 80 cooperatives are not allocated to specific fishery categories.

One Amendment 80 cooperative has formed for the 2022 fishing year. Because all Amendment 80 vessels are part of the cooperative, no PSC limit allocation to the Amendment 80 limited access sector is required for 2022. The 2023 PSC limit allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2022. NMFS will post the 2023 Amendment 80 cooperatives and Amendment 80 limited access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year on January 1, 2023, based on the harvest specifications effective on that date.

Section 679.21(b)(2) and (e)(5) authorize NMFS, after consulting with the Council, to establish seasonal apportionments of halibut and crab PSC amounts for the BSAI non-trawl, BSAI trawl limited access, and Amendment 80 limited access sectors to maximize the ability of the fleet to harvest the available groundfish TAC and to minimize bycatch. The factors considered are (1) seasonal distribution

of prohibited species, (2) seasonal distribution of target groundfish species relative to prohibited species distribution, (3) prohibited species bycatch needs on a seasonal basis relevant to prohibited species biomass and expected catches of target groundfish species, (4) expected variations in bycatch rates throughout the year, (5) expected changes in directed groundfish fishing seasons, (6) expected start of fishing effort, and (7) economic effects of establishing seasonal prohibited species apportionments on segments of the target groundfish industry. Based on this criteria, the Council recommended, and NMFS proposes, the seasonal PSC apportionments in Tables 10 and 11 to maximize harvest among gear types, fisheries, and seasons, while minimizing bycatch of PSC.

TABLE 8—PROPOSED 2022 AND 2023 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON-TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS

PSC species and area [1]	Total PSC	Non-trawl PSC	CDQ PSQ reserve [2]	Trawl PSC remaining after CDQ PSQ	Amendment 80 sector [3]	BSAI trawl limited access sector	BSAI PSC limits not allocated [2]
Halibut mortality (mt) BSAI	3,515	710	315	n/a	1,745	745	n/a
Herring (mt) BSAI	2,723	n/a	n/a	n/a	n/a	n/a	n/a
Red king crab (animals) Zone 1	32,000	n/a	3,424	28,576	14,282	8,739	5,555
C. opilio (animals) COBLZ	4,350,000	n/a	465,450	3,884,550	1,909,256	1,248,494	726,799
C. bairdi crab (animals) Zone 1	830,000	n/a	88,810	741,190	312,115	348,285	80,790
C. bairdi crab (animals) Zone 2	2,520,000	n/a	269,640	2,250,360	532,660	1,053,394	664,306

[1] Refer to § 679.2 for definitions of zones.
[2] The PSQ reserve for crab species is 10.7 percent of each crab PSC limit.
[3] The Amendment 80 program reduced apportionment of the trawl PSC limits for crab below the total PSC limit. These reductions are not apportioned to other gear types or sectors.

TABLE 9—PROPOSED 2022 AND 2023 HERRING AND RED KING CRAB SAVINGS SUBAREA PROHIBITED SPECIES CATCH ALLOWANCES FOR ALL TRAWL SECTORS

Fishery categories	Herring (mt) BSAI	Red king crab (animals) Zone 1
Yellowfin sole	118	n/a
Rock sole/flathead sole/Alaska plaice/other flatfish [1]	58	n/a
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	8	n/a
Rockfish	8	n/a
Pacific cod	14	n/a
Midwater trawl pollock	2,472	n/a
Pollock/Atka mackerel/other species [2 3]	45	n/a
2022 Red king crab savings subarea non-pelagic trawl gear [4]	n/a	
2023 Red king crab savings subarea non-pelagic trawl gear [5]	n/a	8,000
Total trawl PSC	2,723	32,000

[1] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[2] Pollock other than midwater trawl pollock, Atka mackerel, and "other species" fishery category.
[3] "Other species" for PSC monitoring includes skates, sharks, and octopuses.
[4] Section 679.21(e)(3)(ii)(B) establishes criteria under which an annual red king crab bycatch limit must be specified for the Red King Crab Savings Subarea (RKCSS) if the State has established a GHL fishery for red king crab in the Bristol Bay area in the previous year. Based on the final 2021 NMFS trawl survey data for the Bristol Bay red king crab stock, the State of Alaska closed the Bristol Bay red king crab fishery for the 2021/2022 crab season. NMFS and the Council will not specify the red king crab bycatch limit for the RKCSS in 2022, and pursuant to § 679.21(e)(3)(ii)(B)(*1*) directed fishing for groundfish is prohibited for vessels using non-pelagic trawl gear in the RKCSS for 2022.
[5] If the Bristol Bay red king crab fishery remains closed in the 2022/2023 crab season, the RKCSS specification will be zero. If the Bristol Bay red king crab fishery is open in the 2022/2023 crab season, NMFS, after consultation with the Council, will specify an annual red king crab bycatch limit for the RKCSS, which is limited by regulation to up to 25 percent of the red king crab PSC allowance (§ 679.21(e)(3)(ii)(B)(*2*)).
Note: Species apportionments may not total precisely due to rounding.

TABLE 10—PROPOSED 2022 AND 2023 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR

BSAI trawl limited access sector fisheries	Prohibited species and area [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals)	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
		Zone 1		Zone 1	Zone 2
Yellowfin sole	150	7,700	1,192,179	293,234	1,005,879
Rock sole/flathead sole/other flatfish [2].					
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish.					
Rockfish April 15–December 31	4	.....	1,006	.....	849

TABLE 10—PROPOSED 2022 AND 2023 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR—Continued

BSAI trawl limited access sector fisheries	Prohibited species and area [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals)	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
		Zone 1		Zone 1	Zone 2
Pacific cod	391	975	50,281	50,816	42,424
Pollock/Atka mackerel/other species [3]	200	65	5,028	4,235	4,243
Total BSAI trawl limited access sector PSC	745	8,739	1,248,494	348,285	1,053,394

[1] Refer to § 679.2 for definitions of areas and zones.
[2] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[3] "Other species" for PSC monitoring includes skates, sharks, and octopuses.
Note: Species apportionments may not total precisely due to rounding.

TABLE 11—PROPOSED 2022 AND 2023 HALIBUT PROHIBITED SPECIES BYCATCH ALLOWANCES FOR NON-TRAWL FISHERIES

Non-trawl fisheries	Seasons	Halibut mortality (mt) BSAI		
		Catcher/ processor	Catcher vessel	All non-trawl
Pacific cod	Annual Pacific cod	648	13	661
	January 1–June 10	388	9	n/a
	June 10–August 15	162	2	n/a
	August 15–December 31	98	2	n/a
Non-Pacific cod non-trawl-Total	May 1–December 31	n/a	n/a	49
Groundfish pot and jig	n/a	n/a	n/a	Exempt.
Sablefish hook-and-line	n/a	n/a	n/a	Exempt.
Total for all non-trawl PSC	n/a	n/a	n/a	710

Halibut Discard Mortality Rates

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, halibut discard mortality rates (DMRs), and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. Halibut incidental catch rates are based on observers' estimates of halibut incidental catch in the groundfish fishery. DMRs are estimates of the proportion of incidentally caught halibut that do not survive after being returned to the sea. The cumulative halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. DMRs are estimated using the best scientific information available in conjunction with the annual BSAI stock assessment process. The DMR methodology and findings are included as an appendix to the annual BSAI groundfish SAFE report.

In 2016, the DMR estimation methodology underwent revisions per the Council's directive. An interagency halibut working group (International Pacific Halibut Commission, Council, and NMFS staff) developed improved estimation methods that have undergone review by the Plan Team, SSC, and the Council. A summary of the revised methodology is included in the BSAI proposed 2017 and 2018 harvest specifications (81 FR 87863, December 6, 2016), and the comprehensive discussion of the working group's statistical methodology is available from the Council (see **ADDRESSES**). The DMR working group's revised methodology is intended to improve estimation accuracy, transparency, and transferability used for calculating DMRs. The working group will continue to consider improvements to the methodology used to calculate halibut mortality, including potential changes to the reference period (the period of data used for calculating the DMRs). Future DMRs may change based on additional years of observer sampling, which could provide more recent and accurate data and which could improve the accuracy of estimation and progress on methodology. The methodology will continue to ensure that NMFS is using DMRs that more accurately reflect halibut mortality, which will inform the different sectors of their estimated halibut mortality and allow specific sectors to respond with methods that could reduce mortality and, eventually, the DMR for that sector.

In October 2021, the Council recommended halibut DMRs derived from the revised methodology for the proposed 2022 and 2023 DMRs. The proposed 2022 and 2023 DMRs use an updated 2-year reference period. Comparing the proposed 2022 and 2023 DMRs to the final DMRs from the 2021 and 2022 harvest specifications, the DMR for pelagic trawl gear remained at 100 percent, the DMR for motherships and CPs using non-pelagic trawl gear remained at 84 percent, the DMR for CVs using non-pelagic trawl gear increased to 62 percent from 59 percent, the DMR for CPs using hook-and-line gear increased to 10 percent from 9 percent, the DMR for CVs using hook-and-line gear increased to 10 percent from 9 percent, and the DMR for pot gear increased to 33 percent from 32 percent. Table 12 lists the proposed 2022 and 2023 DMRs.

TABLE 12—PROPOSED 2022 AND 2023 PACIFIC HALIBUT DISCARD MORTALITY RATES (DMR) FOR THE BSAI

Gear	Sector	Halibut discard mortality rate percent)
Pelagic trawl	All	100
Non-pelagic trawl	Mothership and catcher/processor	84
Non-pelagic trawl	Catcher vessel	62
Hook-and-line	Catcher vessel	10
Hook-and-line	Catcher/processor	10
Pot	All	33

Listed AFA CP Sideboard Limits

Pursuant to § 679.64(a), the Regional Administrator is responsible for restricting the ability of listed AFA CPs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA fishery and from fishery cooperatives in the directed pollock fishery. These restrictions are set out as sideboard limits on catch. On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CPs from directed fishing for groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and Table 54 to 50 CFR part 679). NMFS proposes to exempt AFA CPs from a yellowfin sole sideboard limit pursuant to § 679.64(a)(1)(v) because the proposed 2022 and 2023 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Section 679.64(a)(2) and Tables 40 and 41 to 50 CFR part 679 establish a formula for calculating PSC sideboard limits for halibut and crab caught by listed AFA CPs. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). PSC species listed in Table 13 that are caught by listed AFA CPs participating in any groundfish fishery other than pollock will accrue against the proposed 2022 and 2023 PSC sideboard limits for the listed AFA CPs. Section 679.21(b)(4)(iii), (e)(3)(v), and (e)(7) authorize NMFS to close directed fishing for groundfish other than pollock for listed AFA CPs once a proposed 2022 or 2023 PSC sideboard limit listed in Table 13 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by listed AFA CPs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories, according to § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 13—PROPOSED 2022 AND 2023 BSAI AMERICAN FISHERIES ACT LISTED CATCHER/PROCESSOR PROHIBITED SPECIES SIDEBOARD LIMITS

PSC species and area [1]	Ratio of PSC to total PSC	Proposed 2022 and 2023 PSC available to trawl vessels after subtraction of PSQ [2]	Proposed 2022 and 2023 CP sideboard limit [2]
BSAI Halibut mortality	n/a	n/a	286
Red king crab Zone 1	0.007	28,576	200
C. opilio (COBLZ)	0.153	3,884,550	594,336
C. bairdi Zone 1	0.140	741,190	103,767
C. bairdi Zone 2	0.050	2,250,360	112,518

[1] Refer to § 679.2 for definitions of areas and zones.
[2] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.

AFA CV Sideboard Limits

Pursuant to § 679.64(b), the Regional Administrator is responsible for restricting the ability of AFA CVs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA and from fishery cooperatives in the pollock directed fishery. On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CVs from directed fishing for a majority of the groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and Table 55 to 50 CFR part 679). The remainder of the sideboard limits for non-exempt AFA CVs are proposed in Table 14.

Section 679.64(b)(3) and (b)(4) establish formulas for setting AFA CV groundfish and halibut and crab PSC sideboard limits for the BSAI. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). NMFS proposes to exempt AFA CVs from a yellowfin sole sideboard limit pursuant to § 679.64(b)(6) because the proposed 2022 and 2023 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt. Table 14 lists the proposed 2022 and 2023 AFA CV sideboard limits.

TABLE 14—PROPOSED 2022 AND 2023 BSAI PACIFIC COD SIDEBOARD LIMITS FOR AMERICAN FISHERIES ACT CATCHER VESSELS (CVS)

[Amounts are in metric tons]

Fishery by area/gear/season	Ratio of 1997 AFA CV catch to TAC	2022 and 2023 initial TAC	2022 and 2023 AFA catcher vessel sideboard limits
BSAI	n/a	n/a	n/a
Trawl gear CV	n/a	n/a	n/a
Jan 20–Apr 1	0.8609	15,896	13,685
Apr 1–Jun 10	0.8609	2,363	2,034
Jun 10–Nov 1	0.8609	3,222	2,774

Note: As proposed, § 679.64(b)(6) would exempt AFA CVs from a yellowfin sole sideboard limit because the proposed 2022 and 2023 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Halibut and crab PSC limits listed in Table 15 that are caught by AFA CVs participating in any groundfish fishery other than pollock will accrue against the 2022 and 2023 PSC sideboard limits for the AFA CVs. Section 679.21(b)(4)(iii), (e)(3)(v), and (e)(7) authorize NMFS to close directed fishing for groundfish other than pollock for AFA CVs once a proposed 2022 and 2023 PSC sideboard limit listed in Table 15 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by AFA CVs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories under § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 15—PROPOSED 2022 AND 2023 AMERICAN FISHERIES ACT CATCHER VESSEL PROHIBITED SPECIES CATCH SIDEBOARD LIMITS FOR THE BSAI [1]

PSC species and area [1]	Target fishery category [2]	AFA catcher vessel PSC sideboard limit ratio	Proposed 2022 and 2023 PSC limit after subtraction of PSQ reserves [3]	Proposed 2022 and 2023 AFA catcher vessel PSC sideboard limit [3]
Halibut	Pacific cod trawl	n/a	n/a	887
	Pacific cod hook-and-line or pot	n/a	n/a	2
	Yellowfin sole total	n/a	n/a	101
	Rock sole/flathead sole/Alaska plaice/ other flatfish [4].	n/a	n/a	228
	Greenland turbot/arrowtooth flounder/ Kamchatka flounder/sablefish.	n/a	n/a	.....
	Rockfish	n/a	n/a	2
	Pollock/Atka mackerel/other species [5] ..	n/a	n/a	5
Red king crab Zone 1	n/a	0.2990	28,576	8,544
C. opilio COBLZ	n/a	0.1680	3,884,550	652,604
C. bairdi Zone 1	n/a	0.3300	741,190	244,593
C. bairdi Zone 2	n/a	0.1860	2,250,360	418,567

[1] Refer to § 679.2 for definitions of areas and zones.
[2] Target fishery categories are defined at § 679.21(b)(1)(ii)(B) and (e)(3)(iv).
[3] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.
[4] ''Other flatfish'' for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[5] ''Other species'' for PSC monitoring includes skates, sharks, and octopuses.

Classification

NMFS has determined that the proposed harvest specifications are consistent with the FMP and preliminarily determined that the proposed harvest specifications are consistent with the Magnuson-Stevens Act and other applicable laws, subject to further review after public comment.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Order 12866.

NMFS prepared an EIS for the Alaska groundfish harvest specifications and alternative harvest strategies (see **ADDRESSES**) and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the ROD for the Final EIS. A SIR is being prepared for the final 2022 and 2023 harvest specifications to provide a subsequent assessment of the action and to address the need to prepare a Supplemental EIS (40 CFR 1501.11(b); § 1502.9(d)(1)). Copies of the Final EIS, ROD, and annual SIRs for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental, social, and economic consequences of the proposed groundfish harvest specifications and alternative harvest strategies on resources in the action area. Based on the analysis in the Final EIS, NMFS concluded that the preferred alternative (Alternative 2) provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information.

Initial Regulatory Flexibility Analysis

This Initial Regulatory Flexibility Analysis (IRFA) was prepared for this proposed rule, as required by Section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), to describe the

economic impact this proposed rule, if adopted, would have on small entities. The IRFA describes the action; the reasons why this proposed rule is proposed; the objectives and legal basis for this proposed rule; the estimated number and description of directly regulated small entities to which this proposed rule would apply; the recordkeeping, reporting, and other compliance requirements of this proposed rule; and the relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule. The IRFA also describes significant alternatives to this proposed rule that would accomplish the stated objectives of the Magnuson-Stevens Act, and any other applicable statutes, and that would minimize any significant economic impact of this proposed rule on small entities. The description of the proposed action, its purpose, and the legal basis are explained earlier in the preamble and are not repeated here.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $11 million for all its affiliated operations worldwide. A shoreside processor primarily involved in seafood processing (NAICS code 311710) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual employment, counting all individuals employed on a full-time, part-time, or other basis, not in excess of 750 employees for all its affiliated operations worldwide.

Number and Description of Small Entities Regulated by This Proposed Rule

The entities directly regulated by the groundfish harvest specifications include: (a) Entities operating vessels with groundfish Federal fisheries permits (FFPs) catching FMP groundfish in Federal waters (including those receiving direction allocations of groundfish); (b) all entities operating vessels, regardless of whether they hold groundfish FFPs, catching FMP groundfish in the state-waters parallel fisheries; and (c) all entities operating vessels fishing for halibut inside three miles of the shore (whether or not they have FFPs). In 2020 (the most recent year of complete data), there were 288 individual CVs and CPs with gross revenues less than or equal to $11 million as well as six CDQ groups. This estimate does not account for corporate affiliations among vessels, and for cooperative affiliations among fishing entities, since some of the fishing vessels operating in the BSAI are members of AFA inshore pollock cooperatives, Gulf of Alaska Rockfish Program cooperatives, or BSAI Crab Rationalization Program cooperatives. Vessels that participate in these cooperatives are considered to be large entities within the meaning of the RFA because the aggregate gross receipts of all participating members exceed the $11 million threshold. After accounting for membership in these cooperatives, there are an estimated 155 small CV and 4 small CP entities remaining in the BSAI groundfish sector. However, the estimate of these 155 CVs may be an overstatement of the number of small entities. This latter group of vessels had average gross revenues that varied by gear type. Average gross revenues for hook-and-line CVs, pot gear CVs, trawl gear CVs, hook-and-line CPs, and pot gear CPs are estimated to be $530,000, $1.1 million, $2.8 million, $6.6 million, and $3.1 million, respectively.

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

The action under consideration is the proposed 2022 and 2023 harvest specifications, apportionments, and prohibited species catch limits for the groundfish fishery of the BSAI. This action is necessary to establish harvest limits for groundfish during the 2022 and 2023 fishing years and is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act. The establishment of the proposed harvest specifications is governed by the Council's harvest strategy to govern the catch of groundfish in the BSAI. This strategy was selected from among five alternatives, with the preferred alternative harvest strategy being one in which the TACs fall within the range of ABCs recommended by the SSC. Under the preferred harvest strategy, TACs are set to a level that falls within the range of ABCs recommended by the SSC; the sum of the TACs must achieve the OY specified in the FMP. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant.

The TACs associated with preferred harvest strategy are those recommended by the Council in October 2021. OFLs and ABCs for the species were based on recommendations prepared by the Council's Plan Team in September 2021, and reviewed by the Council's SSC in October 2021. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations. The sum of all TACs remains within the OY for the BSAI consistent with § 679.20(a)(1)(i)(A). Because setting all TACs equal to ABCs would cause the sum of TACs to exceed an OY of 2 million mt, TACs for some species or species groups are lower than the ABCs recommended by the Plan Team and the SSC.

The proposed 2022 and 2023 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods to calculate stock biomass. The proposed 2022 and 2023 TACs are based on the best available biological and socioeconomic information. The proposed 2022 and 2023 OFLs, ABCs, and TACs are consistent with the biological condition of groundfish stocks as described in the 2020 SAFE report, which is the most recent, completed SAFE report.

Under this action, the proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs are within the range of proposed ABCs recommended by the SSC and do not exceed the biological limits recommended by the SSC (the ABCs and overfishing levels). For some species and species groups in the BSAI, the Council recommended, and NMFS proposes, proposed TACs equal to proposed ABCs, which is intended to maximize harvest opportunities in the BSAI.

However, NMFS cannot set TACs for all species in the BSAI equal to their ABCs due to the constraining OY limit of two million mt. For this reason, some proposed TACs are less than the proposed ABCs. The specific reductions are reviewed and recommended by the Council's AP, and the Council in turn adopted the AP's TAC recommendations for the proposed 2022 and 2023 TACs.

Based upon the best available scientific data, and in consideration of the Council's objectives of this action, it appears that there are no significant alternatives to the proposed rule that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the proposed rule

on small entities. This action is economically beneficial to entities operating in the BSAI, including small entities. The action proposes TACs for commercially-valuable species in the BSAI and allows for the continued prosecution of the fishery, thereby creating the opportunity for fishery revenue. After public process during which the Council solicited input from stakeholders, the Council concluded that the proposed harvest specifications would best accomplish the stated objectives articulated in the preamble for this proposed rule, and in applicable statutes, and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

This action does not modify recordkeeping or reporting requirements, or duplicate, overlap, or conflict with any Federal rules.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

Adverse impacts on marine mammals or endangered or threatened species resulting from fishing activities conducted under these harvest specifications are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: November 29, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–26180 Filed 12–1–21; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 230
Friday, December 3, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No AMS–FGIS–21–0043]

Opportunity To Comment on Applicants for the West Lafayette, Indiana U.S. Grain Standards Act Designation Area

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In the June 28, 2021, **Federal Register**, AMS asked persons interested in providing official U.S. Grain Standards Act services in the West Lafayette, Indiana designation area to submit an application. There are two applicants for the West Lafayette, Indiana area: Champaign-Danville Grain Inspection Departments, Inc. (Champaign) and North Dakota Grain Inspection Service, Inc. (North Dakota). Both applicants are currently designated official agencies and applied for designation to provide official services for the entire area formerly assigned to Titus Grain Inspection, Inc. Each applicant is also currently serving in an interim designation capacity. The geographic area is described in the **SUPPLEMENTARY INFORMATION** below. We are asking for comments on these applicants.

DATES: Comments must be received by January 3, 2022.

ADDRESSES: Submit comments concerning this Notice using any of the following methods:

- *To submit Comments:* Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

Read Applications and Comments: If you would like to view the applications, please contact us at *FGISQACD@usda.gov*. All comments will be available for public inspection online at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Austyn Hughes at *FGISQACD@usda.gov* or 816–266–5066.

SUPPLEMENTARY INFORMATION: The area, in the State of Indiana, includes Benton (east of U.S. Route 41), Carroll (north of State Route 25), Fountain (east of U.S. Route 41), Jasper (south of U.S. Route 24), Newton (east of State Route 55 and south of U.S. Route 24), Pulaski, Tippecanoe, Warren (east of U.S. Route 41), and White Counties.

The following grain elevators are part of this interim geographic area assignment. In Champaign-Danville Grain Inspection Department, Inc.'s area: Boswell Chase Grain, Inc., Boswell, Benton County, Indiana. In North Dakota Grain Inspection Service, Inc.'s area: The Andersons, Delphi, Carroll County; Frick Services, Inc., Leiters Ford, Fulton County; and Cargill, Inc., Linden, Montgomery County, Indiana.

Request for Comments

We are publishing this Notice to provide interested persons the opportunity to comment on the quality of services provided by the Champaign and North Dakota official agencies. In the designation process, we are particularly interested in receiving comments citing reasons and pertinent data supporting or objecting to the designation of the applicant(s). Such comments should be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov*.

We consider applications, comments, and other available information, such as audit reports, when determining which applicants will be designated.

Authority: 7 U.S.C. 71–87k.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–26262 Filed 12–2–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection: Workforce Development Participant Tracking Form Formerly Public Lands Corps Tracking Sheet

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the USDA Forest Service is seeking comments from all interested individuals and organizations on the renewal of a currently approved information collection, currently titled the Public Lands Corps Tracking Sheet and proposed to change to Workforce Development Participant Tracking Form.

DATES: Comments must be received in writing on or before February 1, 2022 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: You may submit comments by any of the following methods; email is encouraged:

- *Email: 21CSC@fs.fed.us.*
- *Mail:* Merlene Mazyck, Civilian Climate Corps Coordinator, USDA Forest Service, Attn: Recreation, Heritage and Volunteer Resources, 1400 Independence Ave. SW, Mailstop Code: 1125, Washington, DC 20250–1125.
- *Hand Delivery/Courier:* USDA Forest Service, Attn: Recreation, Heritage and Volunteer Resources, 1400 Independence Ave. SW, Mailstop Code: 1125, Washington, DC 20250–1125.

The public may inspect comments received at the Office of the Director, Recreation, Heritage and Volunteer Resources, 5th Floor South West, Sidney R. Yates Federal Building, 201 14th Street SW, Washington, DC, during normal business hours. Visitors are encouraged to call ahead to 202–205–0560 to facilitate entry to the building.

SUPPLEMENTARY INFORMATION:

Title: Workforce Development Participant Tracking Form.

OMB Number: 0596–0247.

Expiration Date of Approval: February 28, 2022.

Type of Request: Extension with revisions of a currently approved information collection.

Abstract: Federal land management and other agencies are authorized to offer work and education programs for individuals in natural and cultural resources careers and experiences in partnership with conservation and service corps, and environmental and other organizations that contribute to the rehabilitation, restoration, and repair of public lands resources and infrastructure and climate adaptation and mitigation. Some of the applicable statutes and regulations include special hiring authorities, upon completion of certain requirements. This information collection request will enable participating agencies to capture required and other information that will aid in workforce development and job training for young people, returning veterans and others who are unemployed or underemployed, and to monitor compliance with statutory laws and associated hiring authorities. A primary, but not exclusionary, authorizing source for the information collection is 16 U.S.C. 1702–1727, chapter 37—Youth Conservation Corps, Public Lands Corps, Resource Assistants Program, and Indian Youth Service Corps. The Public Lands Corps is a work and education program involving the nation's land management agencies, conservation and service corps, and environmental organizations that contribute to the rehabilitation, restoration, and repair of public lands resources and infrastructures. Public Lands Corps projects provide opportunities for community and national public service, work experience and training for young people who are unemployed or underemployed persons, students, recent graduates, and others with an interest in natural and cultural resources careers.

The Workforce Development Participant Tracking Form supports the effective management of the Public Lands Corps and other workforce development programs hosted in partnership with public lands agencies. The utilization of a common form will: Assist federal agencies to uniformly collect information regarding work accomplished; track and monitor participant engagement to determine the completion of requirements for non-competitive hiring eligibility as defined in the Act; comply with statutory reporting requirements; inform effective outreach strategies to underrepresented populations and marginalized communities consistent with efforts to promote inclusion priorities; and provide data about project activities that can be aggregated across federal agencies.

Information collected, such as participant demographic information, and project information, will allow the Forest Service and other agencies to monitor the effectiveness of federal efforts to meet the intent of the authorizing statutes, including the Public Lands Corps Act and the Administration's Civilian Climate Corps Initiative. It will allow the Forest Service and other agencies to engage under-represented populations in natural and cultural resource conservation jobs, development and scientific research work, and education on public lands. This information collection request will ensure that partners maintain a record of all workforce development agreements, grants and contracts established, participant demographics and education, project information and work hours, project locations and dates, and status of special hiring eligibilities conferred upon eligible participants.

Proposed Changes to Information Collection: Changes to the information collected will help monitor workforce development partnerships, training and performance outcomes grounded in justice, equity, diversity, and inclusion principles. These changes will also position agencies to begin monitoring Civilian Climate Change engagement pursuant to climate change and diversity objectives as defined in the Build Back Better Act of 2021. Land management and other federal agencies are working across boundaries to improve access for partners and reduce burden, streamline, and standardize reporting and collect data to inform evidence-based decision making and improvements by all parties. Changes to the form will be integrated with a web-based application for data entry and will include expanded demographics reported about veteran and special ability status genders, vocational and technical certifications, and education; enhanced project and type of work data; and better systems integration, interagency standards and checks and balances that improve integrity of systems and security of Personal Identifiable Information and program information.

Type of Respondents: Non-profit Organizations and Non-Federal Governmental entities.

Estimated Annual Number of Respondents: 500.

Estimated Annual Number of Responses per Respondent: 2; twice annually required. The application will be available for respondents to input data more frequently if they choose.

Estimated Total Annual Responses: 500.

Estimated Time per Response: 2 hours per response.

Estimated Total Annual Burden on Respondents: 1,000 hours.

Comment is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection methods or forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission of the information collection request to Office of Management and Budget.

Christopher French,

Deputy Chief, National Forest System.

[FR Doc. 2021–26306 Filed 12–2–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data regarding production practices, costs and returns, and contractor expenses. This data is currently being collected under OMB number 0535–0218.

DATES: Comments on this notice must be received by February 1, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: omb officer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *eFax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *omb officer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Agricultural Resource Management phase 3 Economic Surveys.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to create a new information collection for a period of three years.

Abstract: The Agricultural Resource Management Survey(s) (ARMS) are the primary source of information for the U.S. Department of Agriculture on a broad range of issues related to: Production practices, costs and returns, and contractor expenses. Data are collected on both a whole farm level and on selected commodities. This Notice and information collection will focus on the ARMS phase 3 Economic Surveys, previously included in the Agricultural Resource Management and Chemical Use Surveys Information Collection Request (OMB Control Number 0535–0218).

The ARMS phase 3 Economic Surveys are the only annual source of information available for objective evaluation of many critical issues related to agriculture and the rural economy, such as: Annual whole farm finance data, including data sufficient to construct estimates of income for farms by: Type of operation, loan commodities, income for operator households, credit, structure, and organization; marketing information; and other economic data on input usage, production practices, and crop substitution possibilities.

Data from ARMS are used to produce estimates of net farm income by type of commercial producer as required in 7 U.S.C. 7998 as amended and estimates of enterprise production costs as required in 7 U.S.C. 1441(a) as amended. Data from ARMS are also used as weights in the development of the Prices Paid Index, a component of the Parity Index referred to in the Agricultural Adjustment Act of 1938, as amended. These indexes are used to calculate the annual federal grazing fee rates as described in the Public Rangelands Improvement Act of 1978 and Executive Order 12548 and as promulgated in regulations found at 36 CFR 222.51, as amended.

In addition, ARMS is used to produce estimates of sector-wide production expenditures and other components of income that are used in constructing the estimates of income and value-added which are transmitted to the U.S. Department of Commerce, Bureau of Economic Analysis, by the USDA Economic Research Service (ERS) for use in constructing economy-wide estimates of Gross Domestic Product. This transmittal of data, prepared using the ARMS, is undertaken to satisfy a 1956 agreement between the Office of Management and Budget, and the Departments of Agriculture and Commerce that a single set of estimates be published on farm income.

In this approval request for the next three years; the ARMS 3 surveys will overlap with the 2022 Census of Agriculture (conducted in 2023, OMB Control Number 0535–0226) and the Tenure, Ownership and Transition of Agricultural Land (TOTAL, OMB Control Number 0535–0240) which will be conducted in 2024. In January 2023, the farm operators selected to complete the ARMS phase 3 survey will have the option of completing either the ARMS 3 questionnaire or the Census of Agriculture, but will not have to do both. The ARMS phase 3 questionnaire contains the same essential questions as the Census.

In 2024, farm operators who are selected to complete the ARMS phase 3 and the TOTAL survey will have the option of completing the ARMS 3 questionnaire and not having to complete the TOTAL survey. The ARMS phase 3 questionnaire contains the same essential questions as the TOTAL.

The commodity specific questionnaire versions that are scheduled to be conducted in the next three years are included in the following table.

Crop year	Survey	Target commodity	Reference year	Year survey is conducted
2022	ARMS phase 3	CRR/Censes	2022	2023
		wheat	2022	2023
2023	ARMS phase 3	CRR	2023	2024
		soybeans	2023	2024
		oats	2023	2024
		peanuts	2023	2024
		broilers	2023	2024
2024	ARMS phase 3	TOTAL	2024	2025

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018, Title III of Public Law 115–435, codified in 44 U.S.C. Ch. 35. CIPSEA supports NASS's pledge of confidentiality to all respondents and facilitates the agency's efforts to reduce burden by supporting statistical activities of collaborative agencies through designation of NASS

agents, subject to the limitations and penalties described in CIPSEA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average approximately 95 minutes per respondent.

Respondents: Farmers, ranchers, farm managers, farm contractors, and farm households.

Estimated Number of Respondents: Up to 40,100 respondents will be sampled each year for the ARMS phase 3 Economic Surveys.

Estimated Total Annual Burden on Respondents: Up to 64,000 hours per year.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 10, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021–26276 Filed 12–2–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data on production practices and chemical use. These surveys are funded by State Departments of Agriculture, land grant universities, and other organizations with which NASS has a Memorandum of Understanding (MOU). These surveys were previously included in the ARMS (OMB Control Number 0535–0218) docket and are being moved into a standalone docket for ease of processing.

DATES: Comments on this notice must be received by February 1, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *eFax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Cooperator Funded Chemical Use Surveys.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to create a new information collection for a period of three years.

Abstract: The chemical use data collection activities in this clearance request would be conducted through cooperative agreements with State Departments of Agriculture, land-grant universities, or other organizations with which NASS has a Memorandum of Understanding (MOU). Previously, these collections were included in the Agricultural Resource Management and Chemical Use Surveys Information Collection Request (OMB Control Number 0535–0218). These cooperator funded chemical use surveys are being separated out to allow flexibility for survey changes and possible new surveys without affecting the surveys funded through USDA's Congressional appropriation. The surveys in the Information Collection Request allow flexibility for the cooperators to best address current trends in the farming industry within States.

The Field Crop Production Practice and Chemical Use Surveys in this request will be conducted on an established schedule depending on funding from the cooperators:

- Maryland Department of Agriculture,
- Minnesota Department of Agriculture,
- Mississippi State University Extension Service,
- Illinois Department of Agriculture, and
- Other State Department of Agriculture, land grant university, or other organization with a cooperative agreement with NASS.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018, Title III of Public Law 115–435, codified in 44 U.S.C. Ch. 35. CIPSEA supports NASS's pledge of confidentiality to all respondents and facilitates the agency's efforts to reduce burden by supporting statistical activities of collaborative agencies through designation of NASS agents, subject to the limitations and penalties described in CIPSEA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average approximately 30 minutes per survey.

Respondents: Farmers, ranchers, farm managers, farm contractors, and farm households.

Estimated Number of Respondents: Approximately 35,000 respondents will be sampled each year for the Cooperator Funded Chemical Use Surveys.

Estimated Total Annual Burden on Respondents: Approximately 15,000 hours per year.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection

of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 10, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021–26277 Filed 12–2–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Seek Approval To Revise and Extend a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Agricultural Resources Management Survey (ARMS), phases 1 and 2 as well as Chemical Use Surveys. All phases of the Agricultural Resources Management Survey(s) are included in the current OMB Control Number 0535–0218, but this information collection renewal request will only include the ARMS phases 1 and 2 as well as Chemical Use Surveys. The ARMS phase 3 and cooperator funded chemical use surveys will be moved to two new information collection requests. Splitting these surveys across multiple information collections will allow USDA and cooperators more flexibility for changes to best address current trends in the farming industry. A revision to burden hours will be needed due to this separation as well as changes in the size of the target population, sampling design, and/or questionnaire length.

DATES: Comments on this notice must be received by February 1, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0218, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *eFax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Agricultural Resources Management Survey and Chemical Use Surveys.

OMB Control Number: 0535–0218.

Expiration Date of Current Approval: November 30, 2023.

Type of Request: Intent to revise and extend a currently approved information collection.

Abstract: The Agricultural Resource Management Survey(s) (ARMS) are the primary source of information for the U.S. Department of Agriculture on a broad range of issues related to: Production practices, costs and returns, pest management, chemical usage, and contractor expenses. Data are collected on both a whole farm level and on selected commodities. Historically, the ARMS docket contained a screening phase, a chemical use phase and an economic phase. In addition, it contained chemical use surveys for fruits and vegetables along with specialty surveys conducted through External Project Agreements (EPA). This Notice and information collection will focus on the ARMS phases 1 and 2—the screening, production practices, as well as chemical use surveys.

The combined ARMS surveys are the only source of information available for objective evaluation of many critical issues related to economics, chemical usage, and cropping practices. Breaking these surveys into separate OMB approvals will assist in making timely updates to questionnaires to keep in touch with an ever changing industry.

Cost of Production: A Congressional mandate exists for the development of annual estimates of the cost of producing wheat, feed grains, cotton, and dairy commodities. USDA also collects cost of production data for soybeans, rice, peanuts, hogs, and beef cow-calf in order to provide economic information for comparison among the major farm commodities that compete for U.S. agricultural resources. The economic data collection and publication for the cost of production surveys will be included under a new, separate OMB approval.

Chemical Use Surveys: Congress has mandated that NASS and ERS build nationally coordinated databases on agricultural chemical use and related farm practices; these databases are the primary vehicles used to produce specified environmental and economic estimates. The surveys will help provide the knowledge and technical means for producers and researchers to address on-farm environmental concerns in a manner that maintains agricultural productivity.

The commodities that are scheduled to be included in this approval are in the following table.

CHEMICAL USE TARGET COMMODITIES 2022–2024

Year	Survey	Target commodity
2022	Integrated Screening	ARMS phases 2 & 3 Plus Chemical Use.
	ARMS phase 2 (PPCR)	wheat.
	ARMS phase 2 (PPR)	potatoes.
	Chemical Use	vegetables.
2023	ARMS phase 1	ARMS phases 2 & 3.
	ARMS phase 2 (PPCR)	soybeans, oats, peanuts.
	ARMS phase 2 (PPR)	none.
	Chemical Use	fruit.

CHEMICAL USE TARGET COMMODITIES 2022–2024—Continued

Year	Survey	Target commodity
2024	Integrated Screening	ARMS phases 2 & 3 plus Chemical Use.
	ARMS phase 2 (PPCR)	TBD.
	ARMS phase 2 (PPR)	TBD.
	Chemical Use	vegetables.

PPCR—Production Practices and Costs Report.
PPR—Production Practices Report.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018, Title III of Public Law 115–435, codified in 44 U.S.C. Ch. 35. CIPSEA supports NASS's pledge of confidentiality to all respondents and facilitates the agency's efforts to reduce burden by supporting statistical activities of collaborative agencies through designation of NASS agents, subject to the limitations and penalties described in CIPSEA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average approximately 14 minutes per response.

Respondents: Farmers, ranchers, farm managers, farm contractors, and farm households.

Estimated Number of Respondents: Approximately 112,000 respondents will be sampled each year. Less than 20 percent of these respondents will be contacted more than one time in a single year for the surveys in this docket.

Estimated Total Annual Burden on Respondents: Approximately 45,000 hours per year.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 10, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021–26275 Filed 12–2–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

Office of the Under Secretary for Economic Affairs

Request for Comments on the Execution of the FY 22/26 Learning Agenda

AGENCY: Office of the Under Secretary for Economic Affairs, U.S. Department of Commerce.

ACTION: Request for information.

SUMMARY: In accordance with the Foundations for Evidence-Based Policymaking Act of 2018 (the Evidence Act), Public Law 115–435,[1] the Department of Commerce has developed a draft Learning Agenda for FY 2022 to FY 2026. The Learning Agenda lists significant priority evidence/evaluation questions that will be researched over the next four years to help achieve the Department's Strategic Objectives. The final plan will be published in February 2022 and will be reviewed annually for possible updates and improvements.

Research questions in the plan cover a broad range of topics reflecting the wide-ranging authorities and programs across the Department. One common theme across many bureaus, and consistent with the Administration's focus on equitable economic growth, is the extent to which programs are reaching traditionally underserved communities and populations and meeting their needs. These questions are listed in the **SUPPLEMENTARY INFORMATION.**

General comments are invited but input is particularly requested on:

- Strategies to best engage with underserved communities and populations on research methodology
- Data sets maintained by states, localities, regional organizations, or non-profits that could support the research
- Recent significant research most relevant to the Learning Agenda questions

The information provided will be used to develop and refine the approach used to conduct research. This includes identifying organizations and individuals who will be included in focus groups.

DATES: Comments must be received by 5:00 p.m. Eastern time on January 31, 2022. Written comments in response to the RFI should be submitted according to the instructions in the **ADDRESSES** sections below. Submissions received after that date may not be considered.

ADDRESSES: Comments must be submitted via email to *EvaluationOfficer@doc.gov.* Attachments to the email will be accepted only in ADOBE® portable document format or MICROSOFT WORD® format. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. The Department of Commerce reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice please call 202–604–5634 or email *EvaluationOfficer@doc.gov.*

SUPPLEMENTARY INFORMATION: The following are Learning Agenda topics and questions that would particularly

[1] 5 U.S.C. 312.

benefit from engagement with underserved communities and populations on the approach to the research and available data and expertise.

Equitable Sustained Prosperity

To what extent do minority business enterprises (MBEs) participate, produce, innovate, and compete in manufacturing? What Department actions would be most effective in increasing MBE participation in manufacturing?

What types of Economic Development Administration funded activities (including those funded by CARES and the American Rescue Plan) are associated with the strongest long-term economic advances, particularly for underserved communities and populations?

What is the best approach to increasing capital available to minority businesses?

What are the most significant barriers to providing business assistance to underserved communities and populations? How can they be removed?

Data Availability and Usability

What datasets are available/needed to track the impact of Department programs on historically underserved communities/populations?

What refinements and new statistics can best support better and more equitable management of the economy?

What internal processes and publicly facing Commerce tools will democratize data access and improve awareness of the Commerce data inventory?

Weather and Climate Information

How can NOAA provide more effective and equitable climate mitigation and adaptation science breakthroughs?

How can weather forecasts be communicated effectively to vulnerable populations?

What additional models and tools do communities need to better prepare for coastal inundation at seasonal, annual, and multi-year timescales?

Request for Information: Respondents may organize their submissions in response to this RFI in any manner. Responses may include estimates, which should be identified as such. All responses that comply with the requirements listed in the **DATES** and **ADDRESSES** sections of this RFI will be considered.

Christine Heflin,

Evaluation Officer, Department of Commerce, Office of the Under Secretary for Economic Affairs.

[FR Doc. 2021–26304 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–MN–P

DEPARTMENT OF COMMERCE

International Trade Administration

Advisory Committee on Supply Chain Competitiveness Renewal

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, with the concurrence of the General Services Administration, renewed the Advisory Committee on Supply Chain Competitiveness.

DATES: The charter for the Advisory Committee on Supply Chain Competitiveness was renewed on November 10, 2021.

FOR FURTHER INFORMATION CONTACT: Richard Boll, Supply Chain Team, Room 11004, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; phone 202–482–1135; email: *richard.boll@trade.gov.*

SUPPLEMENTARY INFORMATION: The Department of Commerce, with the concurrence of the General Services Administration, renewed the Advisory Committee on Supply Chain Competitiveness. The effective date of the charter renewal is November 10, 2021. This Notice is published in accordance with the Federal Advisory Committee Act (FACA). It has been determined that renewal of the Committee is necessary and in the public interest. The Committee was established pursuant to Commerce's authority under 15 U.S.C. 1512, in accordance with the FACA, and with the concurrence of the General Services Administration. The Committee provides advice to the Secretary on the necessary elements of a comprehensive policy approach to supply chain competitiveness designed to support U.S. export growth and national economic competitiveness, encourage innovation, facilitate the movement of goods, and improve the competitiveness of U.S. supply chains for goods and services in the domestic and global economy; and to provide advice to the Secretary on regulatory policies and programs and investment priorities that affect the competitiveness of U.S. supply chains. The total number of members that may serve on the Committee is a maximum of 45.

Dated: November 29, 2021.

Heather Sykes,

Director, Office of Supply Chain, Professional, and Business Services.

[FR Doc. 2021–26254 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–484–803, A–570–062, C–570–063]

Large Diameter Welded Pipe From Greece and Cast Iron Soil Pipe Fittings From the People's Republic of China; Rescission of Antidumping and Countervailing Duty Administrative Reviews; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative reviews of the antidumping duty (AD) orders on large diameter welded pipe from Greece and cast iron soil pipe fittings from the People's Republic of China (China) and the countervailing duty (CVD) order on cast iron soil pipe fittings from China covering the periods of review in the table below, based on the timely withdrawal of all review requests.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Andrew Hart at (202) 482–1058 (Greece); Samantha Kinney at (202) 482–2285 (AD China); Dennis McClure at (202) 482–5973 (CVD China) AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

Based upon timely requests for review, Commerce initiated administrative reviews of certain companies for the periods of review and the AD and CVD orders listed in the table below, pursuant to 19 CFR

351.221(c)(1)(i).[1] All requests for these reviews have been timely withdrawn.[2]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested the review withdraw their review requests within 90 days of the date of publication of the notice of initiation for the requested review. All parties withdrew their requests for the reviews listed in the table below within the 90-day deadline. No other parties requested administrative reviews of these AD/CVD orders for the periods noted in the table. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding, in their entirety, the administrative reviews listed in the table below.

	Period of review
AD Proceeding	
Greece:	
Large Diameter Welded Pipe, A–484–803	5/1/2020–4/30/2021
People's Republic of China:	
Cast Iron Soil Pipe Fittings, A–570–062	8/1/2020–7/31/2021
CVD Proceeding	
The People's Republic of China:	
Cast Iron Soil Pipe Fittings, C–570–063	1/1/2020–12/31/2020

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping and/or countervailing duties on all appropriate entries during the periods of review noted above for each of the listed administrative reviews at rates equal to the cash deposit of estimated antidumping or countervailing duties, as applicable, required at the time of entry, or withdrawal of merchandise from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this recission notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of merchandise subject to AD orders of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during the review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in these segments of these proceedings. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: November 17, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–26316 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 35481 (July 6, 2021); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 55811 (October 7, 2021).

[2] The letters withdrawing the review requests may be found in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Deacero S.A.P.I. de C.V. (Deacero) did not make sales of subject merchandise in the United States at prices below normal value during the November 1, 2019, through October 31, 2020, period of review (POR). Additionally, Commerce has preliminarily assigned Grupo Simec an antidumping duty margin based on the application of adverse facts available. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: David Lindgren or Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1671 or (202) 482–5449.

SUPPLEMENTARY INFORMATION:

Background

On November 6, 2014, Commerce published the antidumping duty order on steel concrete reinforcing bar (rebar) from Mexico in the **Federal Register**.[1] On January 6, 2021, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated

[1] *See Steel Concrete Reinforcing Bar from Mexico: Antidumping Duty Order,* 79 FR 65925 (November 6, 2014) (*Order*).

an administrative review of the *Order*.[2] On July 2, 2021, we extended the deadline for the preliminary results to November 30, 2021.[3]

Commerce initiated this administrative review covering the following companies: Aceros Especiales Simec Tlaxcala; Compania Siderurgica del Pacifico S.A. de C.V.; Deacero; Fundiciones de Acero Estructurales, S.A. de C.V.; Grupo Acerero S.A. de C.V.; Grupo Chant, S.A.P.I. de C.V.; Grupo Simec; Operadora de Perfiles Sigosa, S.A. de C.V.; Orge S.A. de C.V.; Perfiles Comerciales Sigosa, S.A. de C.V.; RRLC S.A.P.I. de C.V.; Sidertul S.A. de C.V.; Siderurgicos Noroeste, S.A. de C.V.; Siderurgica del Occidente y Pacifico S.A. de C.V.; Simec International 6 S.A. de C.V.; Simec International 7, S.A. de C.V.; Simec International 9 S.A. de C.V.; and Simec International, S.A. de C.V. On February 8, 2021, we limited the number of respondents selected for individual examination in this administrative review to Deacero and Grupo Simec.[4] We did not select the remaining companies for individual examination, and these companies remain subject to this administrative review.[5]

Scope of the Order

The product covered by the *Order* is steel concrete reinforcing bar from Mexico. For a complete description of the scope, *see* the Preliminary Decision Memorandum.[6]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Constructed export price was calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Application of Facts Available With Adverse Inferences

Pursuant to section 776(a) of the Act, Commerce is preliminarily relying upon facts otherwise available to determine a weighted-average dumping margin for Grupo Simec in this review. Commerce preliminarily finds that necessary information is not available on the record, and that Grupo Simec withheld information requested by Commerce, failed to provide the requested information in the form and manner requested, and significantly impeded the proceeding, warranting a determination on the basis of the facts available under section 776(a) of the Act. Further, Commerce preliminarily determines that Grupo Simec failed to cooperate to the best of its ability, and thus, Commerce is applying facts available with adverse inferences (AFA) to Grupo Simec, in accordance with section 776(b) of the Act. For a full description of the methodology underlying our conclusions regarding the application of AFA, *see* the Preliminary Decision Memorandum.

Rate for Non-Selected Companies

The statute and Commerce's regulations do not identify the dumping margin to apply to respondents not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when determining the dumping margin for respondents that are not individually examined in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins for individually-examined respondents, excluding dumping margins that are zero, *de minimis,* or based entirely on facts available. Where the dumping margins for individually examined respondents are all zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' We have preliminarily calculated a zero percent dumping margin for Deacero and we have preliminarily assigned Grupo Simec a dumping margin of 66.70 percent based entirely on facts available with an adverse inference. Therefore, in accordance with section 735(c)(5)(B) of the Act, we are preliminarily applying to the two companies not selected for individual examination a rate of 33.35 percent, which is an average of the zero percent rate calculated for Deacero and the 66.70 percent AFA rate assigned to Grupo Simec. For additional discussion, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Review

We preliminarily determine the following weighted-average dumping margins exist for the POR:

Producer and/or exporter	Weighted-average dumping margin (percent)
Deacero S.A.P.I de C.V	0.00

[2] *See Initiation of Antidumping Duty and Countervailing Duty Administrative Reviews,* 86 FR 511 (January 6, 2021) (*Initiation Notice*).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated July 2, 2021.

[4] *See* Memorandum, ''2019–2020 Antidumping Duty Administrative Review of Steel Concrete Reinforcing Bar from Mexico: Respondent Selection,'' dated February 8, 2021.

[5] Commerce has previously collapsed 15 of the 18 firms listed in the *Initiation Notice* (*i.e.,* Aceros Especiales Simec Tlaxcala; Compania Siderurgica del Pacifico S.A. de C.V.; Fundiciones de Acero Estructurales, S.A. de C.V.; Grupo Chant, S.A.P.I. de C.V.; Grupo Simec; Operadora de Perfiles Sigosa, S.A. de C.V.; Orge S.A. de C.V.; Perfiles Comerciales Sigosa, S.A. de C.V.; RRLC S.A.P.I. de C.V.; Siderurgicos Noroeste, S.A. de C.V.; Siderurgica del Occidente y Pacifico S.A. de C.V.; Simec International, S.A. de C.V.; Simec International 6 S.A. de C.V.; Simec International 7, S.A. de C.V.; and Simec International 9 S.A. de C.V.) into the single entity ''Grupo Simec.'' *See, e.g., Steel Concrete Reinforcing Bar from Mexico: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019,* 86 FR 50527 (September 9, 2021) (*2018–2019 AR Mexico Rebar Final*).

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review on the Antidumping Duty Order of Steel Concrete Reinforcing Bar from Mexico; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Producer and/or exporter	Weighted-average dumping margin (percent)
Grupo Simec (Aceros Especiales Simec Tlaxcala, S.A. de C.V.; Compania Siderurgica del Pacifico S.A. de C.V.; Fundiciones de Acero Estructurales, S.A. de C.V.; Grupo Chant S.A.P.I. de C.V.; Operadora de Perfiles Sigosa, S.A. de C.V.; Orge S.A. de C.V.; Perfiles Comerciales Sigosa, S.A. de C.V.; RRLC S.A.P.I. de C.V.; Siderúrgicos Noroeste, S.A. de C.V.; Siderurgica del Occidente y Pacifico S.A. de C.V.; Simec International, S.A. de C.V.; Simec International 6 S.A. de C.V.; Simec International 7 S.A. de C.V.; and Simec International 9 S.A. de C.V.) [7]	66.70
Grupo Acerero S.A. de C.V	33.35
Sidertul S.A. de C.V	33.35

Disclosure and Public Comment

We intend to disclose the calculations performed in these preliminary results to parties in this proceeding within five days of the date of publication of this notice.[8] A timeline for the submission of case briefs and written comments will be provided to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[9] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10] Case and rebuttal briefs should be filed using ACCESS [11] and must be served on interested parties.[12] Executive Summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Commerce's electric records system, ACCESS. An electronically filed request must be received successfully in its entirety by 5:00 p.m. Easter Time within 30 days after the date of publication of this notice.[13] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[14] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, unless extended.[15]

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification of the information relied upon for its final results of this administrative review. Accordingly, we intend to take additional steps in lieu of on-site verification to verify the information. Commerce will notify interested parties of any additional documentation or information required.

Assessment Rate

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries. If the weighted-average dumping margin for Deacero is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2). If a respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [16] For entries of subject merchandise during the POR produced by Deacero for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction.[17]

Should we continue to apply facts available with an adverse inference to Grupo Simec in the final results, we will instruct CBP to apply an assessment rate equal to the dumping margin of 66.70 percent, as indicated above, to all entries produced and/or exported by Grupo Simec. The assessment rate for antidumping duties for each of the companies not selected for individual examination will be equal to the weighted-average dumping margin identified in the final results of review. Commerce intends to issue assessment

[7] Commerce has previously collapsed the following entities into a single entity: Grupo Simec; Aceros Especiales Simec Tlaxcala, S.A. de C.V.; Compania Siderurgica del Pacifico S.A. de C.V.; Fundiciones de Acero Estructurales, S.A. de C.V.; Grupo Chant S.A.P.I. de C.V.; Operadora de Perfiles Sigosa, S.A. de C.V.; Orge S.A. de C.V.; Perfiles Comerciales Sigosa, S.A. de C.V.; RRLC S.A.P.I. de C.V.; Siderúrgicos Noroeste, S.A. de C.V.; Siderurgica del Occidente y Pacifico S.A. de C.V.; Simec International 6 S.A. de C.V.; Simec International, S.A. de C.V.; Simec International 7 S.A. de C.V.; and, Simec International 9 S.A. de C.V. *See, e.g., 2018–2019 AR Mexico Rebar Final,* 86 FR at 50528.

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect)''); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] *See generally* 19 CFR 351.303.

[12] *See* 19 CFR 351.303(f).

[13] *See* 19 CFR 351.310(c).

[14] *See* 19 CFR 351.310(d).

[15] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

[16] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[17] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each company listed above will be that established in the final results of this administrative review, except if the rate is less than 0.50 percent, and therefore *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 20.58 percent, the rate established in the investigation of this proceeding.[18] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(1).

Dated: November 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2021–26315 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–DS–P

[18] *See Steel Concrete Reinforcing Bar from Mexico: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 79 FR 54967 (September 15, 2014).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–832]

Urea Ammonium Nitrate Solutions From the Russian Federation: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With the Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of urea ammonium nitrate solutions (UAN) from the Russian Federation (Russia) for the period of investigation (POI) January 1, 2020, through December 31, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson (Acron) and John Hoffner and Laura Griffith (the EuroChem Companies [1]), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4793, (202) 482–3315, and (202) 482–6430, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on July 26, 2021.[2] On August 24, 2021, Commerce postponed the preliminary determination of this investigation to November 29, 2021.[3] For a complete description of events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is UAN from Russia. For a complete description of the scope of the investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[6] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.*

Methodology

Commerce is conducting this investigation in accordance with section

[1] For purposes of this investigation, the EuroChem Companies are Mineral and Chemical Company EuroChem, Joint Stock Company (MCC EuroChem), Joint Stock Company Nevinnomyssky Azot (Nevinka), and Azot, Joint Stock Company (NAK Azot).

[2] *See Urea Ammonium Nitrate Solutions from the Russian Federation and the Republic of Trinidad and Tobago: Initiation of Countervailing Duty Investigations,* 86 FR 40004 (July 26, 2021) (*Initiation Notice*).

[3] *See Urea Ammonium Nitrate Solutions from the Russian Federation and the Republic of Trinidad and Tobago: Postponement of Preliminary Determinations in the Countervailing Duty Investigations,* 86 FR 47296 (August 24, 2021).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Countervailing Duty Investigation of Urea Ammonium Nitrate Solutions from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice,* 86 FR at 40005.

701 the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Commerce notes that, in making these findings, it relied, in part, on facts available and, because it finds that the Government of Russia did not act to the best of its ability to respond to Commerce's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.[8] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences,'' in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final determination in this countervailing duty (CVD) investigation with the final determination in the companion antidumping duty (AD) investigation of UAN from Russia based on a request made by the petitioner.[9] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than April 11, 2022, unless postponed.

All-Others Rate

Sections 703(d)(1)(A)(i) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. Pursuant to section 705(c)(5)(A)(i) of the Act, this rate shall normally be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

Commerce calculated individual estimated countervailable subsidy rates for Public Joint Stock Company Acron and the EuroChem Companies that are not zero, *de minimis,* or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged values for the merchandise under consideration.[10]

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate ad valorem (percent)
The EuroChem Companies[11]	9.84
Public Joint Stock Company Acron[12]	9.66
All Others	9.72

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.244(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[13] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[14] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue;

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* sections 776(a) and (b) of the Act.

[9] *See* Petitioner's Letter, ''Urea Ammonium Nitrate Solutions from the Russian Federation: Petitioner's Request to Align Final Countervailing Duty Determination with the Companion Antidumping Duty Final Determination,'' dated November 22, 2021. The petitioner is CF Industries Nitrogen, LLC and its subsidiaries, Terra Nitrogen, Limited Partnership and Terra International (Oklahoma) LLC.

[10] With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly ranged sales data was available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* Memorandum, ''Countervailing Duty Investigation of Urea Ammonium Nitrate Solutions from the Russian Federation: All-Other Rate for Preliminary Determination,'' dated concurrently with, and hereby adopted by, this notice.

[11] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Joint Stock Company Nevinnomyssky Azot (Nevinka): Mineral and Chemical Company EuroChem, Joint Stock Company (MCC EuroChem) and Azot, Joint Stock Company (NAK Azot).

[12] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Public Joint Stock Company Acron: Joint Stock Company Acron Group and Acron Switzerland AG.

[13] *See* 19 CFR 351.309; *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (*Temporary Rule*); and 19 CFR 351.303 (for general filing requirements).

[14] *See Temporary Rule,* 85 FR at 17006; *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

(2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its determination. If Commerce's final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: November 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is all mixtures of urea and ammonium nitrate in aqueous or ammonia solution, regardless of nitrogen concentration by weight, and regardless of the presence of additives, such as corrosion inhibiters and soluble micro or macronutrients (UAN).

Subject merchandise includes merchandise matching the above description that has been processed in a third country, including by commingling, diluting, adding or removing additives, or performing any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the subject country.

The scope also includes UAN that is commingled with UAN from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The covered merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 3102.80.0000. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2021–26313 Filed 12–2–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–953]

Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Final Results of the Expedited Second Five-Year Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (Commerce) finds that revocation of the countervailing duty order (CVD) order on narrow woven ribbons with woven selvedge (ribbons) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Macey Mayes, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202)–482–4473.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2010, Commerce published in the **Federal Register** a notice of the CVD order on ribbons from China.[1] On August 2, 2021, Commerce published the notice of initiation of the second sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce received a notice of intent to participate from Berwick Offray LLC and its wholly-owned subsidiary Lion Ribbon Company, LLC (collectively, the petitioner), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The petitioner claimed domestic interested party status pursuant to section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as a manufacturer in the United States of the domestic like product.[4]

On September 1, 2021, the petitioner filed an adequate substantive response within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] We received no substantive response from any other interested party in this proceeding. On September 20, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[6] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(l)(ii)(B)(2) and (C)(2).

Scope of the Order

The merchandise subject to the *Order* is narrow woven ribbons with woven selvedge, in any length, but with a width (measured at the narrowest span of the ribbon) less than or equal to 12 centimeters, composed of, in whole or in part, man-made fibers (whether artificial or synthetic, including but not limited to nylon, polyester, rayon, polypropylene, and polyethylene teraphthalate), metal threads and/or metalized yarns, or any combination thereof. The merchandise subject to the *Order* is classifiable under the HTSUS statistical categories 5806.32.1020; 5806.32.1030; 5806.32.1050 and 5806.32.1060. Subject merchandise also may enter under subheadings 5806.31.00; 5806.32.20; 5806.39.20; 5806.39.30; 5808.90.00; 5810.91.00; 5810.99.90; 5903.90.10; 5903.90.25; 5907.00.60; and 5907.00.80 and under statistical categories 5806.32.1080; 5810.92.9080; 5903.90.3090; and

[1] *See Narrow Woven Ribbons with Woven Selvedge from the People's Republic of China: Countervailing Duty Order,* 75 FR 53642 (September 1, 2010) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 41439 (August 2, 2021).

[3] *See* Petitioner's Letter, ''Notice of Intent to Participate in Sunset Review,'' dated August 17, 2021.

[4] *Id.* at 2.

[5] *See* Petitioner's Letter, ''Substantive Response to the Notice of Initiation of Sunset Review,'' dated September 1, 2021.

[6] *See* Commerce's Letter, ''Sunset Review Initiated on August 2, 2021,'' dated September 20, 2021.

6307.90.9889. The HTSUS statistical categories and subheadings are provided for convenience and customs purposes; however, the written description of the merchandise under the *Order* is dispositive.[7]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization in the event of revocation of the *Order* and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Exporters or manufacturers	Net countervailable subsidy rate (percent)
Changtai Rongshu Textile Co., Ltd	143.53
Yama Ribbons and Bows Co., Ltd	27.14
All Others	27.14

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: November 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–26291 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–897]

Large Diameter Welded Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2018–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that the producers or exporters subject to this administrative review did not make sales of large diameter welded pipe from the Republic of Korea in the United States at prices below normal value (NV) during the period of review (POR), August 27, 2018, through April 30, 2020.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin or Katherine Johnson, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6478 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 30, 2021, Commerce published the preliminary results of this administrative review.[1] The review covers 20 producers or exporters of subject merchandise. We invited interested parties to comment on the *Preliminary Results.* A summary of the events that occurred since Commerce published the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results, are discussed in the Issues and Decision Memorandum.[2] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The merchandise covered by the *Order* is welded carbon and alloy steel pipe (other than stainless steel pipe), more than 406.4 mm (16 inches) in nominal outside diameter (large diameter welded pipe), regardless of wall thickness, length, surface finish, grade, end finish, or stenciling. Imports of the product are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.1060, 7305.19.5000, 7305.31.4000, 7305.31.6090, 7305.39.1000 and 7305.39.5000. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive. For a complete description of the scope of the *Order,*

[7] For a complete description of the scope of the *Order, see* Memorandum ''Issues and Decision Memorandum for the Final Results of the Second Sunset Review of the Countervailing Duty Order on Narrow Woven Ribbons with Woven Selvedge from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[1] *See Large Diameter Welded Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2018—2020,* 86 FR 41010 (July 30, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results in the 2018–2020 Antidumping Duty Administrative Review: Diameter Welded Pipe from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Large Diameter Welded Pipe from the Republic of Korea: Amended Final Affirmative Antidumping Determinations and Antidumping Duty Orders,* 84 FR 18767 (May 2, 2019) (*Order*); *see also Large Diameter Welded Pipe from the Republic of Korea: Final Results of Antidumping Duty and Countervailing Duty Changed Circumstances Reviews,* 85 FR 51679 (August 21, 2020).

see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the parties' case and rebuttal briefs are addressed in the Issues and Decision Memorandum and are listed in Appendix I to this notice.[4] The Issues and Decision Memorandum is a public document and is on-file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we made no changes to our preliminary weighted-average dumping margin calculations for Hyundai RB Co., Ltd. (Hyundai RB) and Hyundai Steel Company (Hyundai Steel).

Rate for Non-Examined Respondents

The statute and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be determined for companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when determining the weighted-average dumping margin for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we calculated a weighted-average dumping margin for each of the mandatory respondents, Hyundai RB, and Hyundai Steel, that is zero percent. Where the rates for the individually examined companies are all zero, *de minimis,* or determined entirely using facts available, section 735(c)(5)(B) of the Act instructs that Commerce ''may use any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' One such reasonable method is to weight average the zero and *de minimis* rates, and the rates determined entirely pursuant to facts available. In fact, the SAA states that this is the ''expected'' method in such circumstances.[5] Accordingly, we have determined the weighted-average dumping margin for the eighteen companies that were not selected for individual examination based on the weighted average of the weighted-average dumping margins calculated for Hyundai RB and Hyundai Steel, *i.e.,* zero percent, consistent with section 735(c)(5)(B) of the Act. These are the only rates determined in this review for individually examined companies, and, thus, are applied to the eighteen firms not selected for individual examination.

Final Results of the Review

As a result of this review, we determine the following weighted-average dumping margins exist for the POR:

Exporter or producer	Weighted-average dumping margin (percent)
Hyundai RB Co., Ltd	0.00
Hyundai Steel Company	0.00
Non-Examined Companies[6]	0.00

Disclosure

Normally, Commerce discloses to the parties in a proceeding the calculations that it performed in connection with the final results of review in accordance with 19 CFR 351.224(b). However, because we made no changes to our preliminary weighted-average dumping margin calculations for Hyundai RB and Hyundai Steel, there are no calculations to disclose.

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review.[7] Because the weighted-average dumping margin for the companies listed above is zero percent, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[8]

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by Hyundai Steel or Hyundai RB for which these companies did not know that the merchandise that they sold to an intermediary company (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate the unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[9]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies listed above in the final results of this review will be equal to the weighted-average dumping margin established in the final results of this administrative review (*i.e.,* zero percent); (2) for previously investigated or reviewed companies not subject to this review, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other

[4] *See* Appendix I.

[5] *See* Statement of Administrative Action Accompanying the Uruguay Round Agreements Act, H.R. Doc. 103–316, vol. 1 (1994) (SAA) at 873.

[6] *See* Appendix II.

[7] *See* 19 CFR 351.212(b).

[8] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8102 (February 14, 2012).

[9] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

producers and exporters will continue to be 7.08 percent *ad valorem,* the all-others rate established in the LTFV investigation.[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

[10] *See Order.*

Appendix II

Companies Not Selected for Individual Examination

1. AJU Besteel Co., Ltd.
2. Chang Won Bending Co., Ltd.
3. Daiduck Piping Co., Ltd.
4. Dong Yang Steel Pipe Co., Ltd.
5. Dongbu Incheon Steel Co., Ltd.
6. EEW KHPC Co., Ltd.
7. EEW Korea Co., Ltd.
8. Histeel Co., Ltd.
9. Husteel Co., Ltd.
10. Kiduck Industries Co., Ltd.
11. Kum Kang Kind. Co., Ltd.
12. Kumsoo Connecting Co., Ltd.
13. Nexteel Co., Ltd.
14. SeAH Steel Corporation
15. Seonghwa Industrial Co., Ltd.
16. SIN–E B&P Co., Ltd.
17. Steel Flower Co., Ltd.
18. WELTECH Co., Ltd.

[FR Doc. 2021–26292 Filed 12–2–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–274–809]

Urea Ammonium Nitrate Solutions From the Republic of Trinidad and Tobago: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With the Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to the sole known producer/exporter of urea ammonium nitrate solutions (UAN) from the Republic of Trinidad and Tobago (Trinidad and Tobago) for the period of investigation (POI) January 1, 2020, through December 31, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Ariela Garvett, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3609.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on July 26, 2021.[1] On August 24, 2021, Commerce postponed the preliminary determination of this investigation to November 29, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is UAN from Trinidad and Tobago. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested party commented on the scope of this investigation as it appeared in the *Initiation Notice.*

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient,

[1] *See Urea Ammonium Nitrate Solutions from the Russian Federation and the Republic of Trinidad and Tobago: Initiation of Countervailing Duty Investigations,* 86 FR 40004 (July 26, 2021) (*Initiation Notice*).

[2] *See Urea Ammonium Nitrate Solutions from the Russian Federation and the Republic of Trinidad and Tobago: Postponement of Preliminary Determinations in the Countervailing Duty Investigations,* 86 FR 47296 (August 24, 2021).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Countervailing Duty Investigation of Urea Ammonium Nitrate Solutions from the Republic of Trinidad and Tobago,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 86 FR 40005.

and that the subsidy is specific.[6] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final determination in this countervailing duty (CVD) investigation with the final determination in the companion antidumping duty (AD) investigation of UAN from Trinidad and Tobago based on a request made by the petitioner.[7] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than April 11, 2022, unless postponed.

All-Others Rate

Sections 703(d)(1)(A)(i) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. Pursuant to section 705(c)(5)(A)(i) of the Act, this rate shall normally be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

Commerce calculated an individual estimated countervailable subsidy rate for Methanol Holdings (Trinidad) Limited (MHTL), the only individually examined producer/exporter in this investigation. Because the only individually calculated rate is not zero, *de minimis,* or based entirely on facts otherwise available, the rate calculated for MHTL is the rate assigned to all other producers and exporters not individually examined in this investigation, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate ad valorem (percent)
Methanol Holdings (Trinidad) Limited	1.83
All Others	1.83

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[8] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its determination. If Commerce's final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: November 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is all mixtures of urea and ammonium nitrate in aqueous or ammonia solution, regardless of nitrogen concentration by weight, and regardless of the presence of

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* Petitioner's Letter, ''Urea Ammonium Nitrate Solutions from the Republic of Trinidad and Tobago: Petitioner's Request to Align Final Countervailing Duty Determination with the Companion Antidumping Duty Final Determination,'' dated November 22, 2021. The petitioner is CF Industries Nitrogen, LLC and its subsidiaries, Terra Nitrogen, Limited Partnership and Terra International (Oklahoma) LLC.

[8] *See* 19 CFR 351.309; *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (*Temporary Rule*); and 19 CFR 351.303 (for general filing requirements).

[9] *See Temporary Rule,* 85 FR 17006; *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

additives, such as corrosion inhibiters and soluble micro or macronutrients (UAN).

Subject merchandise includes merchandise matching the above description that has been processed in a third country, including by commingling, diluting, adding or removing additives, or performing any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the subject country.

The scope also includes UAN that is commingled with UAN from sources not subject to these investigations. Only the subject component of such commingled products is covered by the scope of these investigations.

The covered merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 3102.80.0000. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2021–26314 Filed 12–2–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB572]

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Trawl Rationalization Program; 2022 Cost Recovery Fee Notice

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice, 2022 cost recovery fee percentages and average mothership cooperative program pricing.

SUMMARY: This action provides participants in the Pacific Coast Groundfish Trawl Rationalization Program with the 2022 cost recovery fee percentages and the average mothership (MS) price per pound to be used in the catcher/processor (C/P) coop program to calculate the fee amount for the upcoming calendar year. For the 2022 calendar year, NMFS announces the following fee percentages by sector specific program: 3.0 percent for the Shorebased Individual Fishing Quota (IFQ) Program; 0.2 percent for the C/P Co-op Program; and 1.7 percent for the MS Co-op Program. For 2022, the MS pricing to be used as a proxy by the C/P Co-op Program is $0.09/pound (lb) for Pacific whiting.

DATES: Applicable January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Keeley Kent, (206) 247–8252, *keeley.kent@noaa.gov.*

SUPPLEMENTARY INFORMATION: Section 304(d) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) authorizes and requires NMFS to collect fees to recover the costs directly related to the management, data collection and analysis, and enforcement directly related to and in support of a limited access privilege program (LAPP) (16 U.S.C. 1854(d)(2)), also called ''cost recovery.'' Cost recovery fees recover the actual costs directly related to the management, data collection and analysis, and enforcement of the programs (Section 303A(e)). Section 304(d) of the MSA mandates that cost recovery fees not exceed 3 percent of the annual ex-vessel value of fish harvested by a program subject to a cost recovery fee, and that the fee be collected either at the time of landing, filing of a landing report, or sale of such fish during a fishing season or in the last quarter of the calendar year in which the fish is harvested.

The Pacific Coast Groundfish Trawl Rationalization Program is a LAPP, implemented in 2011, and consists of three sector-specific programs: The Shorebased IFQ Program, the MS Co-op Program, and the C/P Co-op Program. In accordance with the MSA, and based on a recommended structure and methodology developed in coordination with the Pacific Fishery Management Council (Council), NMFS began collecting mandatory fees of up to 3 percent of the ex-vessel value of groundfish from each program (Shorebased IFQ Program, MS Co-op Program, and C/P Co-op Program) in 2014. NMFS collects the fees to recover the incremental costs of management, data collection and analysis, and enforcement of the Groundfish Trawl Rationalization Program. Additional background can be found in the cost recovery proposed rule (78 FR 7371; February 1, 2013), and final rule (78 FR 75268; December 11, 2013). The details of cost recovery for the Groundfish Trawl Rationalization Program are in regulation at 50 CFR 660.115 (Trawl fishery—cost recovery program), § 660.140 (Shorebased IFQ Program), § 660.150 (MS Co-op Program), and § 660.160 (C/P Co-op Program).

By December 31 of each year, NMFS announces the next year's fee percentages and the applicable MS pricing for the C/P Co-op Program. To calculate the fee percentages, NMFS used the formula specified in regulation at § 660.115(b)(1), where the fee percentage by sector equals the lower of 3 percent or the direct program costs (DPC) for that sector divided by total ex-vessel value (V) for that sector multiplied by 100 (Fee percentage = the lower of 3 percent or (DPC/V) × 100).

'DPC,' as defined in the regulations at § 660.115(b)(1)(i), are the actual incremental costs for the previous fiscal year directly related to the management, data collection and analysis, and enforcement of each program (Shorebased IFQ Program, MS Co-op Program, and C/P Co-op Program). Actual incremental costs means those net costs that would not have been incurred but for the implementation of the Groundfish Trawl Rationalization Program, including both increased costs for new requirements of the program and reduced costs resulting from any program efficiencies or adjustments to costs from previous years.

''V'', as specified at § 660.115(b)(1)(ii), is the total ex-vessel value, as defined at § 660.111, for each sector from the previous calendar year. To determine the ex-vessel value for the Shorebased IFQ Program, NMFS used the ex-vessel value for calendar year 2020 as reported in the Pacific Fisheries Information Network (PacFIN) from Shorebased IFQ electronic fish tickets as this was the most recent complete set of data. To determine the ex-vessel value for the MS Co-op Program and the C/P Co-op Program, NMFS used the retained catch estimates (weight) for each sector as reported in the North Pacific Observer Program database multiplied by the average price of Pacific whiting as reported by participants in the MS Co-op Program for 2020.

The fee calculations for the 2022 fee percentages are described below.

IFQ Program:

- 4.2 percent = ($1,689,034.21/$40,008,494.00) × 100.

C/P Co-op Program:

- 0.2 percent = ($35,958.08/$22,052,786.85) × 100.

MS Co-op Program:

- 1.7 percent = ($127,649.64/$7,367,454.90) × 100.

However, the calculated fee percentage cannot exceed the statutory limit of 3 percent. The IFQ Program fee calculation (4.2 percent) exceeds this limit, therefore, the 2022 fee percentage for the IFQ Program is 3 percent. Therefore, the final 2022 fee percentages are 3.0 percent for the IFQ Program, 0.2 percent for the C/P Co-op Program, and 1.7 percent for the MS Co-op Program.

MS Average Pricing

MS pricing is the average price per pound that the C/P Co-op Program will use to determine the fee amount due for that sector. The C/P sector value (V) is calculated by multiplying the retained catch estimates (weight) of Pacific whiting harvested by any vessel registered to a C/P-endorsed limited entry trawl permit by the MS pricing. NMFS has calculated the 2022 MS pricing to be used as a proxy by the CP Co-op Program as: $0.09/lb for Pacific whiting.

Cost recovery fees are submitted to NMFS by fish buyers via *Pay.gov* (*https://www.pay.gov/*). Fees are only accepted in *Pay.gov* by credit/debit card or bank transfers. Cash or checks cannot be accepted. Fish buyers registered with *Pay.gov* can login in the upper right-hand corner of the screen. Fish buyers not registered with *Pay.gov* can go to the cost recovery forms directly from the website below. The links to the *Pay.gov* forms for each program (IFQ, MS, or C/P) are listed below:

IFQ: *https://www.pay.gov/public/form/start/58062865;*

MS: *https://www.pay.gov/public/form/start/58378422;* and

C/P: *https://www.pay.gov/public/form/start/58102817.*

As stated in the preamble to the cost recovery proposed and final rules, in the spring of each year, NMFS will release an annual report documenting the details and data used for the fee percentage calculations. Annual reports are available at: *https://www.fisheries.noaa.gov/west-coast/sustainable-fisheries/west-coast-groundfish-trawl-catch-share-program#cost-recovery.*

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C.773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

Dated: November 30, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–26287 Filed 12–2–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB596]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of letter of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that a Letter of Authorization (LOA) has been issued to Anadarko Petroleum Corporation (Anadarko) for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico.

DATES: The LOA is effective from January 15, 2022, through July 15, 2022.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kim Corcoran, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322; January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take

authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

Anadarko plans to conduct a 4D Time Lapse Seismic Survey, using an airgun array as the sound source, in the vicinity of the Holstein spar in the Green canyon area, and in the vicinity of lease block GC 645. The planned survey is the latest in a time series of 3D narrow azimuth (NAZ) surveys. The array consists of 22 elements, with a total volume of 4,280 cubic inches (in^3). Please see Anadarko's application for additional detail.

Consistent with the preamble to the final rule, the survey effort proposed by Anadarko in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (86 FR 5322, 5398; January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) Survey type; (2) location (by modeling zone [1]); (3) number of days; and (4) season.[2] The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

Summary descriptions of available modeled survey geometries (*i.e.,* 2D, 3D NAZ, 3D WAZ, Coil) are available in the preamble to the proposed rule (83 FR 29212, 29220; June 22, 2018). 3D NAZ was selected as the best available proxy survey type because, as noted above, each iteration of the 4D survey is a 3D NAZ survey. The collection of 3D NAZ becomes a 4D ''time lapse'' once data is put together during the processing stage. Available acoustic exposure modeling results assume use of a 72 element, 8,000 in^3 array. In addition, the modeled 3D NAZ survey geometry assumes a significantly greater area covered per day than is planned to occur during Anadarko's survey. Therefore, in this case, estimated take numbers for this LOA are considered very conservative due to differences in both the airgun array and the survey geometry planned by Anadarko, as compared to those modeled for the rule.

The survey is planned to occur for 34 days in Zone 5. Survey activity is planned to begin in winter but effectiveness dates extend through summer. Therefore, the take estimates for each species are based on the season that has the greater value for the species (*i.e.,* winter or summer).

For some species, take estimates based solely on the modeling yielded results that are not realistically likely to occur when considered in light of other relevant information available during the rulemaking process regarding marine mammal occurrence in the GOM. Thus, although the modeling conducted for the rule is a natural starting point for estimating take, our rule acknowledged that other information could be considered (see, *e.g.,* 86 FR 5322, 5442 (January 19, 2021), discussing the need to provide flexibility and make efficient use of previous public and agency review of other information and identifying that additional public review is not necessary unless the model or inputs used differ substantively from those that were previously reviewed by NMFS and the public). For this survey, NMFS has other relevant information reviewed during the rulemaking that indicates use of the acoustic exposure modeling to generate a take estimate for certain marine mammal species produces results inconsistent with what is known regarding their occurrence in the GOM. Accordingly, we have adjusted the calculated take estimates for those species as described below.

Rice's whales (formerly known as GOM Bryde's whales) [3] are generally found within a small area in the northeastern GOM in waters between 100–400 meters (m) depth along the continental shelf break (Rosel *et al.,* 2016). Whaling records suggest that Rice's whales historically had a broader distribution within similar habitat parameters throughout the GOM (Reeves *et al.,* 2011; Rosel and Wilcox, 2014), and a NOAA survey reported observation of a Rice's whale in the western GOM in 2017 (NMFS, 2018). Habitat-based density modeling identified similar habitat (*i.e.,* approximately 100–400 m water depths along the continental shelf break) as being potential Rice's whale habitat (Roberts *et al.,* 2016), although a ''core habitat area'' defined in the northeastern GOM (outside the scope of the rule) contained approximately 92 percent of the predicted abundance of Rice's whales. See discussion provided at, *e.g.,* 83 FR 29212, 29228, 29280 (June 22, 2018); 86 FR 5322, 5418 (January 19, 2021).

Although it is possible that Rice's whales may occur outside of their core habitat, NMFS expects that any such occurrence would be limited to the narrow band of suitable habitat described above (*i.e.,* 100–400 m). Anadarko's planned activity will occur in water depths of approximately 1,100–1,400 m in the central GOM. NMFS does not expect there to be the reasonable potential for take of Rice's whale in association with this survey and, accordingly, does not authorize take of Rice's whale through this LOA.

Killer whales are the most rarely encountered species in the GOM, typically in deep waters of the central GOM (Roberts *et al.,* 2015; Maze-Foley and Mullin, 2006). The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. NMFS has determined that the approach results in unrealistic projections regarding the likelihood of encountering killer whales.

As discussed in the final rule, the density models produced by Roberts *et al.* (2016) provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. GOM. The predictions represent the output of models derived from multi-year observations and associated environmental parameters that incorporate corrections for detection bias. However, in the case of killer whales, the model is informed by few data, as indicated by the coefficient of variation associated with the abundance predicted by the model (0.41, the second-highest of any GOM species model; Roberts *et al.,* 2016). The model's authors noted the expected non-uniform distribution of this rarely-encountered species (as discussed above) and expressed that, due to the limited data available to inform the model, it ''should be viewed cautiously'' (Roberts *et al.,* 2015).

NOAA surveys in the GOM from 1992–2009 reported only 16 sightings of killer whales, with an additional three encounters during more recent survey effort from 2017–18 (Waring *et al.,* 2013; *www.boem.gov/gommapps*). Two other species were also observed on less than 20 occasions during the 1992–2009 NOAA surveys (Fraser's dolphin and false killer whale [4]). However, observational data collected by protected species observers (PSOs) on

[1] For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

[2] For purposes of acoustic exposure modeling, seasons include Winter (December–March) and Summer (April–November).

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

[4] However, note that these species have been observed over a greater range of water depths in the GOM than have killer whales.

industry geophysical survey vessels from 2002–2015 distinguish the killer whale in terms of rarity. During this period, killer whales were encountered on only 10 occasions, whereas the next most rarely encountered species (Fraser's dolphin) was recorded on 69 occasions (Barkaszi and Kelly, 2019). The false killer whale and pygmy killer whale were the next most rarely encountered species, with 110 records each. The killer whale was the species with the lowest detection frequency during each period over which PSO data were synthesized (2002–2008 and 2009–2015). This information qualitatively informed our rulemaking process, as discussed at 86 FR 5322, 5334 (January 19, 2021), and similarly informs our analysis here.

The rarity of encounter during seismic surveys is not likely to be the product of high bias on the probability of detection. Unlike certain cryptic species with high detection bias, such as *Kogia* spp. or beaked whales, or deep-diving species with high availability bias, such as beaked whales or sperm whales, killer whales are typically available for detection when present and are easily observed. Roberts *et al.* (2015) stated that availability is not a major factor affecting detectability of killer whales from shipboard surveys, as they are not a particularly long-diving species. Baird *et al.* (2005) reported that mean dive durations for 41 fish-eating killer whales for dives greater than or equal to 1 minute in duration was 2.3–2.4 minutes, and Hooker *et al.* (2012) reported that killer whales spent 78 percent of their time at depths between 0–10 m. Similarly, Kvadsheim *et al.* (2012) reported data from a study of four killer whales, noting that the whales performed 20 times as many dives to 1–30 m depth than to deeper waters, with an average depth during those most common dives of approximately 3 m.

In summary, killer whales are the most rarely encountered species in the GOM and typically occur only in particularly deep water. While this information is reflected through the density model informing the acoustic exposure modeling results, there is relatively high uncertainty associated with the model for this species, and the acoustic exposure modeling applies mean distribution data over areas where the species is in fact less likely to occur. NMFS' determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for killer whales would result in high estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected killer whale take (86 FR 5322, 5403; January 19, 2021).

In past authorizations, NMFS has often addressed situations involving the low likelihood of encountering a rare species such as killer whales in the GOM through authorization of take of a single group of average size (*i.e.,* representing a single potential encounter). See 83 FR 63268, December 7, 2018. See also 86 FR 29090, May 28, 2021; 85 FR 55645, September 9, 2020. For the reasons expressed above, NMFS determined that a single encounter of killer whales is more likely than the model-generated estimates and has authorized take associated with a single killer whale group encounter (*i.e.,* up to 7 animals).

Based on the results of our analysis, NMFS has determined that the level of taking authorized for each species in the LOA is consistent with the findings made for the total taking allowable under the regulations. See Table 1 in this notice and Table 9 of the rule (86 FR 5322; January 19, 2021).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed ''small numbers.'' In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS' discussion of the MMPA's small numbers requirement provided in the final rule (86 FR 5322, 5438; January 19, 2021).

The take numbers for authorization are determined as described above. Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than one day (see 86 FR 5322, 5404; January 19, 2021). The output of this scaling, where appropriate, is incorporated into an adjusted total take estimate that is the basis for NMFS' small numbers determination, as depicted in Table 1 for Anadarko's 34-day survey.

This product is used by NMFS in making the necessary small numbers determination, through comparison with the best available abundance estimates (see discussion at 86 FR 5322, 5391; January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock abundance reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and model-predicted abundance information (*https://seamap.env.duke.edu/models/Duke/GOM/*). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.,* three-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in Table 1.

TABLE 1—TAKE ANALYSIS

Species	Authorized take	Scaled take [1]	Abundance [2]	% abundance
Rice's whale [3]	0	n/a	51	0.0
Sperm whale	1,477	624.7	2,207	28.3
Kogia spp.	[4] 525	164.2	4,373	4.1
Beaked whales	6,779	684.7	3,768	18.2
Rough-toothed dolphin	980	281.15	4,853	5.8
Bottlenose dolphin	5,224	1,499.3	176,108	0.9
Clymene dolphin	3,104	890.82	11,895	7.5
Atlantic spotted dolphin	2,026	581.5	74,785	0.8
Pantropical spotted dolphin	14,085	4,042.5	102,361	3.9
Spinner dolphin	3,774	1,083.2	25,114	4.3

TABLE 1—TAKE ANALYSIS—Continued

Species	Authorized take	Scaled take [1]	Abundance [2]	% abundance
Striped dolphin	1,212	347.9	5,229	6.7
Fraser's dolphin	338	97.0	1,665	5.8
Risso's dolphin	934	275.5	3,764	7.3
Melon-headed whale	1,978	583.6	7,003	8.3
Pygmy killer whale	426	125.7	2,126	5.9
False killer whale	678	200.0	3,204	6.2
Killer whale	7	n/a	267	2.6
Short-finned pilot whale	572	168.8	1,981	8.5

[1] Scalar ratios were applied to ''Authorized Take'' values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.

[2] Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For the killer whale, the larger estimated SAR abundance estimate is used.

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

[4] Includes 13 takes by Level A harassment and 512 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

Based on the analysis contained herein of Anadarko's proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes and therefore is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to Anadarko authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: November 30, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–26311 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; High Seas Fishing Permit Application, Logbook Reporting and Vessel Marking

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 19, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: High Seas Fishing Permit Application, Logbook Reporting and Vessel Marking.

OMB Control Number: 0648–0304.

Form Number(s): None.

Type of Request: Regular [extension of a current information collection].

Number of Respondents: 600.

Average Hours per Response: Permit application with vessel photo, 30 minutes; request to authorize a fishery on the high seas, 40 hours; transshipment notices and reports, 1 hour; power-down and power-on requests, 10 minutes; observer notification, 5 minutes.

Total Annual Burden Hours: 151.

Needs and Uses: This request is for extension of a currently approved information collection. United States vessels that fish on the high seas (waters beyond the U.S. exclusive economic zone) are required to possess a permit issued under the High Seas Fishing Compliance Act (HSFCA). Applicants for this permit must submit information to identify their vessels, owners and operators of the vessels, and intended fishing areas.

The application information is used to process permits and to maintain a register of vessels authorized to fish on the high seas. The HSFCA also requires vessels be marked for identification and enforcement purposes. Vessels must be marked in three locations (port and starboard sides of the deckhouse or hull, and on a weather deck) with their official number or radio call sign. These requirements apply to all vessels fishing on the high seas.

Affected Public: Business or other for-profit organizations.

Frequency: Every five years or on occasion.

Respondent's Obligation: Mandatory.

Legal Authority: High Seas Fishing Compliance Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0304.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–26321 Filed 12–2–21; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add product(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete product(s) and service(s) previously furnished by such agencies.

DATES: Comments must be received on or before: January 02, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) and service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) and service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product(s)

NSN(s)—Product Name(s): MR 10814—Ice Ball Tray, Includes Shipper 20814
Designated Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Military Resale-Defense Commissary Agency
Mandatory for: The requirements of military commissaries and exchanges in accordance with the 41 CFR 51–6.4
Distribution: C-List

NSN(s)—Product Name(s):
8925–01–E62–6898—Syrup, Maple, Imitation, Thick
8925–01–E62–6897—Syrup, Maple, Imitation
Designated Source of Supply: Golden Rule Industries of Muskogee, Inc., Muskogee, OK
Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT
Mandatory for: 100% of the requirement of the Department of Defense
Distribution: C-List

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7510–01–579–9319—Binder, Removable Slant-D Rings, 100% Recyclable, Turned Edge, Black, 3'' Capacity, Letter
Designated Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA

NSN(s)—Product Name(s): 7510–01–579–9319—Binder, Removable Slant-D Rings, 100% Recyclable, Turned Edge, Black, 3'' Capacity, Letter
Designated Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Service(s)

Service Type: Furniture Design and Configuration Services
Mandatory for: New Hampshire National Guard, Newington, NH, 302 Newmarket Street Newington, NH
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: DEPT OF THE ARMY, W7NN USPFO ACTIVITY NH ARNG

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2021–26251 Filed 12–2–21; 8:45 am]

BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Proposed Information Collection; Comment Request; Application Package for NCCC Impact Evaluation

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service, operating as AmeriCorps, is proposing a renewal to expand the scope of the existing public information collection request (ICR) entitled NCCC Impact Evaluation to include COVID–19 vaccine distribution and related activities case studies.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 3, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable supporting documentation, may be obtained by calling Dr. Melissa Gouge, at 202–606–6736 or by email to *mgouge@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of AmeriCorps, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on September 4, 2021 at Vol. 86, No. 168, 49319. This comment period ended November 3. We received no public comment from this Notice.

Title of Collection: NCCC Impact Evaluation.

OMB Control Number: 3045–0189.

Type of Review: Renewal.

Respondents/Affected Public: Current and former AmeriCorps NCCC members, team leads, and project sponsors conducting COVID–19 vaccine distribution and related activities projects.

Total Estimated Number of Additional Responses: 210.

Total Estimated Number of Additional Burden Hours: 305 hours.

Abstract: NCCC program members have been a crucial part of AmeriCorps COVID–19 pandemic response as personnel on vaccine distribution mission assignments alongside FEMA and other agencies. No one could have anticipated the COVID–19 pandemic, but we have seized an opportunity to develop questions that build on the existing study but are specific to these ongoing activities.

These activities are an essential element of our agency's COVID–19 pandemic response—one that is also essential to our mission to improve lives and strengthen communities. To further our mission in a time of increasing uncertainty, we aim to collect information on current activity that must be measured now in order to assess, identify, and make any identified programmatic changes. Peak performance of these projects is crucial to our agency's COVID–19 pandemic response and public safety writ large.

COVID–19 vaccine delivery is of increasing importance as COVID–19 pandemic continues an unpredictable course. In time, we hope, the pandemic will subside, but it is crucial we analyze these mission assignments now to make improvements that will literally save lives. How will this save lives? Currently, just over 59% of Americans are fully vaccinated against the virus (Source: *CDC.gov,* accessed 11/29/2021). AmeriCorps NCCC members are increasing access to vaccines and related activities through their service. Vaccines have proven to decrease severity and fatalities from the COVID–19 virus. Programmatic improvements instituted ''in real time'' to enhance their efforts will lead to even greater access and a healthier public.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov.*

Dated: November 29, 2021.

Mary Hyde,

Director, Office of Research and Evaluation.

[FR Doc. 2021–26232 Filed 12–2–21; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF EDUCATION

Applications for New Awards; High School Equivalency Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2022 for the High School Equivalency Program (HEP), Assistance Listing Number 84.141A. This notice relates to the approved information collection under the Office of Management and Budget (OMB) control number 1894–0006.

DATES:

Applications Available: December 6, 2021.

Deadline for Transmittal of Applications: February 1, 2022.

Deadline for Intergovernmental Review: April 4, 2022.

Pre-Application Webinar Information: The Department will hold pre-application workshops via webinar for prospective applicants on Wednesday, December 8, 2021, at 1:30 p.m. Eastern Time. We will repeat the webinar on Thursday, December 9, 2021, at 1:30 p.m. Eastern Time.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Millicent Bentley-Memon, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E311, Washington, DC 20202. Telephone: (202) 401–1427. Email: *Millicent.Bentley-Memon@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The HEP is designed to assist migratory or seasonal farmworkers (or immediate family members of such workers) to obtain the equivalent of a secondary school diploma and subsequently to gain improved employment, enter into military service, or be placed in an institution of higher education (IHE) or other postsecondary education or training.

Priorities: This competition includes one competitive preference priority and one invitational priority. In accordance with 34 CFR75.105(b)(2)(iv), the competitive preference priority is from section 418A(e) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070d–2(e)).

Competitive Preference Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 15 points to an application, depending on how well the application meets this priority.

Consideration of Prior Experience. (Up to 15 points)

Projects that are expiring (current HEP grantees in their final budget period) will be considered for additional points under this competitive preference priority. In accordance with section 418A(e) of the HEA, the Department will award up to 15 points for this priority. In accordance with 34 CFR 206.31, the Secretary will consider the applicant's prior experience in implementing its expiring HEP project, based on information that includes:

(a) The number of HEP participants served;

(b) The percentage of HEP participants exiting the program having

received a High School Equivalency (HSE) diploma;

(c) The percentage of HSE diploma recipients who enter postsecondary education or training programs, upgraded employment, or the military; and

(d) The extent to which the applicant met administrative requirements.

Note: This competitive preference priority applies to expiring projects (current HEP grantees in their final budget period) that first received their current HEP award in FY 2017.

Invitational Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Meeting Student Social, Emotional, and Academic Needs.

Projects that are designed to improve students' social, emotional, academic, and career development through one or both of the following:

(a) Creating a supportive, positive, identity-safe, and inclusive climate for students who are migratory or seasonal farmworkers or immediate family members of such workers.

(b) Fostering partnerships, including across government agencies (*e.g.,* housing, human services, or employment agencies), local educational agencies, community-based organizations, adult learning providers, and postsecondary education institutions, to provide comprehensive services to students who are migratory or seasonal farmworkers, or immediate family members of such workers, to support student social, emotional, mental health and academic needs.

Definitions: The definitions of ''migrant farmworker'' and ''seasonal farmworker'' are from 34 CFR 206.5. The definitions of ''demonstrates a rationale,'' ''experimental study,'' ''logic model,'' ''project component,'' ''promising evidence,'' ''quasi-experimental design study,'' ''relevant outcome,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Migrant farmworker means a seasonal farmworker—as defined in this notice—whose employment required travel that precluded the farmworker from returning to his or her domicile (permanent place of residence) within the same day.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Seasonal farmworker means a person whose primary employment was in farmwork on a temporary or seasonal basis (that is, not a constant year-round activity) for a period of at least 75 days within the past 24 months.

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of

evidence as described in the WWC Handbooks documentation.

Program Authority: 20 U.S.C. 1070d–2.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 206. (e) The Migrant Education Program (MEP) definitions in 34 CFR 200.81. (f) The National Farmworker Jobs Program (NFJP) definitions in 20 CFR 685.110 and eligibility regulations in 20 CFR 685.320.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

Note: The MEP definitions and NFJP definitions and eligibility regulations apply to individuals seeking to qualify for HEP based on past participation in the MEP or NFJP.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $12,574,487 for new awards for this program for FY 2022. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $180,000–$475,000.

Estimated Average Size of Awards: $475,000.

Maximum Award: We will not make an award exceeding $475,000 for a single budget period of 12 months. Under 34 CFR 75.104(b) the Secretary may reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount.

Minimum Award: The Department will not make an award for less than the amount of $180,000 for a single budget period of 12 months. Under section 418A of the HEA, the Secretary is prohibited from making an award for less than the stated award amount. Therefore, we will reject any application that proposes a HEP award that is less than the stated minimum award amount.

Note: This approach is intended to promote fairness and transparency in the competitive process.

Estimated Number of Awards: 26.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months (five 12-month budget periods). Under section 418(e) of the HEA, except under extraordinary circumstances, the Secretary must award grants for a five-year period. Under 34 CFR 75.117(b), applicants must submit a budget narrative accompanied by a budget form prescribed by the Secretary that provides budget information for each budget period of the proposed project period. Therefore, we may reject any application that does not propose a five-year project period as reflected on the applicant's ED 524 form, Section A and budget narrative form, submitted as a part of the application.

III. Eligibility Information

1. *Eligible Applicants:* An IHE (as defined in section 101 and 102 of the HEA) or a private nonprofit (as those terms are defined in 34 CFR 77.1) organization may apply for a grant to operate a HEP project. If a private nonprofit organization other than an IHE applies for a HEP grant, that organization must plan the project in cooperation with an IHE and must propose to operate some aspects of the project with the facilities of that IHE.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and nonprofit organizations. The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee.

4. *Other:* Projects funded under this competition must budget for a three-day Office of Migrant Education annual meeting for HEP Directors in the Washington, DC area during each year of the project period. Such expenses are allowable uses of grant funds and may be included in the proposed project budget. This meeting may be held virtually if conditions warrant such format.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs,

published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application. Under 34 CFR 206.20, applicants are required to make additional submissions with their application. Those requirements are available at *www.ecfr.gov/current/title-34/subtitle-B/chapter-II/part-206/subpart-C/section-206.20.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for HEP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 25 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative. An application will not be disqualified if it exceeds the recommended page limit.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) Need for project (Up to 10 points).

(1) The Secretary considers the need for the proposed project.

(2) In determining the need for the proposed project, the Secretary considers the magnitude of the need for the services to be provided or the activities to be carried out by the proposed project. (Up to 10 points)

(b) Quality of the project design (Up to 24 points).

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (Up to 7 points)

(ii) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (Up to 5 points)

(iii) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population. (Up to 5 points)

(iv) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (Up to 7 points)

(c) Quality of project services (Up to 24 points).

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 3 points)

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (Up to 7 points)

(ii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services. (Up to 7 points)

(iii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services. (Up to 7 points)

(d) Quality of project personnel (Up to 10 points).

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 3 points)

(3) In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel. (Up to 7 points)

(e) Adequacy of resources. (Up to 12 points).

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization. (Up to 4 points)

(ii) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project. (Up to 4 points)

(iii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (Up to 4 points)

(f) Quality of the project evaluation. (Up to 20 points).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (Up to 10 points)

(ii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (Up to 5 points)

(iii) The extent to which the methods of evaluation will, if well implemented, produce promising evidence (as defined in this notice) about the project's effectiveness. (Up to 5 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Additional factors we consider in selecting an application for an award are in section 418A of the HEA. In accordance with section 418A, the Secretary makes HEP awards based on the number, quality, and promise of the applications. Additionally, in accordance with section 418A, if final FY 2022 HEP and College Assistance Migrant Program appropriations exceed $40,000,000, the Secretary will consider the need to provide an equitable geographic distribution of HEP awards. The Secretary may consider the need to provide equitable geographic distribution of HEP awards when—

1. Two or more applicants receive the same score at the funding cutoff for this competition;

2. The Secretary determines that a geographic region is overserved by current HEP projects;

3. The Secretary determines that a geographic region is underserved by current HEP projects; or

4. Two or more applicants propose to operate similar HEP projects in the same geographical region.

When evaluating a potentially overserved or underserved geographic region, the Secretary may consider factors such as migrant or seasonal farmworker population data for a State or region, approximate distance between current and proposed projects, the type of entity of the current or proposed project (*e.g.,* private nonprofit organization, 2-year IHE, 4-year IHE), and the number of students proposed to be served by the current or proposed HEP project.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the

terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 (GPRA) and reporting under 34 CFR 75.110, the Department developed the following performance measures to evaluate the overall effectiveness of HEP: (1) The percentage of HEP participants exiting the program having received a HSE diploma (GPRA 1), and (2) the percentage of HSE diploma recipients who enter postsecondary education or training programs, upgraded employment, or the military (GPRA 2).

Applicants must propose annual targets for these measures and establish annual student enrollment targets in their applications. Applicants should identify these targets within their application abstracts. The national target for GPRA 1 for FY 2022 is that 69 percent of HEP participants exit the program having received an HSE credential. The national target for GPRA 2 for FY 2022 is that 80 percent of HEP HSE diploma recipients will enter postsecondary education or training programs, upgraded employment, or the military. The national targets for subsequent years may be adjusted based on additional baseline data.

Peer reviewers evaluate how well applicants propose to meet their application's goals and objectives. Peer reviewers will score related selection criteria on the basis of how well an applicant addresses these GPRA measures in addition to any other goals and objectives included in the application. Therefore, applicants will want to consider how to demonstrate a sound capacity to provide reliable data on the GPRA measures, including the project's annual performance targets for addressing the GPRA performance measures, as is required by the OMB-approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these GPRA performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF), text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the authority to perform the functions and duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021–26267 Filed 12–2–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; College Assistance Migrant Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2022 for the College Assistance Migrant Program (CAMP), Assistance Listing Number 84.149A. This notice relates to the approved information collection under the Office of Management and Budget (OMB) control number 1894–0006.

DATES:

Applications Available: December 6, 2021.

Deadline for Transmittal of Applications: February 1, 2022.

Deadline for Intergovernmental Review: April 4, 2022.

Pre-Application Webinar Information: The Department will hold pre-application workshops via webinar for prospective applicants on Wednesday, December 8, 2021, at 1:30 p.m. Eastern Time. We will repeat the webinar on Thursday, December 9, 2021, at 1:30 p.m. Eastern Time.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at

www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.

FOR FURTHER INFORMATION CONTACT: Millicent Bentley-Memon, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E311, Washington, DC 20202. Telephone: (202) 401–1427. Email: *Millicent.Bentley-Memon@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The CAMP is designed to assist migratory or seasonal farmworkers (or immediate family members of such workers) who are enrolled or are admitted for enrollment on a full-time basis at an institution of higher education (IHE) to complete their first academic year.

Priorities: This competition includes one competitive preference priority and one invitational priority. In accordance with 34 CFR 75.105(b)(2)(iv), the competitive preference priority is from section 418A(e) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070d–2(e)).

Competitive Preference Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 15 points to an application, depending on how well the application meets this priority.

Consideration of Prior Experience. (Up to 15 points)

Projects that are expiring (current CAMP grantees in their final budget period) will be considered for additional points under this competitive preference priority. In accordance with section 418A(e) of the HEA, the Department will award up to 15 points for this priority. In accordance with 34 CFR 206.31, the Secretary will consider the applicant's prior experience in implementing its expiring CAMP project, based on information that includes:

(a) The number of CAMP participants served;

(b) The percentage of CAMP participants completing the first academic year of their postsecondary education program;

(c) The percentage of CAMP participants who, after completing the first academic year of college, continue their postsecondary education; and

(d) The extent to which the applicant met administrative requirements.

Note: This competitive preference priority applies to expiring projects (current CAMP grantees in their final budget period) that first received their current CAMP award in FY 2017.

Invitational Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Meeting Student Social, Emotional, and Academic Needs.

Projects that are designed to improve students' social, emotional, academic, and career development, with a focus on underserved students, through one or both of the following:

(a) Creating a supportive, positive, identity-safe, and inclusive climate for students who are migratory or seasonal farmworkers or immediate family members of such workers.

(b) Fostering partnerships, including across government agencies (*e.g.,* housing, human services or employment agencies), local educational agencies, community-based organizations, adult learning providers, and postsecondary education institutions, to provide comprehensive services to students who are migratory or seasonal farmworkers or immediate family members of such workers, to support student social, emotional, mental health and academic needs.

Definitions: The definitions of ''migrant farmworker'' and ''seasonal farmworker'' are from 34 CFR 206.5. The definitions of ''demonstrates a rationale,'' ''experimental study,'' ''logic model,'' ''project component,'' ''promising evidence,'' ''quasi-experimental design study,'' ''relevant outcome,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Migrant farmworker means a seasonal farmworker—as defined in this notice—whose employment required travel that precluded the farmworker from returning to his or her domicile (permanent place of residence) within the same day.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the

corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Seasonal farmworker means a person whose primary employment was in farmwork on a temporary or seasonal basis (that is, not a constant year-round activity) for a period of at least 75 days within the past 24 months.

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Program Authority: 20 U.S.C. 1070d–2.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 206. (e) The Migrant Education Program (MEP) definitions in 34 CFR 200.81. (f) The National Farmworker Jobs Program (NFJP) definitions in 20 CFR 685.110 and eligibility regulations in 20 CFR 685.320.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

Note: The MEP definitions and NFJP definitions and eligibility regulations apply to individuals seeking to qualify for CAMP based on past participation in the MEP or NFJP.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $13,800,166 for new awards for this program for FY 2022. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $180,000–$475,000.

Estimated Average Size of Awards: $475,000.

Maximum Award: We will not make an award exceeding $475,000 for a single budget period of 12 months. Under 34 CFR 75.104(b) the Secretary may reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount.

Minimum Award: The Department will not make an award for less than the amount of $180,000 for a single budget period of 12 months. Under section 418A of the HEA, the Secretary is prohibited from making an award for less than the stated award amount. Therefore, we will reject any application that proposes a CAMP award that is less than the stated minimum award amount.

Note: This approach is intended to promote fairness and transparency in the competitive process.

Estimated Number of Awards: 29.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months (five 12-month budget periods). Under section 418(e) of the HEA, except under extraordinary circumstances, the Secretary must award grants for a five-year period. Under 34 CFR 75.117(b), applicants must submit a budget narrative accompanied by a budget form prescribed by the Secretary that provides budget information for each budget period of the proposed project period. Therefore, we may reject any application that does not propose a five-year project period as reflected on the applicant's ED 524 form, Section A and budget narrative form, submitted as a part of the application.

III. Eligibility Information

1. *Eligible Applicants:* An IHE (as defined in section 101 and 102 of the HEA) or a private nonprofit (as those terms are defined in 34 CFR 77.1) organization may apply for a grant to operate a CAMP project. If a private nonprofit organization other than an IHE applies for a CAMP grant, that organization must plan the project in cooperation with an IHE and must propose to operate the project with the facilities of that IHE.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that

the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and nonprofit organizations. The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee.

4. *Other:* Projects funded under this competition must budget for a three-day Office of Migrant Education annual meeting for CAMP Directors in the Washington, DC area during each year of the project period. Such expenses are allowable uses of grant funds and may be included in the proposed project budget. This meeting may be held virtually if conditions warrant such format.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application. Under 34 CFR 206.20, applicants are required to make additional submissions with their application. Those requirements are available at *www.ecfr.gov/current/title-34/subtitle-B/chapter-II/part-206/subpart-C/section-206.20.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for CAMP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 25 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative. An application will not be disqualified if it exceeds the recommended page limit.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) Need for project (Up to 10 points).

(1) The Secretary considers the need for the proposed project.

(2) In determining the need for the proposed project, the Secretary considers the magnitude of the need for the services to be provided or the activities to be carried out by the proposed project. (Up to 10 points)

(b) Quality of the project design (Up to 24 points).

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (Up to 7 points)

(ii) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (Up to 5 points)

(iii) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population. (Up to 5 points)

(iv) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (Up to 7 points)

(c) Quality of project services (Up to 24 points).

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are

members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 3 points)

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (Up to 7 points)

(ii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services. (Up to 7 points)

(iii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services. (Up to 7 points)

(d) Quality of project personnel (Up to 10 points).

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 3 points)

(3) In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel. (Up to 7 points)

(e) Adequacy of resources. (Up to 12 points).

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization. (Up to 4 points)

(ii) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project. (Up to 4 points)

(iii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (Up to 4 points)

(f) Quality of the project evaluation. (Up to 20 points).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (Up to 10 points)

(ii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (Up to 5 points)

(iii) The extent to which the methods of evaluation will, if well implemented, produce promising evidence (as defined in this notice) about the project's effectiveness. (Up to 5 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Additional factors we consider in selecting an application for an award are in section 418A of the HEA. In accordance with section 418A, the Secretary makes CAMP awards based on the number, quality, and promise of the applications. Additionally, in accordance with section 418A, if the final FY 2022 CAMP and High School Equivalency Program appropriations exceed $40,000,000, the Secretary will consider the need to provide an equitable geographic distribution of CAMP awards. The Secretary may consider the need to provide equitable geographic distribution of CAMP awards when—

1. Two or more applicants receive the same score at the funding cutoff for this competition;

2. The Secretary determines that a geographic region is overserved by current CAMP projects;

3. The Secretary determines that a geographic region is underserved by current CAMP projects; or

4. Two or more applicants propose to operate similar CAMP projects in the same geographical region.

When evaluating a potentially overserved or underserved geographic region, the Secretary may consider factors such as migrant or seasonal farmworker population data for a State or region, approximate distance between current and proposed projects, the type of entity of the current or proposed project (*e.g.,* private nonprofit organization, 2-year IHE, 4-year IHE), and the number of students proposed to be served by the current or proposed CAMP project.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 (GPRA) and reporting under 34 CFR 75.110, the Department developed the following performance measures to evaluate the overall effectiveness of CAMP: (1) The percentage of CAMP participants completing the first academic year of their postsecondary program, and (2) the percentage of CAMP participants who, after completing the first academic year of college, continue their postsecondary education.

Applicants must propose annual targets for these measures and establish annual student enrollment targets in their applications. Applicants should identify these targets within their application abstracts. The national target for GPRA measure 1 for FY 2022 is that 86 percent of CAMP participants will complete the first academic year of their postsecondary program. The national target for GPRA measure 2 for FY 2022 is that 92 percent of CAMP participants continue their postsecondary education after completing the first academic year of college. The national targets for subsequent years may be adjusted based on additional baseline data.

Peer reviewers evaluate how well applicants propose to meet their application's goals and objectives. Peer reviewers will score related selection criteria on the basis of how well an applicant addresses these GPRA measures in addition to any other goals and objectives included in the application. Therefore, applicants will want to consider how to demonstrate a sound capacity to provide reliable data on the GPRA measures, including the project's annual performance targets for addressing the GPRA performance measures, as is required by the OMB-approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these GPRA performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF), text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at

www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policies and Programs, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary Office of Elementary and Secondary Education.

[FR Doc. 2021–26270 Filed 12–2–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–15–000.

Applicants: New York Power Authority.

Description: Petition for Declaratory Order of New York Power Authority.

Filed Date: 11/23/21.

Accession Number: 20211123–5231.

Comment Date: 5 p.m. ET 12/23/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–231–001.

Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.

Description: Tariff Amendment: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.17(b): 2021–11–29_SA 3730 ATC-New Glarus Sub D–T to be effective 12/28/2021.

Filed Date: 11/29/21.

Accession Number: 20211129–5229.

Comment Date: 5 p.m. ET 12/20/21.

Docket Numbers: ER22–484–000.

Applicants: Ford County Wind Farm LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 12/1/2021.

Filed Date: 11/29/21.

Accession Number: 20211129–5185.

Comment Date: 5 p.m. ET 12/20/21.

Docket Numbers: ER22–485–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ISA, SA No. 4881; Queue No. AA2–017 to be effective 12/11/2021.

Filed Date: 11/29/21.

Accession Number: 20211129–5210.

Comment Date: 5 p.m. ET 12/20/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–26280 Filed 12–2–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–345–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: SCRM Filing Nov 2021 to be effective 1/1/2022.

Filed Date: 11/29/21.

Accession Number: 20211129–5087.

Comment Date: 5 p.m. ET 12/13/21.

Docket Numbers: RP22–346–000.

Applicants: Trunkline Gas Company, LLC.

Description: § 4(d) Rate Filing: Update GT&C Section 6 to be effective 1/1/2022.

Filed Date: 11/29/21.

Accession Number: 20211129–5116.

Comment Date: 5 p.m. ET 12/13/21.

Docket Numbers: RP22–347–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Quarterly Fuel and Lost and Unaccounted For Update Filing to be effective 1/1/2022.

Filed Date: 11/29/21.

Accession Number: 20211129–5130.

Comment Date: 5 p.m. ET 12/13/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–26278 Filed 12–2–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–17–000]

Rio Grande LNG, LLC; Notice of Application for Limited Amendment and Establishing Intervention Deadline

Take notice that on November 17, 2021, Rio Grande LNG, LLC (RGLNG), 1000 Louisiana Street, 39th Floor, Houston, TX 77002, filed an application under section 3(a) of the Natural Gas Act (NGA) requesting to amend its November 22, 2019 Authorization Order [1] to incorporate carbon capture and sequestration systems into the approved site and design of the RGLNG Terminal.[2] RGLNG states that

[1] *Rio Grande LNG, LLC,* 169 FERC ¶ 61,131 (2019), *order on reh'g,* 170 FERC ¶ 61,046 (2020).

[2] The RGLNG terminal site (approximately 1,000 acres) is located on the north embankment of the

Continued

construction and operation of the carbon capture and sequestration systems will enable it to capture and sequester at least 90% of the carbon dioxide (CO2) produced at the RGLNG Terminal. Once captured, RGLNG would transport the CO2, via pipeline, to an underground geologic formation permitted by the Environmental Protection Agency and relevant Texas State agencies under its underground injection control Class VI permitting program for geologic sequestration.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding the proposed project should be directed to Ivan Van der Walt, Chief Operating Officer, Rio Grande LNG, LLC, 1000 Louisiana Street, 39th Floor, Houston, TX 77002, 832–356–3015, *ivanderwalt@next-decade.com*; or

David L. Wochner, K&L Gates LLP, 1601 K Street, NW, Washington, DC, 20006, 202–778–9000, *David.Wochner@klgates.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[3] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Brownsville Ship Channel in Cameron County, Texas and, once constructed, will consist primarily of five natural gas liquefaction trains, four full-containment LNG storage tanks, two LNG carrier loading berths, one 1,500-foot-diameter turning basin, LNG truck loading and unloading facilities, two Natural Gas Liquids (NGL) truck loading bays, and other support structures such as administrative buildings, a central control building, and communication systems.

[3] 18 CFR (Code of Federal Regulations) 157.9.

Public Participation

There are two ways to become involved in the Commission's review of this project: You can file comments on the project, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 20, 2021.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 20, 2021.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number CP22–17–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address below . Your written comments must reference the Project docket number (CP22–17–000).

To mail via USPS, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[4] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is December 20, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as the your interest in the proceeding. [For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have

[4] 18 CFR 385.102(d).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

property directly impacted by the project in order to intervene.] For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP22–17–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP22–17–000.

To mail via USPS, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Motions to intervene must be served on the applicant either by mail or email at: 1000 Louisiana Street, 39th Floor, Houston, TX 77002 or at *ivanderwalt@next-decade.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [7] motions to intervene are automatically granted by operation of Rule 214(c)(1).[8] Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[9] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on December 20, 2021.

Dated: November 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–26279 Filed 12–2–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9059–6]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed November 19, 2021 10 a.m. EST Through November 29, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210178, Final, USFWS, OR, Final Bighorn Sheep Management Plan Environmental Impact Statement, Review Period Ends: 01/03/2022, Contact: Shannon Ludwig 541–947–3315.

EIS No. 20210179, Draft, Caltrans, CA, Cajalco Road Widening and Safety Enhancement Project, Comment Period Ends: 01/18/2022, Contact: Aaron Burton 909–383–2841.

EIS No. 20210180, Final, NOAA, CT, Connecticut National Estuarine Research Reserve, Review Period Ends: 01/03/2022, Contact: Erica Seiden 240–533–0781.

EIS No. 20210181, Final, FRA, NY, Western Rail Yard Infrastructure Project, Contact: Marlys Osterhues 617–494–2147.

Under 23 U.S.C. 139(n)(2), FRA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

Dated: November 29, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–26285 Filed 12–2–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Interpretation 11, Debt Cancellation: An Interpretation of SFFAS 7, Paragraph 313

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued Interpretation of Federal Financial Accounting Standards 11, *Debt Cancellation: An Interpretation of SFFAS 7, Paragraph 313.*

ADDRESSES: The issuance is available on the FASAB website at *https://fasab.gov/accounting-standards/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

[7] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[8] 18 CFR 385.214(c)(1).

[9] 18 CFR 385.214(b)(3) and (d).

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. app.), and the FASAB Rules of Procedure, as amended in October 2010.

Dated: November 29, 2021.

Monica R. Valentine,

Executive Director.

[FR Doc. 2021–26296 Filed 12–2–21; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0392; FR ID 60601]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 1, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0392.

Title: 47 CFR 1 Subpart J—Pole Attachment Complaint Procedures.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Businesses or other for-profit.

Number of Respondents and Responses: 1,760 respondents; 1,760 responses.

Estimated Time per Response: 0.50 hours (30 minutes)—75 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 224.

Total Annual Burden: 2,759 hours.

Total Annual Cost: $15,000.

Privacy Act Impact Assessment: No privacy impact(s).

Nature and Extent of Confidentiality: No questions of a confidential nature are asked. However, respondents may request that materials or information submitted to the Commission in a complaint proceeding be withheld from public inspection under 47 CFR 0.459.

Needs and Uses: Currently, OMB Collection No. 3060–0392, tracks the burdens associated with requests for access to a utility's poles as well as the filing of complaints and petitions for stay against the actions of said utility. The Commission will use the information collected to assess whether the petition or complaint can proceed as a docketed case.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–26295 Filed 12–2–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Privacy Act of 1974; System of Records

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the FDIC is establishing FDIC–037, FDITECH Information. This system of records maintains information collected by FDITECH, FDIC's innovation arm. FDITECH is the focal point for the FDIC's efforts to promote responsible innovation in the financial services sector. Through partnerships and engagements, FDITECH allows innovators to engage with the FDIC, provide ideas, and assist the FDIC in the implementation of innovative technology ideas.

DATES: This action will become effective on December 3, 2021. The routine uses in this action will become effective on January 3, 2022, unless the FDIC makes changes based on comments received. Written comments should be submitted on or before January 3, 2022.

ADDRESSES: Interested parties are invited to submit written comments identified by Privacy Act Systems of Records by any of the following methods:

- *Agency website: https://www.fdic.gov/resources/regulations/federal-register-publications/index.html.* Follow the instructions for submitting comments on the FDIC website.
- *Email: Comments@fdic.gov.*
- *Mail:* Shannon Dahn, Chief, Privacy Program, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Shannon Dahn, Chief, Privacy Program, (703) 516–5500, *privacy@fdic.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act of 1974, FDIC is establishing a new system of records, FDIC–037 FDITECH Information. FDITECH promotes FDIC's mission to maintain stability and public confidence in the nation's financial system by promoting the adoption of innovative and transformative technologies in the financial services sector. FDITECH works with private sector innovators and its regulatory partners to help lay the foundation for the future of banking. Its staff engages across the financial and non-financial sectors to encourage and help facilitate the development of technology-driven capabilities that create safer banks, provide consumers better and safer choices, and make the FDIC more efficient.

Through partnerships and engagements with universities,

companies, and private citizens, FDITECH allows innovators to engage with the FDIC, provide ideas, and assist the FDIC in the implementation of innovative technology ideas. As part of the engagement process, FDIC may review information to ensure that prospective participants and partners do not have conflicts or issues that may disqualify them from working with the FDIC. This SORN describes information collected from individuals who seek information or seek to participate in activities hosted by FDITECH.

SYSTEM NAME AND NUMBER:

FDITECH Information, FDIC–037.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The systems of record is located on the FDIC intranet. Duplicate systems may exist, in whole or in part, at secure sites and on secure servers maintained by third-party service providers for the FDIC.

SYSTEM MANAGER(S):

Chief Innovation Officer, 3501 N. Fairfax Drive, Arlington, VA 22226, *innovation@fdic.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

12 U.S.C. 1819(a), 1820(a); 15 U.S.C. 3719, as amended.

PURPOSE(S) OF THE SYSTEM:

FDIC collects the information in this system of record to facilitate an individual's participation in projects and programs hosted by FDITECH. FDIC may use the information collected to communicate and collaborate with interested individuals or entities on FDITECH initiatives and to ensure that any individuals are eligible to work with the FDIC or participate in FDITECH activities. Additionally, FDIC may use the information to follow up with individuals who interact with FDITECH for future collaboration.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who request information from FDITECH or participate or partner in FDITECH initiatives.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records includes: Name; phone number; email address; current or previous organizational or institutional affiliation; areas of expertise (*e.g.,* developer, designer, data scientist); relevant work experience; eligibility check results; industry type.

RECORD SOURCE CATEGORIES:

The information in this system is collected in part directly from the individual or submitted on behalf of an individual by a team lead. Information may also be collected from FDIC source systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside the FDIC as a routine use as follows:

(1) To appropriate Federal, State, local and foreign authorities responsible for investigating or prosecuting a violation of, or for enforcing or implementing a statute, rule, regulation, or order issued, when the information indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto;

(2) To a court, magistrate, or other administrative body in the course of presenting evidence, including disclosures to counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal proceedings, when the FDIC is a party to the proceeding or has a significant interest in the proceeding, to the extent that the information is determined to be relevant and necessary;

(3) To a congressional office in response to an inquiry made by the congressional office at the request of the individual who is the subject of the record;

(4) To appropriate agencies, entities, and persons when (a) the FDIC suspects or has confirmed that there has been a breach of the system of records; (b) the FDIC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the FDIC (including its information systems, programs, and operations), the Federal Government, or national security; the FDIC and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the FDIC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm;

(5) To another Federal agency or Federal entity, when the FDIC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(6) To other U.S. and international financial regulators, when necessary to facilitate regulatory discussions around technology innovations.

(7) To participants of FDITECH initiatives and other entities, to the extent that the disclosure facilitates collaboration and discussion around technology innovation.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Electronic media are indexed and retrieved by team name, program name, individual name, organization, and industry type.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Registration records and any other associated records are retained for 5 years. Disposal is by deletion or other appropriate disposal methods.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records are access restricted and accessible only by authorized personnel according to a need to know.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to records about them in this system of records must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must include full name, address, and verification of identity in accordance with FDIC regulations at 12 CFR part 310.

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest or request an amendment to their records in this system of records must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must specify the information being contested, the reasons for contesting it, and the proposed amendment to such information in accordance with FDIC regulations at 12 CFR part 310.

NOTIFICATION PROCEDURES:

Individuals wishing to know whether this system contains information about them must submit their request in writing to the FDIC FOIA & Privacy Act Group, 550 17th Street NW, Washington, DC 20429, or email *efoia@fdic.gov.* Requests must include full name, address, and verification of identity in accordance with FDIC regulations at 12 CFR part 310.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 30, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–26259 Filed 12–2–21; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 20, 2021.

A. *Federal Reserve Bank of Kansas City* (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Susan Johnson, Colorado Springs, Colorado; Charles Vasilius and Stephanie Vasilius, both of Denver, Colorado; Nicholas Vasilius, Kirkland, Washington; and Alexandra Pitnell, Pittsford, New York;* to join the Dwan/Vasilius Family Group, a group acting in concert, to retain voting shares of Central Bancorp, Inc., Colorado Springs, Colorado, and thereby indirectly retain voting shares of Farmers & Stockmens Bank, Clayton, New Mexico.

Also, the *Charles J. Vasilius Trust, the Janet M. Vasilius Trust, and Justin Leveille, individually, and as trustee to both trusts,* and *the Susan Dwan Johnson Trust, the Elizabeth Dwan McNamara Trust, the Patricia Dwan Smith Trust, the Clare Dwan Harting Trust, the Kathleen Dwan Trust, the Ann T. Dwan Trust, and Tim Coutts, individually, and as trustee to each of the 5 trusts, and all of Colorado Springs, Colorado* to join the Dwan/Vasilius Family Group, a group acting in concert, to acquire additional voting shares of Central Bancorp, Inc., and thereby indirectly acquire additional voting shares of Farmers & Stockmens Bank.

Board of Governors of the Federal Reserve System, November 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26226 Filed 12–2–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Recordkeeping and Disclosure Requirements Associated with Regulation Y for Minimum Requirements for Appraisal Management Companies (FR HY–5; OMB No. 7100–0370).

DATES: Comments must be submitted on or before February 1, 2022.

ADDRESSES: You may submit comments, identified by FR HY–5, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: The Recordkeeping and Disclosure Requirements Associated with Regulation Y for Minimum Requirements for Appraisal Management Companies.

Agency form number: FR HY–5.

OMB control number: 7100–0370.

Frequency: Event-generated.

Respondents: The FR HY–5 panel comprises federally regulated and state regulated appraisal management companies (AMCs) and U.S. states, except that AMCs that oversee 15 or fewer appraisers in a state or less than 25 appraisers in two or more states are exempt from these recordkeeping and disclosure requirements.

Estimated number of respondents: Section 225.193(a), 1; Section 225.192(b), 1,239; Section 225.193(b), 1,146; Section 225.195(c), 13; Section 225.196, 51.

Estimated average hours per response: Section 225.193(a), 40; Section 225.192(b), 0.08; Section 225.193(b), 1; Section 225.195(c), 2; Section 225.196, 1.

Estimated annual burden hours: Section 225.193(a), 40; Section 225.192(b), 99; Section 225.193(b), 2,292; Section 225.195(c), 26; Section 225.196, 51.

General description of report: The Board's recordkeeping and disclosure requirements associated with the minimum requirements for AMCs are found in sections 225.192, 225.193, 225.195, and 225.196 of the Board's Regulation Y, Subpart M.

Pursuant to section 225.193(a), each participating state must establish and maintain within its appraiser certifying and licensing agency a registration and supervision program with the legal authority and mechanisms to, among other things, review and approve or deny an AMC's application for initial registration; require AMCs to submit reports, information, and documents; and report violations of appraisal-related laws, regulations, or orders, as well as disciplinary and enforcement actions, to the Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council.

Section 225.192(b) provides that an appraiser in an AMC's network or panel is deemed to remain a part of the AMC's appraiser panel until the AMC (1) sends a written notice to the appraiser removing the appraiser with an explanation or (2) receives a written notice from the appraiser asking to be removed or a notice of the death or incapacity of the appraiser. Section 225.193(b) requires each participating state to require non-federally regulated AMCs to register with the state appraiser certifying and licensing agency.

Section 225.195(c) requires a federally regulated AMC to report to the state or states in which it operates the information required to be submitted by the state pursuant to the ASC's policies regarding the determination of the AMC National Registry fee, including information relating to certain ownership limitations in the regulation.

Section 225.196 requires that each participating state submit to the ASC the information required to be submitted by the ASC regulations or guidance concerning AMCs that operate in the state.

Legal authorization and confidentiality: The Financial Institutions Reform, Recovery, and Enforcement Act of 1989 authorizes the FR HY–5. Agencies must ''jointly, by rule, establish minimum requirements to be applied by a State in the registration of [AMCs].'' [1] The Agencies further must ''jointly promulgate regulations for the reporting of the activities of [AMCs] to the [ASC] in determining the payment of the annual registry fee.'' [2] Each participating state with an appraiser certifying and licensing agency must also transmit to the ASC ''[1] a roster listing individuals who have received a State certification or license . . . [2] reports on the issuance and renewal of licenses and certifications, sanctions, disciplinary actions, and license and certification revocations, and license and certification suspensions on a timely basis to the national registry of the [ASC] . . . [3] including investigations initiated and disciplinary actions taken.'' [3]

The HY–5 reporting and recordkeeping requirements are required to obtain a benefit for states because AMCs, unless they are owned and controlled by a federally regulated depository institution, are barred from providing appraisal management services for federally related transactions in a state that has not adopted the minimum AMC requirements.[4] The FR HY–5 recordkeeping and disclosure requirements are mandatory for an AMC that is: (1) An AMC that is a subsidiary owned and controlled by a financial institution and regulated by a federal financial institution regulatory agency,[5] or (2) is registered with a state that has a state appraiser certifying and licensing agency.

The Federal Reserve does not collect information subject to the HY–5 recordkeeping and reporting requirements. If information subject to the HY–5 requirements is obtained as part of an examination or supervision of a financial institution, it may be considered confidential under exemption 8 of the Freedom of Information Act (FOIA).[6] Information subject to the HY–5 requirements may also be kept confidential under FOIA

[1] 12 U.S.C. 3353(a).

[2] 12 U.S.C. 3353(e).

[3] 12 U.S.C. 3338(a).

[4] 12 U.S.C. 3353.

[5] 12 U.S.C. 3353(c).

[6] 5 U.S.C. 552(b)(8).

exemption 4 if it is confidential commercial or financial information that is both customarily and actually treated as private.[7]

Consultation outside the agency: The Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, and the Federal Housing Finance Agency collaborated in reassessing and confirming their burden estimates and methodologies for this submission and discussed potential improvements and evaluations for future submissions.

Board of Governors of the Federal Reserve System, November 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26318 Filed 12–2–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Senior Credit Officer Opinion Survey on Dealer Financing Terms (FR 2034; OMB No. 7100–0325).

DATES: Comments must be submitted on or before February 1, 2022.

ADDRESSES: You may submit comments, identified by FR 2034, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: Senior Credit Officer Opinion Survey on Dealer Financing Terms.

Agency form number: FR 2034.

OMB control number: 7100–0325.

Frequency: Quarterly.

Respondents: The current reporting panel consists of U.S. banking institutions and U.S. branches and agencies of foreign banks, the majority of which are affiliated with a Primary Government Securities Dealer.[1] Other types of respondents, such as other depository institutions, bank holding companies, or other financial entities, may be surveyed when appropriate. Respondents may also include institutions that, while not primary dealers, play a significant role in over-the-counter derivatives or securities financing activities.

Estimated number of respondents: 25.

Estimated average hours per response: 5.

Estimated annual burden hours: 500.

[7] 5 U.S.C. 552(b)(4).

[1] A list of the current Primary Dealers in Government Securities is available at *https://www.newyorkfed.org/markets/primarydealers.html.*

General description of report: This survey collects qualitative and limited quantitative information from senior credit officers at responding financial institutions on (1) stringency of credit terms, (2) credit availability and demand across the entire range of securities financing and over-the-counter derivatives transactions, and (3) the evolution of market conditions and conventions applicable to such activities. The FR 2034 survey is conducted quarterly, along with the Senior Loan Officer Opinion Survey on Bank Lending Practices (FR 2018; OMB No. 7100–0058). The survey contains 79 core questions divided into three broad sections, as well as additional questions on topics of timely interest.

Legal authorization and confidentiality: The FR 2034 is authorized by sections 2A and 12A of the Federal Reserve Act (FRA).[2] Section 2A of the FRA requires that the Board and the Federal Open Market Committee (FOMC) maintain long-run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.[3] Section 12A of the FRA further requires the FOMC to implement regulations relating to the open market operations conducted by Federal Reserve Banks with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country.[4] The Board and FOMC use the information obtained through the FR 2034 to discharge these responsibilities.

Responding to the FR 2034 is voluntary. The information contained in responses to the core questions of the FR 2034 is nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent. The Board therefore may keep such information confidential pursuant to exemption 4 of the Freedom of Information Act (FOIA).[5] Supplemental questions asked on each survey may vary, and the Board's ability to keep confidential responses to such questions must therefore be determined on a case-by-case basis. Responses to supplemental questions may contain nonpublic commercial information that may be kept confidential by the Board pursuant to exemption 4 of the FOIA. Some such responses may also contain information contained in or related to an examination of a financial institution, which may be kept confidential under exemption 8 of the FOIA.[6]

Board of Governors of the Federal Reserve System, November 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26320 Filed 12–2–21; 8:45 am]

BILLING CODE 6210–01–P

[2] 12 U.S.C. 1828(c). The Board also has the authority to require reports from state member banks (12 U.S.C. 248(a) and 324).

[3] 12 U.S.C. 225a.

[4] 12 U.S.C. 263.

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

[6] 5 U.S.C. 552(b)(8).

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Recordkeeping and Disclosure Requirements Associated with Regulation II (FR II; OMB No. 7100–0349).

DATES: Comments must be submitted on or before February 1, 2022.

ADDRESSES: You may submit comments, identified by FR II, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper

performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: Recordkeeping and Disclosure Requirements Associated with Regulation II.

Agency form number: FR II.

OMB control number: 7100–0349.

Frequency: On occasion.

Respondents: State member banks, national banks, insured nonmember banks, savings associations, and federally-chartered credit unions.

Estimated number of respondents: Implement policies and procedures, 1; Review and update policies and procedures, 527; General recordkeeping, 527; Annual notification and change in status, 527.

Estimated average hours per response: Implement policies and procedures, 160; Review and update policies and procedures, 40; General recordkeeping, 1; Annual notification and change in status, 1.

Estimated annual burden hours: Implement policies and procedures, 160; Review and update policies and procedures, 21,080; General recordkeeping, 527; Annual notification and change in status, 527.

General description of report: Regulation II—Debit Card Interchange Fees and Routing (12 CFR part 235) implements, among other things, standards for assessing whether interchange transaction fees for electronic debit transactions are reasonable and proportional to the cost incurred by the issuer with respect to the transaction, as required by section 920(a) of the Electronic Fund Transfer Act (EFTA) (15 U.S.C. 1693o–2(a)).

Regulation II limits the interchange transaction fee that covered issuers (issuers that, together with affiliates, have assets of $10 billion or more) can charge for electronic debit transactions. Under the rule, a covered debit card issuer is allowed to receive or charge an interchange transaction fee in the amount of 21 cents plus 5 basis points multiplied by the value of the transaction. In addition, a covered issuer may receive or charge an amount of no more than 1 cent per transaction (the ''fraud-prevention adjustment'') for the costs associated with preventing fraudulent electronic debit transactions (fraud-prevention adjustment) if the issuer complies with the standards and requirements set forth in the rule. In addition to these interchange fee provisions, Regulation II prohibits any issuer (*i.e.,* not just covered issuers) or payment card network from directly or indirectly restricting the number of payment card networks on which an electronic debit transaction may be processed to less than two unaffiliated networks, and from directly or indirectly inhibiting the ability of a merchant to direct the routing of electronic debit transactions for processing over any payment card network that may process such transactions. Finally, Regulation II prohibits any issuer from receiving net compensation from a payment card network with respect to electronic debit transactions or debit card-related activities within a calendar year.

Legal authorization and confidentiality: The Recordkeeping and Disclosure Requirements Associated with Regulation II are authorized by section 920(a)(3) of the EFTA.[1] The fraud-prevention and disclosure requirements are additionally authorized by section 920(a)(5) of the EFTA.[2] Regulation II's general recordkeeping requirement for issuers is mandatory. Regulation II's fraud-prevention recordkeeping requirements and disclosure requirements are required to obtain a benefit.

The Recordkeeping and Disclosure Requirements Associated with Regulation II are generally not submitted to the Board or to any of the federal financial regulatory agencies. In the event that the Board obtains such information, it may be kept confidential under exemption 4 of the Freedom of Information Act (FOIA) to the extent that it contains commercial or financial information both customarily and actually treated as private.[3] If such information is obtained through the examination or enforcement process, it may be kept confidential under exemption 8 of the FOIA.[4]

Board of Governors of the Federal Reserve System, November 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26319 Filed 12–2–21; 8:45 am]

BILLING CODE 6210–01–P

[1] 15 U.S.C. 1693*o*–2(a)(3) (authorizing the Board to prescribe regulations regarding interchange transaction fees and require issuers or payment card networks to provide to the Board such information as deemed necessary).

[2] 15 U.S.C. 1693*o*–2(a)(5) (permitting the Board to allow for the fraud-prevention adjustment and condition it upon compliance with fraud-related standards promulgated by the Board).

[3] 5 U.S.C. 552(b)(4).

[4] 5 U.S.C. 552(b)(8).

FEDERAL TRADE COMMISSION

[File No. 211 0101/Docket No. C–4754]

ANI/Novitium; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 3, 2022.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''ANI/Novitium; File No. 211 0101'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202–326–3085), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 3, 2022. Write ''ANI/Novitium; File No. 211 0101'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to protective actions in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''ANI/Novitium; File No. 211 0101'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *https://www.ftc.gov* to read this Notice and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before January 3, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from ANI Pharmaceuticals, Inc. (''ANI'') and Novitium Pharma LLC and Esjay LLC (collectively, ''Novitium'') designed to remedy the anticompetitive effects resulting from ANI's acquisition of the non-corporate interests of Novitium. Pursuant to an agreement dated March 8, 2021, ANI proposes to acquire Novitium in a transaction valued at approximately $210 million. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening future competition in the following two U.S. markets: (1) Generic SMX–TMP oral suspension; and (2) generic dexamethasone tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (''Order''), Respondents are required to divest all of ANI's rights and assets related to the following two products to Prasco LLC (''Prasco''): (1) Generic sulfamethoxazole-trimethoprim (''SMX–TMP'') oral suspension; and (2) generic dexamethasone tablets. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Prasco. The Commission also issued the Order to Maintain Assets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the Consent Agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent ANI is a public specialty pharmaceutical company headquartered in Baudette, Minnesota selling both branded and generic pharmaceutical products.

Respondent Novitium is a privately-held company based in East Windsor, New Jersey. The company develops, manufactures, and commercializes generic pharmaceutical products.

II. The Products and Structure of the Markets

In human pharmaceutical markets, price(s) generally decreases as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the SMX–TMP oral suspension market, where ANI is a current competitor and Novitium is likely to enter the market. Generic SMX–TMP oral suspension is an antibiotic product used to treat a variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX–TMP oral suspension in the near future.

Similarly, the Proposed Acquisition would reduce future competition in the 4 mg strength of generic dexamethasone tablets market, where both ANI and Novitium are likely to enter the market in the near future. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Dexamethasone tablets are available in a variety of strengths, although the most widely used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies likely to enter the market in the near future.

III. Entry

Entry into the two markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The Proposed Acquisition likely would delay or reduce the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the two markets at issue. While five companies, including ANI, currently market the generic SMX–TMP product in the United States, at least one has had difficulty manufacturing the product, and Novitium is one of a limited number of suppliers capable of entering the market in the near future. In the generic dexamethasone tablets market, only two companies sell the 4 mg strength in the United States today and ANI and Novitium are two of a limited number of companies entering the market in the near future. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

V. The Proposed Order and the Order To Maintain Assets

The proposed Order and the Order to Maintain Assets effectively remedy the competitive concerns raised by the Proposed Combination for the two generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest ANI's rights and assets related to the two products to Prasco. The parties must accomplish these divestitures no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

While ANI and Novitium do not compete again each other in the market for generic erythromycin and ethylsuccinate granules for oral suspension, Novitium has an unexecuted option to acquire a product from another company and ANI sells a product today. The proposed Order requires prior Commission approval before ANI or Novitium may acquire any rights or interests in certain products containing, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate. This provision allows the Commission to evaluate whether a future acquisition of the erythromycin and ethylsuccinate product would reduce competition at the time the acquisition is proposed. The proposed Order also requires ANI and Novitium to seek Commission approval before acquiring any other SMX–TMP or dexamethasone tablet product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure the divestitures are successful. ANI will supply Prasco with SMX–TMP oral suspension and dexamethasone tablets for up to three years while the company transfers the manufacturing technology to Prasco's contract manufacturing designee. The proposed Order also requires ANI to provide transitional services to Prasco to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to have the products manufactured in substantially the same manner and quality employed or achieved by ANI. It also includes advice and training from knowledgeable employees of the parties. Further, the proposed Order requires prior Commission approval before Prasco may sell, license, or otherwise convey any of the assets divested pursuant to the proposed Order.

Under the proposed Order, the Commission also will appoint a Monitor to ensure ANI and Novitium comply with their obligations under the proposed Order and Order to Maintain Assets. The Commission has appointed Denise Smart of Smart Consulting Group, LLC as the Monitor. Ms. Smart is an expert in areas such as pharmaceutical R&D, regulatory approval, manufacturing and supply, and marketing, and she has over thirty years of experience in the pharmaceutical area and has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and other government agencies, including the FDA, Department of Defense, and Health and Human Services.

The proposed Order also contains a prior approval provision relating to Prasco, which prohibits Prasco from selling the acquired products for a combined period of ten years after the Order is issued, except to an acquirer that receives the prior approval of the Commission.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed

Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–26294 Filed 12–2–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CK–22–003, Emerging Infections Sentinel Networks (EISN) Research; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CK–22–003, Emerging Infections Sentinel Networks (EISN) Research; January 11, 2022, 10:00 a.m.–5:00 p.m., EST, Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027, in the original FRN. The meeting was published in the **Federal Register** on November 8, 2021, Volume 86, Number 213, page 61767.

The meeting is being amended to change the contact information and should read as follows:

FOR FURTHER INFORMATION CONTACT: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, Telephone: (404) 718–8833; Email: *GAnderson@cdc.gov.*

The meeting is closed to the public.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26298 Filed 12–2–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS). This meeting is open to the public.

DATES: The meeting will be held on February 10, 2022, from 11:00 a.m. to 5:15 p.m., EST (times subject to change).

ADDRESSES: Instructions to access the meeting are posted here: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm.*

FOR FURTHER INFORMATION CONTACT: Rebecca Hines, M.H.S., Executive Secretary, NCHS/CDC, Board of Scientific Counselors, 3311 Toledo Road, Room 2627, Hyattsville, Maryland 20782, Telephone: (301) 458–4717; Email: *RSHines@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to be Considered: The meeting agenda will include welcome remarks and a Center update by the NCHS Director; a welcome and introductions for five new Board members who will be attending their first BSC meeting; discussion with members on plans and potential revisions to NCHS surveys, including the addition of new questions; a report out from the Population Health Survey Planning, Methodology and Data Presentation (PHSPMDP) Workgroup on their assessment of the use of panel survey data by NCHS; an update on approaches to enhancing identification of opioid-Involved hospitalizations with clinical data and notes from electronic health records, and; an update on several NCHS Programs. Agenda items are subject to change as priorities dictate.

Meeting Information: Please visit the BSC website for details: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm* for more information on the meeting agenda, including instructions for accessing the live meeting broadcast.

The Board will reserve time for public comment at the end of the day.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26317 Filed 12–2–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0167]

Proposed Information Collection Activity; ACF–801: Child Care and Development Fund (CCDF) Quarterly Case-Level Report

AGENCY: Office of Child Care, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Care (OCC), Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF–801: CCDF Quarterly Case-Level Report (OMB #0970–0167, expiration 2/28/2022). OCC proposes minor changes to the response categories under the following three data elements: Child's gender, ethnicity, and race.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ACF–801 provides monthly case-level data on the children and families receiving direct child care services under CCDF. The ACF–801 case-level data are reported either monthly or quarterly. OCC added ''no response'' categories under the following three data elements: Child's gender, ethnicity, and race.

Respondents: State and Territory Lead Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–801: CCDF Quarterly Case-Level Report	56	4	25	5,600

Estimated Total Annual Burden Hours: 5,600.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 658K of the Child Care and Development Block Grant Act (42 U.S.C. 9858); regulations 45 CFR 98.70 and 98.71.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–26272 Filed 12–2–21; 8:45 am]

BILLING CODE 4184–81–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Notice for Public Comment on Administration for Native Americans' Program Policies and Procedures

AGENCY: Administration for Native Americans, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans (ANA) is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the proposed changes no less than 30 days before such changes become effective.

DATES: Comments are due by January 3, 2022. If ANA does not receive any significant comments within the 30-day comment period, ANA will proceed with the proposed changes in the respective published NOFOs. The NOFOs will serve as the final notice of these proposed changes.

ADDRESSES: Comments may be submitted to: Carmelia Strickland, Director of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201 or via email to: *ANAComments@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201; Telephone: (877) 922–9262; Email: *ANAComments@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities in Fiscal Year (FY) 2022. Changes to FY 2022 Notice of Funding Opportunity (NOFOs) will be based on the following previously published programs: Environmental Regulatory Enhancement (ERE), HHS–2021–ACF–ANA–NR–1907; Native American Language Preservation and Maintenance—Esther Martinez Immersion (EMI), HHS–2021–ACF–ANA–NB–1958; Native American Language Preservation and Maintenance (P&M), HHS–2021–ACF–ANA–NL–1924; Social and Economic Development Strategies (SEDS), HHS–2021—ACF–ANA–NA–1906; Social and Economic Development Strategies—Alaska (SEDS–AK); and HHS–2021—ACF–ANA–NK–1902.

Section 814 of NAPA, as amended, (42 U.S.C. 2992b–1) incorporates provisions of the Administrative Procedure Act that require ANA to provide notice of its proposed interpretive rules and statements of policy and to seek public comment on such proposals. This notice serves to fulfill the statutory notice and public comment requirement. ANA voluntarily includes rules of practice and procedures in this notice in an effort to be transparent. The proposed interpretive rules, statements of policy, and rules of ANA practice and procedure reflected in clarifications, modifications, and new text will appear in the five FY 2022 NOFOs: ERE, EMI, P&M, SEDS, and SEDS–AK.

A. *Interpretive rules, statements of policy, procedures, and practice.* The proposals below reflect ANA's proposed changes in rules, policy, or procedure that will take effect in the FY 2022 NOFOs.

1. Discontinuation of SEDS–GO

ANA has several new legislative economic development priorities under the Indian Community Economic Enhancement Act of 2020 (Public Law 116–261 Section 5), and Congress would like ANA to prioritize at least 50 percent of our available SEDS funding to go towards those types of projects. Therefore, ANA will discontinue SEDS–GO, and applicants can propose governance or organizational capacity building projects under regular SEDS.

2. Raising the Funding Level of SEDS–AK NOFO

Operating costs for grant-funded projects in Alaska are often higher than in the lower 48 states. In addition, ANA has seen a decline in the number of applications received over the last few years for the SEDS–AK funding competition. Therefore, in an effort create more interest in the program and to address the higher expenses, ANA

will increase the funding level for SEDS–AK from $200,000 to $300,000.

3. Clarification to EMI NOFO

In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must submit an official document that certifies the applicant has at least 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language. ANA has decided not to fund applicants that did not provide the certification as required by law. To reiterate and also clarify, the applicant must provide the required certification of having not less than 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language. The applicant may partner with other eligible entities (as defined under *Section III.1 Eligible Applicants* in the NOFO) that do not have to meet the certification requirement.

Statutory Authority: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Hope MacDonald LoneTree,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 2021–26271 Filed 12–2–21; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0921]

Agency Information Collection Activities; Proposed Collection; Comment Request; Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the standards for the growing, harvesting, packing, and holding of produce for human consumption.

DATES: Submit either electronic or written comments on the collection of information by February 1, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 1, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 1, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0921 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; 21 CFR Part 112

OMB Control Number 0910–0816—Extension

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, we have established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The standards are codified in part 112 (21 CFR part 112) and set forth procedures and processes that include information collection activities such as establishing monitoring and sampling plans, documenting data and training, and ensuring disclosure that produce for human consumption meets these requirements. The regulations also provide for certain exemptions and variances to qualified respondents. We use the information to verify that the standards established by the regulations are followed such that produce entering the marketplace is reasonably unlikely to be associated with foodborne illness.

In addition to the referenced regulations, we have developed two draft guidance documents: ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' and ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations;'' both are available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm.* The former was developed to help covered farms comply with the requirements of the Produce Safety regulation. This draft guidance, when finalized, will not create any additional burden not already considered as part of the Produce Safety regulation.

The latter (the Sprouts draft guidance) was developed to assist sprout operations also subject to the Produce Safety regulation. Sprouts represent a special food safety concern because the conditions under which they are produced (time, temperature, water activity, pH, and available nutrients) are ideal for the growth of pathogens, if present. The Sprouts draft guidance, when finalized, will assist sprout operations subject to the regulations in part 112 in complying with the sprout-specific requirements in subpart M.

Description of Respondents: Respondents to this information collection include farms that grow, harvest, pack, or hold produce for human consumption, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Exemptions under § 112.7	3,285	1	3,285	0.5 (30 minutes)	1,643
Training under § 112.30	24,420	1	24,420	7.25	177,045
Testing requirements for agricultural water under §§ 112.44 and 112.45.	48,361	2.990	144,599	0.825 (~ 50 minutes)	119,294
Records related to agricultural water	160,605	2.242	360,076	2.160	777,765
Testing requirements for sprouts under §§ 112.144, 112.145, and 112.147.	126	245.660	30,953.16	0.825 (~ 50 minutes)	25,536
Records related to sprouts	126	62.061	7,819.686	1.412 (~ 85 minutes)	11,041
''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations''.	126	233	29,358	1	29,358
Documentation supporting compliance with § 112.2	4,568	1	4,568	0.079 (~ 5 minutes)	361
Total	241,617		605,079		1,142,043

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers rounded to nearest 1/1,000.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

21 CFR section	Number of respondents	Number of disclosures per Respondent	Total disclosures	Average burden per disclosure	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142	77,165	3.459	266,914	1.422 (~ 85 minutes)	379,551

[1] There are no capital costs or operating or maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26261 Filed 12–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0417]

Request for Nominations of Voting Members on a Public Advisory Committee; National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current and upcoming vacancies effective February 1, 2022, with this notice. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before February 1, 2022, will be given first consideration for membership on the National Mammography Quality Assurance Advisory Committee. Nominations received after February 1, 2022, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership:* James P. Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993, 301–796–6313, *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the National Mammography Quality Assurance Advisory Committee.

I. General Description of the Committee Duties

The National Mammography Quality Assurance Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Criteria for Voting Members

The committee consists of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26258 Filed 12–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0417]

Request for Nominations on the National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of appropriate nonvoting members to represent industry interests must send a letter stating that interest to FDA by January 3, 2022 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by January 3, 2022.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Division of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993, 301–796–5960, email: *Margaret.Ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives on the National Mammography Quality Assurance Advisory Committee:

I. General Description of the Committee Duties

The National Mammography Quality Assurance Advisory Committee (the committee) shall advise FDA on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in these areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for a nonvoting representative of industry interests are encouraged from the mammography manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26264 Filed 12–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Proposed Healthy People 2030 Objectives and Request for Information on the Relationship Between Voter Participation and Health

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary of Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) solicits written comments on three new objectives proposed to be added to Healthy People 2030 since its launch in August 2020; written comments from the public proposing additional new core, developmental, or research objectives to be included in Healthy People 2030; and evidence-based information regarding the relationship between voter participation and health status as a measure of civic engagement. Public comment informed the development of Healthy People 2030. HHS will provide opportunities for public input periodically throughout the decade to ensure Healthy People 2030 reflects current public health priorities and public input. The updated set of Healthy People 2030 objectives will be incorporated on *www.health.gov/HealthyPeople2030.* This updated set will reflect further review and deliberation by federal Healthy People topic area workgroups, the Federal Interagency Workgroup on Healthy People 2030, and other federal subject matter experts.

DATES: Written comments and evidence-based information will be accepted through 11:59 p.m. ET, January 10, 2022.

ADDRESSES: Written comments should be submitted by email to *HP2030Comment@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Carter Blakey, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Email: *HP2030@hhs.gov*.

SUPPLEMENTARY INFORMATION: Since 1980, Healthy People has provided a comprehensive set of national health promotion and disease prevention objectives with 10-year targets aimed at improving the health of all. Healthy People 2030 objectives present a picture of the nation's health at the beginning of the decade, establish national goals and targets to be achieved by the year 2030, and monitor progress over time. The U.S. Department of Health and Human Services (HHS) is soliciting the submission of written comments regarding three new objectives proposed to be added to Healthy People 2030 since the initiative's launch in August 2020. The public is also invited to submit proposals for additional new core, developmental, or research objectives that meet the criteria outlined below.

In addition, HHS is seeking evidence-based information regarding the relationship between voter participation and health as a measure of civic engagement to support the Healthy People social determinants of health (SDOH) framework. Civic engagement is a component of the Social and Community Context domain of the Healthy People SDOH framework.

Healthy People 2030 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2030's development. During the first phase of planning for Healthy People 2030, HHS asked for the public's comments on the initiative's vision, mission, and overarching goals. Those comments helped set the framework for Healthy People 2030. The public was also invited to submit comments on proposed Healthy People 2030 objectives, which helped shape the current set of Healthy People 2030 objectives.

The public now is invited to comment on three new objectives proposed to be added to Healthy People 2030. These new objectives were developed by Healthy People topic area workgroups led by various agencies within the Federal Government. They have been reviewed by the Federal Interagency Workgroup on Healthy People 2030 and are presented now for the public's review and comment. They are:

1. Disability and Health-NEW–06: Increase the percentage of adults who can resume 50 percent or more of preinjury activities (with or without supports) 5 years after receiving acute inpatient rehabilitation for traumatic brain injury. Data Source: Traumatic Brain Injury Model Systems (TBIMS) National Database.

2. Public Health Infrastructure-NEW–08: Increase the proportion of tribal communities that have developed a health improvement plan. Data Source: Public Health in Indian Country Capacity Survey (PHICCS), National Indian Health Board (NIHB).

3. Public Health Infrastructure-NEW–09: Increase the proportion of tribal public health agencies that use Core Competencies for Public Health Professionals in continuing education for personnel. Data Source: Public Health in Indian Country Capacity Survey (PHICCS), National Indian Health Board (NIHB).

The public is also invited to propose additional core, developmental, or research objectives for consideration that address critical public health issues. Proposed new objectives must meet all the objective selection criteria (see below).

Objective Selection Criteria

Core Objectives

Core objectives must meet the following 5 criteria to be included in Healthy People 2030. Core objectives should (1) have a reliable, nationally representative data source with baseline data no older than 2015; (2) have at least 2 additional data points beyond the baseline during the decade; (3) be of national importance; (4) have effective, evidence-based interventions available to achieve the objective; and (5) have data to help address disparities and achieve health equity.

Developmental Objectives

Developmental objectives will have the following characteristics: (1) Represent high priority issues; (2) do not have reliable baseline data yet; and (3) have evidence-based interventions available.

Research Objectives

Research objectives will have the following characteristics: (1) Represent key opportunities to make progress in areas with limited prior research, a high health or economic burden, or significant disparities between population groups; (2) may or may not have reliable baseline data; and (3) do not have evidence-based interventions available.

Written comments and evidence-based information should be submitted by email to *HP2030Comment@hhs.gov* by 11:59 p.m. ET on January 10, 2022. Comments received in response to this notice will be reviewed and considered by the Healthy People topic area workgroups, Federal Interagency Workgroup on Healthy People 2030, and other federal subject matter experts.

Authority: 42 U.S.C. 200u.

Paul Reed,

Deputy Assistant Secretary for Health,RADM, U.S. Public Health Service, Office of Disease Prevention and Health Promotion.

[FR Doc. 2021–26184 Filed 12–2–21; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Host-Bacterial Interactions and Infections.

Date: December 14, 2021.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pauline Cupit, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–3275, *cupitcunninghpm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–26247 Filed 12–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, December 7, 2021, 1:00 p.m. to December 9, 2021, 5:00 p.m., National Cancer Institute-Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 which was published in the **Federal Register** on October 05, 2021, FR Doc 2021–21666, 86 FR 54990.

This notice is being amended to change the open session end time and agenda on December 7, 2021. There will now only be one NCAB Subcommittee Meeting held on December 7, 2021, the *Ad Hoc* Subcommittee on Experimental Therapeutics from 1:15 p.m. to 2:15 p.m.

This notice is also being amended to change the open session end times on December 8, 2021 and December 9, 2021. The open session end time on December 8, 2021 has changed from 5:00 p.m. to 5:30 p.m., as such, the meeting will now be held from 1:00 p.m. to 5:30 p.m. The open session end time on December 9, 2021 has changed from 5:00 p.m. to 5:15 p.m., as such, the meeting will now be held from 1:00 p.m. to 5:15 p.m. The meeting is partially closed to the public.

Dated: November 30, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–26273 Filed 12–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell, Molecular Biology and Special Topics.

Date: December 15, 2021.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ronit I. Yarden, Ph.D., MHSA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 904B, Bethesda, MD 20892, (202) 552–9939, *yardenri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2021.

David W. Freeman, Program Analyst,

Office of Federal Advisory Committee Policy.

[FR Doc. 2021–26250 Filed 12–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; AI/ML strategies to integrate genetics and multi-omics data from human cohort studies to improve quality of life of Older Adults with MCI and ADRD.

Date: January 19, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6477, *rajasri.roy@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 29, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–26249 Filed 12–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0016]

Meetings To Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Announcement of meetings; correction.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a document in the **Federal Register** of November 3, 2021, concerning two meetings to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. The document contained incorrect dates.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at *OB3I@fema.dhs.gov* or via phone at (202) 212–1666.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 3, 2021, in FR Doc. 86–60636, on page 60636–60637, in the second column, correct the ''Dates'' caption to read:

DATES: The first meeting will take place on Tuesday, December 7, 2021, from 10 a.m. to 12 p.m. Eastern Time (ET). The second meeting will take place on Thursday, December 9, 2021, from 10 a.m. to 12 p.m. ET.

Dated: November 30, 2021.

Shabnaum Q. Amjad,

Deputy Associate Chief Counsel, Regulatory Affairs Division, Office of Chief Counsel, Federal Emergency Management Agency.

[FR Doc. 2021–26303 Filed 12–2–21; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–0053]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Allegation of Counterfeiting and Intellectual Piracy

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) invites the general public and other Federal agencies to comment on this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, this information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted until February 1, 2022.

ADDRESSES: All submissions received must include the OMB Control Number 1653–0053 in the body of the correspondence, the agency name and Docket ID ICEB–2014–0003. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number ICEB–2014–0003.

FOR FURTHER INFORMATION CONTACT: If you have questions related to this revision, please contact: Michael Rose (313) 530–7236, *michael.t.rose@ice.dhs.gov,* U.S. Immigration and Customs Enforcement. (This is not a toll-free number. Comments are not accepted via telephone message.)

SUPPLEMENTARY INFORMATION:

Comment

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering ICEB–2014–0003 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Allegation of Counterfeiting and Intellectual Piracy.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form 73–048;

U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This electronic form/collection will be utilized by the public and law enforcement partners as part of an automated allegation and deconfliction program.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* ICE estimates a total of 21,711 responses at 5 minutes (0.0833 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden is 1,809 hours.

(7) *An estimate of the total annual public burden (in cost) associated with this collection:* The estimated total annual cost burden is $101,577.00.

Dated: November 30, 2021.

Scott Elmore,

PRA Clearance Officer, U.S. Immigrations and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2021–26312 Filed 12–2–21; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW]

Agency Information Collection Activities; New Collection: Request for a Certificate of Non-Existence

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until January 3, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2021–0021. All submissions received must include the OMB Control Number 1615–NEW in the body of the letter, the agency name and Docket ID USCIS–2021–0021.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on September 23, 2021, at 86 FR 52920, allowing for a 60-day public comment period. USCIS received two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2021–0021 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Request for a Certificate of Non-Existence.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–1566; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS will use the information collected on Form G–1566 to determine whether any immigration records about the subject of record listed on the form exist. If no records about the subject of record exist, USCIS will provide a Certificate of Nonexistence. If USCIS finds records related to the subject of record, a Certificate of Non-Existence will not be issued, but the requestor will be notified that records were found.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection G–1566 is 2,000 and the estimated hour burden per response is 0.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $122,000.

Dated: November 29, 2021.

Jerry L. Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2021–26245 Filed 12–2–21; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7034–N–68]

30-Day Notice of Proposed Information Collection: Maintenance Wage Rate Recommendation, OMB Control No: 2501–0011

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* January 3, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 24, 2021 at 86 FR 53110.

A. Overview of Information Collection

Title of Information Collection: Maintenance Wage Rate Recommendation.

OMB Approval Number: 2501–0011.

Type of Request: Revision with change of a previously approved collection.

Form Number: HUD–4750, HUD–4751, HUD–4752.

Description of the need for the information and proposed use:

This is a revision of a currently approved collection. Agencies administering low income and affordable housing programs subject to maintenance prevailing wage rates use HUD Form 4750 to recommend maintenance wage rates to HUD and use HUD Forms 4751 and 4752 to collect data from local entities that employ personnel performing the same duties as the agency's maintenance staff. HUD uses the data collected from HUD Forms 4750, 4751, and 4752 to determine or adopt prevailing wage rates for maintenance laborers and mechanics employed in the operation of low income and affordable housing projects subject to Federal prevailing wage rates.

HUD and local agencies that administer HUD-assisted projects will no longer be required to use the HUD Form 4230A for additional classification requests. Instead, HUD and local agencies will utilize the form SF–1444 and submit employer additional classification and wage rate requests to DOL when DOL approval is required. The information collection of the SF–1444 is contained in the OMB Control No. 9000–0066.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Total cost
HUD–4750 Maintenance Wage Recommendation	1,381.00	1.00	1,381.00	2.00	2,762.00	$42.01	$116,031.62
HUD–4751 Maintenance Wage Rate Survey	1,133.00	1.00	1,133.00	2.00	2,266.00	42.01	95,194.66
HUD–4752 Maintenance Wage Rate Survey—Summary Sheet	1,133.00	1.00	1,133.00	4.00	4,532.00	42.01	190,389.32
Total	3,647.00		3,647.00	8.00	9,560.00	42.01	401,615.60

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) If the information will be processed and used in a timely manner;

(3) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(4) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(5) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2021–26301 Filed 12–2–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of South Dakota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Amendment to the Gaming Compact (Amendment) between the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation (Tribe) and the State of South Dakota (State).

DATES: The Amendment takes effect on December 3, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, *paula.hart@bia.gov,* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment authorizes the Tribe to engage in sports wagering at the Tribe's class III gaming facilities. The Amendment is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–26274 Filed 12–2–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORB06000.L10200000.EE0000.21X.LXSS043H0000.HAG 21–0079]

Notice of Intent To Prepare the Bridge Creek Area Allotment Management Plans Environmental Impact Statement in the Andrews Field Office, Burns District, Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Oregon/Washington Burns District's Andrews Field Office intends to prepare the Bridge Creek Area (BCA) Allotment Management Plans (AMP) Environmental Impact Statement (EIS) and, by this notice, is announcing the beginning of the public scoping period to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the EIS. Comments may be submitted in writing until January 3, 2022. The BLM will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2013546/510.*
- *Email: BLM_OR_BU_BCA_AMP@blm.gov.*
- *Fax:* (541) 573–4411.
- *Mail:* BCA, c/o Burns District BLM 28910 Hwy 20 West, Hines, OR 97738, Attention: Don Rotell.

Documents associated with this proposal are available at the BLM Burns District Office, 28910 Hwy 20 West, Hines, OR 97738, or at *https://eplanning.blm.gov/eplanning-ui/project/2013546/510.*

FOR FURTHER INFORMATION CONTACT: Andrews Field Office Manager, Don Rotell; telephone (541) 573–4422, or email *BLM_OR_BU_BCA_AMP@blm.gov.* Contact Mr. Rotell to have your name added to the project mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Mr. Rotell during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The EIS will analyze several alternatives for livestock management and related actions in the 26,378-acre project area in southeastern Oregon near the town of Frenchglen. The project covers four allotments: The Hammond, Mud Creek, Hardie Summer, and Hammond Fenced Federal Range allotments. The alternatives will consider issuance of 10-year grazing permits to up to three applicants and approval of four AMPs that outline seasonal grazing systems, grazing utilization thresholds, monitoring, and range developments. The proposed range developments currently include about 8 miles of new fence construction and a similar amount of fence removal. These modifications include short riparian management fences but are largely to realign fences along boundaries of BLM-administered public land and privately owned land. The 2015 Greater Sage-grouse Approved Resource Management Plan Amendment and Record of Decision for Oregon identified the entire project area as habitat for Greater Sage-grouse. Since 1980, approximately 38,624 acres (cumulative) in the project area have been impacted by fire, with some acres burning multiple times. The burned acres have largely been within the Hammond and Mud Creek allotments.

There is currently no grazing preference or grazing authorization associated with the four allotments in the project area. The allotments have been largely un-grazed since 2014 following the BLM's decision to not renew the expiring livestock grazing authorization, which covered all four allotments. This decision was administratively appealed by the permittee, and the Secretary of the Interior resolved the administrative appeal in January 2019 by instructing the BLM to reissue the grazing permit. That decision was litigated in the U.S. District Court for the District of Oregon. The Court issued an order partially granting and partially denying a request for preliminary injunction that allowed only a limited amount of grazing to proceed in the 2019 season. The Court vacated the reissued permit and related Secretarial action and remanded the matter to the Department.

On January 19, 2021, the Secretary of the Interior signed a decision concerning the apportionment of available forage within the allotments and the assignment of grazing preference, and directing the BLM to issue a 10-year livestock grazing permit with allotment management plans and authorize the construction and removal of range improvements. On February 26, 2021, the Senior Advisor to the Secretary Exercising the Delegated Authority of the Assistant Secretary for Land and Minerals Management rescinded the decision and directed the BLM to ''initiate any additional processes and opportunities for public involvement that it may determine appropriate under applicable law following a careful and considered review of the protests.''

Through the public-scoping process, the BLM is seeking input on issues, actions, and alternatives that should be addressed in the EIS. Potential issues include the effects of proposed management actions on livestock grazing management, sagebrush ecosystem health, sage-grouse habitat, vegetation, fuels (including invasive

annual grasses), riparian/water quality/fisheries, socioeconomics, visual resources, and Wilderness Study Areas. Potential management actions to consider include alternative grazing systems and schedules; issuance of 10-year grazing permits in the four allotments; proposed AMPs; raising the allowable forage use in the Hammond allotment to address higher production of crested wheatgrass seedings; authorization of temporary, non-renewable forage use to reduce standing fine fuel biomass; and installation, modification, or removal of range developments.

The Burns District will consult with the Burns Paiute Tribe throughout the EIS process. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the proposal, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency. The BLM will coordinate with Federal, State, and local officials and the grazing permit applicants throughout the EIS process.

Comments can be submitted to the BLM using one of the methods listed in the **ADDRESSES** section of this notice and on the BLM's ePlanning page for this EIS. To be most helpful, please submit comments by the close of the 30-day scoping period. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9, 1506.6; 43 CFR 4120.2 and 4130.2)

Kathryn J. Stangl,

Associate State Director, Oregon/Washington.

[FR Doc. 2021–26305 Filed 12–2–21; 8:45 am]

BILLING CODE 4310–33–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–660 and 731–TA–1543–1544 (Final)]

Utility Scale Wind Towers From India and Malaysia

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of utility scale wind towers (''wind towers'') from India and Malaysia, provided for in subheadings 7308.20.00 and 8502.31.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of India.[2]

Background

The Commission instituted antidumping and countervailing duty investigations effective September 30, 2020, following receipt of petitions filed with the Commission and Commerce by the Wind Tower Trade Coalition (Arcosa Wind Towers Inc., Dallas, Texas; and Broadwind Towers, Inc., Manitowoc, Wisconsin). The Commission established a general schedule for the conduct of the final phase of its investigations on wind towers from India, Malaysia, and Spain following preliminary determinations by Commerce that imports of wind towers were subsidized by the governments of India and Malaysia. Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 16, 2021 (86 FR 20197). Counsel for the Wind Tower Trade Coalition withdrew its previously filed request to appear at the hearing, after no other parties submitted a request to appear, and indicated a willingness to submit written responses to any Commission questions in lieu of a hearing. Consequently, since no party to the proceeding requested a hearing, the Commission canceled its hearing in connection with this proceeding (86 FR 31730, June 9, 2021). Parties to this proceeding responded to written questions posed by the Commission in their posthearing briefs.

The investigation schedules became staggered when Commerce did not align its countervailing duty investigation (86 FR 15887, March 25, 2021) with its antidumping duty investigation regarding imports from Malaysia, its antidumping duty investigation regarding imports from Spain, or its countervailing and antidumping duty investigations regarding imports from India. On July 26, 2021, the Commission issued a final affirmative determination in its countervailing duty investigation of wind towers from Malaysia (86 FR 41087, July 30, 2021). On August 9, 2021, the Commission issued a final affirmative determination in its antidumping duty investigation of wind towers from Spain (86 FR 44748, August 13, 2021). Following notification of final determinations by Commerce that imports of wind towers from India were being subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and that imports of wind towers from India and Malaysia were being sold at LTFV within the meaning of section 735(a) of the Act (19 U.S.C. 1673d(a)), notice of the supplemental scheduling of the final phase of the Commission's countervailing duty investigation regarding India and antidumping duty investigations regarding India and Malaysia was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 20, 2021 (86 FR 58098).

The Commission made these determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 29, 2021. The views of the Commission are contained in USITC Publication 5247 (November 2021), entitled *Utility Scale Wind Towers from India and Malaysia: Investigation Nos. 701–TA–660 and 731–TA–1543–1544 (Final).*

By order of the Commission.

Issued: November 29, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–26235 Filed 12–2–21; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 56890, October 13, 2021; 86 56894, October 13, 2021; and 86 FR 56896, October 13, 2021.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1211]

Certain Vaporizer Cartridges and Components Thereof; Notice of Commission Determination To Review in Part an Initial Determination Granting a Motion for Summary Determination on Violation of Section 337; Schedule for Filing Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review in part an initial determination (''ID'') (Order No. 65) of the presiding administrative law judge (''ALJ'') granting a summary determination on violation of section 337 by the respondents found in default in the above-captioned investigation. The Commission is requesting briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On August 14, 2020, the Commission instituted this investigation based on a complaint, as supplemented, filed on behalf of Juul Labs, Inc. (''JLI'') of San Francisco, California. 85 FR 49679 (Aug. 14, 2020). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vaporizer cartridges and components thereof by reason of infringement of U.S. Design Patent Nos. D842,536; D858,870; D858,869; and D858,868 (collectively, the ''Asserted Patents''). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation names forty-nine respondents, including: (1) 101 Smoke Shop, Inc. of Los Angeles, California (''101 Smoke Shop''); (2) Eon Pods LLC of Jersey City, New Jersey (''Eon Pods''); (3) Jem Pods, U.S.A. of Snellville, Georgia (''Jem Pods''); (4) Sky Distribution LLC of Addison, Illinois (''Sky Distribution''); (5) Vapers & Papers, LLC of Schenectady, New York (''Vapers & Papers''); (6) Access Vapor LLC d/b/a Cali Pods of Orlando, Florida (''Access Vapor''); (7) eLiquid Stop of Glendale, California (''eLiquid Stop''); (8) Shenzhen Apoc Technology Co., Ltd. of Shenzhen, China; (9) Shenzhen Ocity Times Technology Co., Ltd. of Shenzhen, China; (10) Evergreen Smokeshop of Oakland, California (''Evergreen Smokeshop''); (11) Shenzhen Azure Tech USA LLC f/k/a DS Vaping P.R.C. of Redding, California (''Shenzhen Azure''); (12) DripTip Vapes LLC of Plantation, Florida (''DripTip Vapes''); (13) Modern Age Tobacco of Gainesville, Florida (''Modern Age Tobacco''); (14) Dongguan Hengtai Biotechnology Co., Ltd. d/b/a Mr. Fog of Bensenville, Illinois; (15) Shenzhen Yark Technology Co., Ltd. of Shenzhen, China; (16) Guangdong Cellular Workshop Electronic Technology Co., Ltd. of Dongguan City, China; (17) Shenzhen Bauway Technology Ltd. of Shenzhen, China; and (18) Shango Distribution LLC d/b/a Puff E-Cig of Imlay City, Michigan (''Shango Distribution'') (collectively, the ''Defaulting Respondents''). *See id.; see also* 85 FR 73748 (Nov. 19, 2020). The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See* 85 FR 49679. The complaint and notice of investigation were later amended to, *inter alia,* correct the names and addresses of certain respondents. *See* 85 FR 73748

This investigation has previously terminated as to twenty-nine respondents pursuant to Commission Rule 210.21(c) (19 CFR 210.21(c)) based on consent orders; and one respondent pursuant to Commission Rule 210.21(a) (19 CFR 210.21(a)) due to JLI's failure to serve that entity with the Complaint and Notice of Investigation. Order No. 23 (Oct. 29, 2020) (terminating and issuing consent order to Midwest Goods), *unreviewed by* Notice (Nov. 18, 2020); Order Nos. 26–29 (Dec. 8, 2020) (terminating and issuing consent orders to Vape 'N Glass, Vaperistas, Aqua Haze, and 2nd Wife Vape), *unreviewed by* Notice (Dec. 22, 2020); Order Nos. 30 & 31 (Dec. 10, 2020) (terminating and issuing consent orders to EZFumes and eJuiceDB), *unreviewed by* Notice (Jan. 4, 2021); Order No. 32 (Dec. 14, 2020) (terminating and issuing a consent order to JC Pods), *unreviewed by* Notice (Jan. 4, 2021); Order Nos. 33 & 34 (Dec. 15, 2020) (terminating and issuing consent orders to Tobacco Alley and WeVapeUSA), *unreviewed by* Notice (Jan. 5, 2021); Order No. 37 (Dec. 30, 2020) (terminating and issuing a consent order to Vape Central Group), *unreviewed by* Notice (Jan. 21, 2021); Order No. 38 (Jan. 5, 2021) (terminating and issuing a consent order to Ana Equity), *unreviewed by* Notice (Jan. 21, 2021); Order Nos. 40–42 (Feb. 1, 2021) (terminating and issuing consent orders to eCig-City, All Puff Store, and Wireless N Vapor Citi), *unreviewed by* Notice (Feb. 16, 2021); Order Nos. 43–48 (Feb. 2, 2021) (terminating and issuing consent orders to JUULSite, Alternative Pods, Limitless Accessories, Price Point, Naturally Peaked Health, and Smoker's Express), *unreviewed by* Notice (Feb. 22, 2021); Order Nos. 49 & 50 (Feb. 3, 2021) (terminating and issuing consent orders to Kind Group and CaryTown), *unreviewed by* Notice (Feb. 22, 2021); Order Nos. 53 & 54 (Feb. 17, 2021) (terminating and issuing consent orders to Cigar Road and Nilkant), *unreviewed by* Notice (Mar. 15, 2021); Order No. 58 (Mar. 18, 2021) (terminating and issuing a consent order to Cloud 99 Vapes), *unreviewed by* Notice (Apr. 2, 2021); Order No. 60 (Apr. 9, 2021) (terminating and issuing a consent order to Canal Smoke), *unreviewed by* Notice, (Apr. 22, 2021); Order No. 61 (Apr. 28, 2021) (terminating and issuing a consent order to Perfect Vape), *unreviewed by* Notice (May 17, 2021); Order No. 51 (Feb. 8, 2021) (terminating investigation as to Keep Vapor), *unreviewed by* Notice (Feb. 22, 2021). Additionally, Access Vapor LLC and Cali Pods were originally identified as two distinct respondents, *see* 85 FR at 49679–80, however, Cali Pods is a business alias of Access Vapor, *see* ID at 2, n.1.

On March 19, 2021, pursuant to Commission Rule 210.18 (19 CFR 210.18), JLI filed a motion for summary determination that the Defaulting Respondents have violated section 337 through the importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain vaporizer cartridges and components thereof that infringe the

Asserted Patents. On April 7, 2021, OUII filed a response in support of JLI's motion.

On October 14, 2021, the ALJ issued the subject ID, Order No. 65, granting the motion for summary determination on violation. Specifically, the ID finds, *inter alia:* (1) That JLI established the importation requirement as to each Defaulting Respondent; (2) that JLI established infringement as to the accused products and the Asserted Patents; and (3) that JLI satisfied the domestic industry requirement for each Asserted Patent. The ALJ's Recommended Determination (''RD'') on remedy and bonding recommended that the Commission issue a general exclusion order and impose a 100 percent bond during the period of Presidential review. The RD also recommends that the Commission issue cease and desist orders directed to the domestic Defaulting Respondents, namely, 101 Smoke Shop, Eon Pods, Jem Pods, Sky Distribution, Vapers & Papers, Access Vapor, eLiquid Stop, Evergreen Smokeshop, Shenzhen Azure, DripTip Vapes, Modern Age Tobacco, and Shango Distribution.

No party filed a petition for review of the subject ID. The Commission did not receive briefing on the public interest in response to either Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)) or the **Federal Register** notice published following issuance of the subject ID and RD. 86 FR 58099 (Oct. 20, 2021).

Having examined the record in this investigation, including the ID, the Commission has determined to review in part the ID. The Commission's review is limited to the economic prong of the domestic industry requirement.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that results in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994) (Commission Opinion).

When the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

When the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* section 337(j), 19 U.S.C. 1337(j) and the Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the RD on remedy and bonding. The Commission is not requesting briefing on the issue under review (*i.e.,* the economic prong of the domestic industry requirement).

In their initial submissions, Complainant and OUII are also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the date that the asserted patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on December 13, 2021. Reply submissions must be filed no later than the close of business on December 20, 2021. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to 25 pages. Reply submissions are limited to 20 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1211) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on November 29, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part

210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 29, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–26248 Filed 12–2–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Oil Pollution Act

On November 30, 2021, the Department of Justice and the Texas Office of the Attorney General filed a civil Complaint and lodged a proposed Consent Decree with the United States District Court for the Southern District of Texas in the lawsuit entitled *United States of America and State of Texas* v. *Kirby Inland Marine, LP,* Civil Action No. 3:21–cv–00335. The United States is acting at the request of the designated federal trustees for natural resources: The Department of Commerce through the National Oceanic and Atmospheric Administration and the United States Department of the Interior through the United States Fish and Wildlife Service and the National Park Service. The State of Texas is acting through its designated State trustees: The Texas General Land Office, the Texas Commission on Environmental Quality, and the Texas Parks and Wildlife Department.

This is a civil action brought against Defendant Kirby Inland Marine, LP for recovery of damages for injury to, destruction of, loss of, or loss of use of natural resources, under Section 1002 of the Oil Pollution Act, 33 U.S.C. 2702. The United States and Texas seek damages in order to compensate for and restore natural resources injured by Kirby's oil discharge that occurred in the Houston Ship Channel at the Texas City ''Y'' crossing on March 22, 2014. The United States and the State also seek to recover unreimbursed costs of assessing such injuries.

The Complaint in this natural resource damages case was filed against Kirby concurrently with the lodging of the proposed Consent Decree. The Complaint alleges that Kirby is liable for damages under the Oil Pollution Act. The Complaint alleges that oil was discharged from a Kirby barge during a collision in the Ship Channel and that natural resources were injured as a result of the discharge.

Kirby will pay $15,334,768.83 under the proposed Consent Decree. Of this total, $15.3 million is designated for the trustees to restore, replace, or acquire the equivalent of the natural resources allegedly injured, destroyed, or lost as a result of the oil spill, and the remaining amount will go to reimburse the trustees for their remaining unpaid assessment costs.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and State of Texas* v. *Kirby Inland Marine, LP,* D.J. Ref. No. 90–5–1–1–11096/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted by either email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to:Consent Decree Library,U.S. DOJ—ENRD,P.O. Box 7611,Washington, DC 20044–7611.

Please enclose a check or money order for $6.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief,Environmental Enforcement Section,Environment and Natural Resources Division.

[FR Doc. 2021–26307 Filed 12–2–21; 8:45 am]

BILLING CODE 4410–CW–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Information Collection: Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice; request for comment.

SUMMARY: The Institute of Museum and Library Services (IMLS) has under OMB review the following proposed Information Collection Request ''Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)'' for approval under the Paperwork Reduction Act (PRA). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This Notice proposes a generic clearance to gather customer and stakeholder feedback via customer interviews, feedback surveys, and rapid feedback user testing of website experiences in order to improve customer experience with IMLS services of various kinds. For more information on the types of proposed information collection requests IMLS may make under this clearance, contact the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Submit comments on or before January 2, 2022.

ADDRESSES: Submit comments identified by Information Collection 3137–NEW, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation) to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

Instructions: Please submit comments only and cite Information Collection 3137–NEW, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation) in all correspondence related to this collection.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Amira Boland, Office of Management and Budget, 725 17th St. NW, Washington, DC 20006, by phone at 202–881–9453, or via email to *amira.c.boland@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. To learn more, visit *www.imls.gov.*

Title: Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

Abstract: A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership.

This proposed information collection activity provides a means to garner customer and stakeholder feedback in an efficient, timely manner to improve customer service delivery as discussed in Section 280 of OMB Circular A–11 at *https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf.*

As discussed in OMB guidance, agencies should identify their highest-impact customer journeys (using customer volume, annual program cost, and/or knowledge of customer priority as weighting factors) and select touchpoints/transactions within those journeys to collect feedback.

These results will be used to improve the delivery of Federal services and programs. It will also provide government-wide data on customer experience that can be displayed on *www.performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

IMLS will only submit collections if they meet the following criteria:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used for general service improvement and program management purposes;
- Upon agreement between OMB and the agency all or a subset of information may be released as part of A–11, Section 280 requirements only on *performance.gov.* Summaries of customer research and user testing activities may be included in public-facing customer journey maps or summaries.
- Additional release of data must be done coordinated with OMB.

These collections will allow for ongoing, collaborative and actionable communications between the Agency, its customers and stakeholders, and OMB as it monitors agency compliance on Section 280. These responses will inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on services will be unavailable.

Current Action: New Collection of Information.

Type of Review: New.

Affected Public: Museums, Libraries, Institutions of Higher Education, Non-profits, State, Local or Tribal Government.

Estimated Number of Respondents: Below is a preliminary estimate of the aggregate burden hours for this new collection. IMLS will provide refined estimates of burden in subsequent notices.

Average Expected Annual Number of Activities: Three types of customer experience activities: Interviews, feedback surveys, and user testing.

Average Number of Respondents per Activity: 1 response per respondent per activity.

Annual Responses: 2,740.

Average Minutes per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 30 minutes to participate in an interview.

Burden Hours: IMLS requests approximately 454 burden hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection.

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 Office of Management and Budget control number.

Dated: November 29, 2021.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2021–26255 Filed 12–2–21; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On October 27, 2021, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on November 29, 2021, to:

Permit No. 2022–020

1. David Rootes, Antarctic Logistics and Expeditions

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–26289 Filed 12–2–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on External Engagement hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, December 8, 2021, from 10:30–11:30 p.m. EST.

PLACE: This meeting will be held by teleconference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Review and discuss *Science & Engineering Indicators* 2022 engagement plans; near-term engagement goals including meetings, briefings, roundtables, and media pieces; and a draft proposal for February's external panel.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Nadine Lymn, *nlymn@nsf.gov,* 703/292–7000. To listen to this teleconference, members of the public must send an email to *nationalsciencebrd@nsf.gov* at least 24 hours prior to the teleconference. The National Science Board Office will send requesters a toll-free dial-in number. Meeting information and updates may be found at the National Science Board website at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–26339 Filed 12–1–21; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board's Committee on Oversight hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, December 6, 2021, from 2:30–4:00 p.m. EDT.

PLACE: This meeting will be held by teleconference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Chair's opening remarks; approval of prior Committee minutes; review Merit Review Digest revision and Overview, and vote to approve; discussion of NSB Engagement with the Future of NSF EPSCoR Subcommittee to the NSF Committee on Equal Opportunity in Science and Engineering (CEOSE); Office of the Inspector General update; and Chief Financial Officer update.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. To listen to this teleconference, members of the public must send an email to *nationalsciencebrd@nsf.gov* at least 24 hours prior to the teleconference. The National Science Board Office will send requesters a toll-free dial-in number. Meeting information and updates may be found at the National Science Board website at *www.nsf.gov/nsb.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–26338 Filed 12–1–21; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. This is the required notice of a requested permit modification.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by January 3, 2022. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2018–025) to Bill Davis, Quark Expeditions Inc. on November 24, 2017. The issued permit allows the applicant to conduct waste management activities associated with the operation and activities of multiple tour vessels in Antarctica. Activities include shore excursions, paddling activities, skiing, mountaineering, and ice climbing as well as vessel-supported short overnight stays, also known as coastal camping. A modification to this permit issued on December 4, 2019, updated the name of the permit-holder to Allison Kean, Vice-president of operations.

Now the applicant proposes a modification to his permit to include

activities associated with the use of two twin-engine helicopters (Airbus H145) for passenger excursion and sightseeing flights during the operator's 2021–2022 season. Helicopter-supported activities include sightseeing flights and shore-landings as well as helicopter-based skiing and trekking activities. Designated pollutants brought ashore during these activities include cooking fuel and batteries that are to be used in emergency circumstances only. All materials brought shore during helicopter-based activities will be removed from the continent following each activity and measures will be taken to minimize environmental impact in the event of a release. Helicopters will only be refueled aboard the operator's vessel and measures will be in place to prevent accidental discharge.

Location: Antarctic Peninsula Region.

Dates: January 1, 2022–March 31, 2022.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–26290 Filed 12–2–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 6, 13, 20, 27, 2021, January 3, 10, 2022.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of December 6, 2021

Tuesday, December 7, 2021

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting); (Contact: Larniece McKoy Moore: 301–415–1942)

Additional Information: The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/*. For those who would like to attend in person, note that all visitors are required to complete the NRC Self-Health Assessment and Certification of Vaccination forms. Visitors who certify that they are not fully vaccinated or decline to complete the certification must have proof of a negative Food and Drug Administration-approved polymerase chain reaction (PCR) or Antigen (including rapid tests) COVID–19 test specimen collection from no later than the previous 3 days prior to entry to an NRC facility. The forms and additional information can be found here *https://www.nrc.gov/about-nrc/covid-19/guidance-for-visitors-to-nrc-facilities.pdf.*

Thursday, December 9, 2021

9:00 a.m. Briefing on 10 CFR part 53 Licensing and Regulations of Advanced Nuclear Reactors (Public Meeting); (Contact: Donna Williams: 301–415–1322)

Additional Information: The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/*. For those who would like to attend in person, note that all visitors are required to complete the NRC Self-Health Assessment and Certification of Vaccination forms. Visitors who certify that they are not fully vaccinated or decline to complete the certification must have proof of a negative Food and Drug Administration-approved PCR or Antigen (including rapid tests) COVID–19 test specimen collection from no later than the previous 3 days prior to entry to an NRC facility. The forms and additional information can be found here *https://www.nrc.gov/about-nrc/covid-19/guidance-for-visitors-to-nrc-facilities.pdf.*

Week of December 13, 2021—Tentative

Tuesday, December 14, 2021

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

Week of December 20, 2021—Tentative

There are no meetings scheduled for the week of December 20, 2021.

Week of December 27, 2021—Tentative

There are no meetings scheduled for the week of December 27, 2021.

Week of January 3, 2022—Tentative

There are no meetings scheduled for the week of January 3, 2022.

Week of January 10, 2022—Tentative

There are no meetings scheduled for the week of January 10, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov*. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov* or *Betty.Thweatt@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 1, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–26423 Filed 12–1–21; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301; NRC–2020–0277]

NextEra Energy Point Beach, LLC; Point Beach Nuclear Plant, Unit Nos. 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft supplemental environmental impact statement; public comment meetings.

SUMMARY: On November 9, 2021, the U.S. Nuclear Regulatory Commission (NRC) published in the **Federal Register** a notice of availability of the draft plant-specific Supplement 23, Second Renewal, to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants, NUREG–1437, regarding the proposed subsequent renewal of Renewed Facility Operating License Nos. DPR–24 and DPR–27 for an additional 20 years of operation for Point Beach Nuclear Plant, Unit Nos. 1 and 2 (Point Beach). The NRC is announcing two public comment webinars to receive comments on this document. The meetings will allow

interested members of the public to submit their comments.

DATES: The NRC staff will hold the webinars on the draft Supplemental Environmental Impact Statement (SEIS) on December 8, 2021 from 1:00 p.m. to 3:00 p.m. Central Time (CT) and from 5:00 p.m. to 7:00 p.m. CT. The staff will present the preliminary findings of the draft SEIS and will receive public comments during transcribed public meetings. Members of the public are invited to continue to submit written comments by January 3, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0277. Address questions about Docket IDs to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.
- *Email comments to: PointBeach-SLRSEIS@nrc.gov.* For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Phyllis M. Clark, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6447; email: *Phyllis.Clark@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0277 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0277.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* Draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available in ADAMS under Accession No. ML21306A226.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.
- *Project Website:* Information related to the Point Beach second license renewal can be accessed on the NRC's Point Beach website at *https://www.nrc.gov/reactors/operating/licensing/renewal/applications/point-beach-subsequent.html.* Under the section titled ''Public Involvement,'' click on the date of the ''Draft Report.''
- *Public Library:* A copy of draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available at the following location (library access and hours are determined by local policy):

○ Lester Public Library, 1001 Adams Street, Two Rivers, WI 54241.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0277 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Meeting Information

On November 9, 2021, the NRC published in the **Federal Register** (86 FR 62220) a notice of availability of the draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, regarding the proposed subsequent renewal of Point Beach and requested public comments on this document. The NRC is announcing that the NRC staff will hold two public webinars. The webinars will include a telephone line for members of the public to provide comments. A court reporter will transcribe all comments received during the webinars. To be considered, comments must be provided either at the transcribed public meeting or in writing, as discussed in the **ADDRESSES** section of this notice. The public webinars will be held on December 8, 2021, from 1:00 p.m. to 3:00 p.m. CT and from 5:00 p.m. to 7:00 p.m. CT. Persons interested in attending these webinars should monitor the NRC's Public Meeting Schedule website at *https://www.nrc.gov/pmns/mtg* for additional information, agenda for the meetings, and access information for the webinars. Please contact Ms. Phyllis Clark no later than December 6, 2021, if accommodations or special equipment is needed to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated.

Dated: November 29, 2021.

For the Nuclear Regulatory Commission.

Robert B. Elliott,

Chief, Environmental Review License Renewal Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2021–26230 Filed 12–2–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2020–82; MC2022–25 and CP2022–27]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 6, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2020–82; *Filing Title:* USPS Notice of Amendment to Parcel Select & Parcel Return Service Contract 10, Filed Under Seal; *Filing Acceptance Date:* November 24, 2021; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 6, 2021.

2. *Docket No(s).:* MC2022–25 and CP2022–27; *Filing Title:* USPS Request to Add Priority Mail Contract 731 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 24, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* December 6, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–26233 Filed 12–2–21; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34428; File No. 812–15204]

Calamos Hunt Alternative Income Fund, et al.

November 30, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under section 17(d) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain closed-end management investment companies to co-invest in portfolio companies with each other and with affiliated investment funds.

APPLICANTS: Calamos Hunt Alternative Income Fund (''Calamos Hunt Fund'' or the ''Existing Regulated Entity''), Calamos Advisors LLC (''Calamos Advisors'') and Hunt Capital Management, LLC (''HCM'').

DATES: The application was filed on February 19, 2021, and amended on June 24, 2021 and September 30, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on December 23, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, *Secretarys-Office@sec.gov.* Applicants: *legalnotices@calamos.com.*

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, at (202) 551–6817 or Kaitlin C. Bottock, Branch Chief, at (202) 551–6825 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations:

1. Calamos Hunt Fund is a Delaware statutory trust and is a diversified, closed-end management investment company operated as an interval fund and registered under the Act. Calamos Hunt Fund's investment objective is to produce current income with a secondary objective of capital appreciation. The board of directors (''Board'') of the Calamos Hunt Fund has five members, four of whom not an ''interested person'' of the Calamos Hunt Fund within the meaning of

Section 2(a)(19) of the Act (the ''Independent Trustees'').[1]

2. Calamos Advisors serves as the investment advisor to the Existing Regulated Entity. Calamos Advisors is registered as an investment advisor under the Investment Advisers Act of 1940 (''Advisers Act'').

3. HCM is a Delaware limited liability company that is registered as an investment adviser under the Advisers Act. HCM serves as the sub-advisor to the Existing Regulated Entity. Calamos Advisors is not an affiliated person (as defined in Section 2(a)(3) of the Act) of HCM.

4. Applicants seek an order (''Order'') to permit a Regulated Entity [2] and one or more other Regulated Entities and one or more Affiliated Funds [3] to (a) participate in the same investment opportunities through a proposed co-investment program where such participation would otherwise be prohibited under section 17 of the Act; and (b) make additional investments in securities of such issuers (''Follow-On Investments''), including through the exercise of warrants, conversion privileges, and other rights to purchase securities of the issuers. ''Co-Investment Transaction'' means any transaction in which a Regulated Entity (or its Wholly-Owned Investment Subsidiary, as defined below) participated together with one or more other Regulated Entities and/or Affiliated Funds in reliance on the requested Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Entity (or its Wholly-Owned Investment Subsidiaries) could not participate together with one or more other Regulated Entities and/or one or more Affiliated Funds without obtaining and relying on the Order.[4]

5. Applicants state that Calamos Advisors has delegated responsibility for the co-investment program to HCM and cannot cause the Calamos Hunt Fund or any Affiliated Fund to enter into a Potential Co-Investment Transaction. Applicants further state that (a) HCM has sole responsibility for causing a Regulated Entity to enter into a Potential Co-Investment Transaction and (b) a Hunt Affiliated Advisor is responsible for ensuring that the Regulated Entities and any Affiliated Funds comply with the conditions of the application, subject to oversight of the applicable Board.

6. Applicants state that a Regulated Entity may, from time to time, form one or more Wholly-Owned Investment Subsidiaries.[5] Such a subsidiary would be prohibited from investing in a Co-Investment Transaction with any other Regulated Entity or Affiliated Fund because it would be a company controlled by its parent Regulated Entity for purposes of rule 17d–1. Applicants request that each Wholly-Owned Investment Subsidiary be permitted to participate in Co-Investment Transactions in lieu of its parent Regulated Entity and that the Wholly-Owned Investment Subsidiary's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Entity were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Subsidiary would have no purpose other than serving as a holding vehicle for the Regulated Entity's investments and, therefore, no conflicts of interest could arise between the Regulated Entity and the Wholly-Owned Investment Subsidiary. The Regulated Entity's Board would make all relevant determinations under the conditions with regard to a Wholly-Owned Investment Subsidiary's participation in a Co-Investment Transaction, and the Regulated Entity's Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Subsidiary in the Regulated Entity's place. If the Regulated Entity proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subsidiaries, the Board will also be informed of, and take into consideration, the relative participation of the Regulated Entity and the Wholly-Owned Investment Subsidiary.

7. When considering Potential Co-Investment Transactions for any Regulated Entity, the relevant Advisor will consider only the Objectives and Strategies,[6] investment policies, investment positions, capital available for investment, and other pertinent factors applicable to that Regulated Entity. The Advisors expect that any portfolio company that is an appropriate investment for a Regulated Entity should also be an appropriate investment for one or more other Regulated Entities and/or one or more Affiliated Funds, with certain exceptions based on available capital or diversification.[7]

8. Other than pro rata dispositions and Follow-On Investments as provided in conditions 7 and 8, and after making the determinations required in conditions 1 and 2(a), the applicable

[1] The term ''Independent Trustees'' refers to the independent directors, managers, or trustees of any Regulated Entity (defined below).

[2] ''Regulated Entity'' means the Existing Regulated Entity and any Future Regulated Entity. ''Future Regulated Entity'' means any closed-end management investment company formed in the future that is (a) registered under the Act, (b) whose investment advisor is a Calamos Affiliated Advisor, (c) whose investment sub-advisor is a Hunt Affiliated Advisor, and (d) that intends to participate in the co-investment program described in the Application. The term ''Calamos Affiliated Advisor'' means (a) Calamos Advisors and (b) any future investment advisor that is controlled by or under common control with Calamos Advisors and is registered as an investment advisor under the Advisers Act. The term ''Hunt Affiliated Advisor'' means HCM, any investment advisor controlled by HCM or any future investment advisor that (i) is controlled by HCM, (ii) is registered as an investment advisor under the Advisers Act, and (iii) is not a Regulated Entity or a subsidiary of a Regulated Entity. The term ''Advisor'' means (a) any Calamos Affiliated Advisor or (b) any Hunt Affiliated Advisor; provided that a Hunt Affiliated Advisor serving as a sub-advisor to an Affiliated Fund (defined below) is included in this term only if (i) the investment advisor is also a Hunt Affiliated Advisor and (ii) such Advisor controls the entity. Applicants state that the Calamos Affiliated Advisors will only be subject to Conditions 2(c)(iv), 12 and 13 of the application.

[3] ''Affiliated Fund'' means any Future Affiliated Fund or any Hunt Proprietary Account. ''Future Affiliated Fund'' means any investment fund that would be an ''investment company'' but for Section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act, is formed in the future, and whose investment advisor (and any sub-advisor, if any) is a Hunt Affiliated Advisor. No Affiliated Fund is or will be a subsidiary of a Regulated Entity. ''Hunt Proprietary Account'' means HCM in a principal capacity, and any direct or indirect, wholly-owned subsidiary of HCM that, from time to time, invests in and holds, in a principal capacity, financial assets of the type and nature pursued by the Calamos Hunt Fund.

[4] All existing entities that currently intend to rely upon the requested Order have been named as applicants. Any other existing or future entity that subsequently relies on the Order will comply with the terms and conditions of the application. No Regulated Entity or Affiliated Fund that relies on this Order will rely on any other order of the Commission authorizing Co-Investment Transactions pursuant to section 17(d) and 57(i) of the 1940 Act and no entity that relies on another such order of the Commission will rely on this Order.

[5] The term ''Wholly-Owned Investment Subsidiary'' means an entity: (a) That is wholly-owned by a Regulated Entity (with such Regulated Entity at all times holding, beneficially and of record, 100% of the voting and economic interests); (b) whose sole business purpose is to hold one or more investments on behalf of such Regulated Entity; (c) with respect to which the board of directors of such Regulated Entity has the sole authority to make all determinations with respect to the entity's participation under the conditions of the application; and (d) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act. All subsidiaries participating in Co-Investment Transactions will be Wholly-Owned Investment Subsidiaries and will have Objectives and Strategies (as defined below) that are either the same as, or a subset of, their parent Regulated Entity's Objectives and Strategies.

[6] The term ''Objectives and Strategies'' means a Regulated Entity's investment objectives and strategies as described in the Regulated Entity's registration statement on Form N–2, other filings the Regulated Entity has made with the Commission under the Securities Act of 1933 (the ''Securities Act'') or the Securities Exchange Act of 1934, and the Regulated Entity's reports to shareholders.

[7] The Regulated Entities, however, will not be obligated to invest, or co-invest, when investment opportunities are referred to them.

Advisor will present each Potential Co-Investment Transaction and the proposed allocation to the directors of the Board eligible to vote on that Co-Investment Transaction (the ''Eligible Trustees'') [8] and the majority of such directors of the Board who are Independent Trustees (a ''Required Majority'') will approve each Co-Investment Transaction prior to any investment by the participating Regulated Entity.

9. With respect to the pro rata dispositions and Follow-On Investments provided in conditions 7 and 8, a Regulated Entity may participate in a pro rata disposition or Follow-On Investment without obtaining prior approval of the Required Majority if, among other things: (i) The proposed participation of each Regulated Entity and each Affiliated Fund in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition or Follow-On Investment, as the case may be; and (ii) the Board of the Regulated Entity has approved that Regulated Entity's participation in pro rata dispositions and Follow-On Investments as being in the best interests of the Regulated Entity. If the Board does not so approve, any such disposition or Follow-On Investment will be submitted to the Regulated Entity's Eligible Trustees. The Board of any Regulated Entity may at any time rescind, suspend or qualify its approval of pro rata dispositions and Follow-On Investments with the result that all dispositions and/or Follow-On Investments must be submitted to the Eligible Trustees.

10. No Independent Trustee of a Regulated Entity will have a direct or indirect financial interest in any Co-Investment Transaction (other than indirectly through share ownership in one of the Regulated Entities), including any interest in any company whose securities would be acquired in a Co-Investment Transaction.

11. Under condition 15, if an Advisor, its principals, or any person controlling, controlled by, or under common control with the Advisor or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Entity (the ''Shares''), then the Holders will vote such Shares as required under Condition 15. Applicants believe that this condition will ensure that the Independent Trustees will act independently in evaluating the co-investment program, because the ability of an Advisor or its principals to influence the Independent Trustees by a suggestion, explicit or implied, that the Independent Trustees can be removed will be limited significantly. Applicants represent that the Independent Trustees will evaluate and approve any such independent third party, taking into account its qualifications, reputation for independence, cost to the Regulated Entity's shareholders, and other factors that they deem relevant.

Applicants' Legal Analysis:

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit affiliated persons of a registered investment company from participating in joint transactions with the company unless the Commission has granted an order permitting such transactions. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

2. Applicants state that in the absence of the requested relief, the Regulated Entities may be, in some circumstances, limited in their ability to participate in attractive and appropriate investment opportunities. Applicants believe that the proposed terms and conditions will ensure that the Co-Investment Transactions are consistent with the protection of each Regulated Entity's shareholders and with the purposes intended by the policies and provisions of the Act. Applicants state that the Regulated Entities' participation in the Co-Investment Transactions will be consistent with the provisions, policies, and purposes of the Act and on a basis that is not different from or less advantageous than that of other participants.

Applicants' Conditions:

Applicants agree that the Order will be subject to the following conditions:

1. Each time an Advisor considers a Potential Co-Investment Transaction for another Regulated Entity or an Affiliated Fund that falls within a Regulated Entity's then-current Objectives and Strategies, the Regulated Entity's Advisor will make an independent determination of the appropriateness of the investment for the Regulated Entity in light of the Regulated Entity's then-current circumstances.

2. (a) If the Advisor deems a Regulated Entity's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Entity, the Advisor will then determine an appropriate level of investment for the Regulated Entity.

(b) If the aggregate amount recommended by the applicable Advisor to be invested by the applicable Regulated Entity in the Potential Co-Investment Transaction together with the amount proposed to be invested by the other participating Regulated Entities and Affiliated Funds, collectively, in the same transaction, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on each participant's capital available for investment in the asset class being allocated, up to the amount proposed to be invested by each. The applicable Advisor will provide the Eligible Trustees of each participating Regulated Entity with information concerning each participating party's available capital to assist the Eligible Trustees with their review of the Regulated Entity's investments for compliance with these allocation procedures.

(c) After making the determinations required in conditions 1 and 2(a), the applicable Advisor will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each Regulated Entity and each Affiliated Fund) to the Eligible Trustees of each participating Regulated Entity for their consideration. A Regulated Entity will co-invest with another Regulated Entity or an Affiliated Fund only if, prior to the Regulated Entity's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the Potential Co-Investment Transaction, including the consideration to be paid, are reasonable and fair to the Regulated Entity and its investors and do not involve overreaching in respect of the Regulated Entity or its investors on the part of any person concerned;

(ii) the Potential Co-Investment Transaction is consistent with:

(A) The interests of the Regulated Entity's investors; and

(B) the Regulated Entity's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Entities or any Affiliated Funds would not disadvantage the Regulated Entity, and participation by the Regulated Entity would not be on a basis different from or less advantageous than that of any other Regulated Entities or any Affiliated Funds; provided that, if any other Regulated Entity or any Affiliated Fund, but not the Regulated Entity itself, gains the right to nominate a director for election to a portfolio

[8] Eligible Trustees may not have a financial interest in such transaction, plan, or arrangement.

company's board of directors or the right to have a board observer or any similar right to participate in the governance or management of the portfolio company, such event shall not be interpreted to prohibit the Required Majority from reaching the conclusions required by this condition (2)(c)(iii), if:

(A) The Eligible Trustees will have the right to ratify the selection of such director or board observer, if any; and

(B) the applicable Advisor agrees to, and does, provide periodic reports to the Board of the Regulated Entity with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and

(C) any fees or other compensation that any Regulated Entity or any Affiliated Fund or any affiliated person of any Regulated Entity or any Affiliated Fund receives in connection with the right of a Regulated Entity or an Affiliated Fund to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among the participating Affiliated Funds (who may each, in turn, share its portion with its affiliated persons) and the participating Regulated Entities in accordance with the amount of each party's investment; and

(iv) the proposed investment by the Regulated Entity will not benefit any Advisor, the other Regulated Entities, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by condition 13, (B) to the extent permitted by section 17(e) of the Act, as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in condition 2(c)(iii)(C).

3. Each Regulated Entity has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. The applicable Advisor will present to the Board of each Regulated Entity, on a quarterly basis, a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Entities or Affiliated Funds during the preceding quarter that fell within the Regulated Entity's then-current Objectives and Strategies that were not made available to the Regulated Entity, and an explanation of why the investment opportunities were not offered to the Regulated Entity. All information presented to the Board pursuant to this condition will be kept for the life of the Regulated Entity and at least two years thereafter, and will be subject to examination by the Commission and its staff.

5. Except for Follow-On Investments made in accordance with condition 8,[9] a Regulated Entity will not invest in reliance on the Order in any issuer in which another Regulated Entity, Affiliated Fund, or any affiliated person of another Regulated Entity or Affiliated Fund is an existing investor.

6. A Regulated Entity will not participate in any Potential Co-Investment Transaction unless the terms, conditions, price, class of securities to be purchased, settlement date, and registration rights will be the same for each participating Regulated Entity and Affiliated Fund. The grant to another Regulated Entity or an Affiliated Fund, but not the Regulated Entity, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this condition 6, if conditions 2(c)(iii)(A), (B) and (C) are met.

7. (a) If any Regulated Entity or an Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security that was acquired in a Co-Investment Transaction, the applicable Advisor will:

(i) Notify each Regulated Entity that participated in the Co-Investment Transaction of the proposed disposition at the earliest practical time; and

(ii) formulate a recommendation as to participation by each Regulated Entity in the disposition.[10]

(b) Each Regulated Entity will have the right to participate in such disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the participating Regulated Entities and Affiliated Funds.

(c) A Regulated Entity may participate in such disposition without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Entity and each Affiliated Fund in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition; (ii) the Board of the Regulated Entity has approved as being in the best interests of the Regulated Entity the ability to participate in such dispositions on a pro rata basis (as described in greater detail in the application); and (iii) the Board of the Regulated Entity is provided on a quarterly basis with a list of all dispositions made in accordance with this condition. In all other cases, the Advisor will provide its written recommendation as to the Regulated Entity's participation to the Regulated Entity's Eligible Trustees, and the Regulated Entity will participate in such disposition solely to the extent that a Required Majority determines that it is in the Regulated Entity's best interests.

(d) Each Regulated Entity and each Affiliated Fund will bear its own expenses in connection with any such disposition.

8. (a) If a Regulated Entity or an Affiliated Fund desires to make a Follow-On Investment in a portfolio company whose securities were acquired in a Co-Investment Transaction, the applicable Advisor will:

(i) Notify each Regulated Entity that participated in the Co-Investment Transaction of the proposed transaction at the earliest practical time; and

(ii) formulate a recommendation as to the proposed participation, including the amount of the proposed Follow-On Investment, by each Regulated Entity.

(b) A Regulated Entity may participate in such Follow-On Investment without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Entity and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer immediately preceding the Follow-On Investment; and (ii) the Board of the Regulated Entity has approved as being in the best interests of the Regulated Entity the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application). In all other cases, the Advisor will provide its written recommendation as to the Regulated Entity's participation to the Eligible Trustees, and the Regulated Entity will participate in such Follow-On Investment solely to the extent that a Required Majority determines that it is in the Regulated Entity's best interests.

(c) If, with respect to any Follow-On Investment:

(i) The amount of a Follow-On Investment is not based on the Regulated Entities' and the Affiliated

[9] This exception applies only to Follow-On Investments by a Regulated Entity in issuers in which that Regulated Entity already holds investments.

[10] Any Hunt Proprietary Account that is not advised by an Advisor is itself deemed to be an Advisor for purposes of Conditions 7(a)(i) and 8(a)(i).

Funds' outstanding investments immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisor to be invested by each Regulated Entity in the Follow-On Investment, together with the amount proposed to be invested by the participating Affiliated Funds in the same transaction, exceeds the amount of the opportunity; then the amount invested by each such party will be allocated among them pro rata based on each party's capital available for investment in the asset class being allocated, up to the amount proposed to be invested by each.

(d) The acquisition of Follow-On Investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and subject to the other conditions set forth in the application.

9. The Independent Trustees of each Regulated Entity will be provided quarterly for review all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Entities and the Affiliated Funds that the Regulated Entity considered but declined to participate in, so that the Independent Trustees may determine whether all investments made during the preceding quarter, including those investments which the Regulated Entity considered but declined to participate in, comply with the conditions of the Order. In addition, the Independent Trustees will consider at least annually the continued appropriateness for the Regulated Entity of participating in new and existing Co-Investment Transactions.

10. Each Regulated Entity will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Entities were a business development company (as defined in section 2(a)(48) of the Act) and each of the investments permitted under these conditions were approved by the Required Majority under section 57(f) of the Act.

11. No Independent Trustee of a Regulated Entity will also be a director, general partner, managing member or principal, or otherwise an ''affiliated person'' (as defined in the Act) of an Affiliated Fund.

12. The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by an Advisor under the investment advisory agreements with the Regulated Entities and the Affiliated Funds, be shared by the Affiliated Funds and the Regulated Entities in proportion to the relative amounts of the securities held or to be acquired or disposed of, as the case may be.

13. Any transaction fee [11] (including break-up or commitment fees but excluding broker's fees contemplated by section 17(e) of the Act, as applicable), received in connection with a Co-Investment Transaction will be distributed to the participating Regulated Entities and Affiliated Funds on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by the Advisor pending consummation of the transaction, the fee will be deposited into an account maintained by the Advisor at a bank or banks having the qualifications prescribed in section 26(a)(1) of the Act, and the account will earn a competitive rate of interest that will also be divided pro rata among the participating Regulated Entities and Affiliated Funds based on the amounts they invest in such Co-Investment Transaction. None of the Affiliated Funds, the Advisors, the other Regulated Entities or any affiliated person of the Regulated Entities or Affiliated Funds will receive additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction (other than (a) in the case of the Regulated Entities and Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in condition 2(c)(iii)(C); and (b) in the case of the Advisors, investment advisory fees paid in accordance with the agreements between the Advisors and the Regulated Entities or the Affiliated Funds).

14. The Advisors will each maintain policies and procedures reasonably designed to ensure compliance with the foregoing conditions. These policies and procedures will require, among other things, that the applicable Advisor will be notified of all Potential Co-Investment Transactions that fall within a Regulated Entity's then-current Objectives and Strategies and will be given sufficient information to make its independent determination and recommendations under conditions 1, 2(a), 7 and 8.

15. If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Entity, then the Holders will vote such Shares in the same percentages as the Regulated Entity's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) all other matters under either the Act or applicable State law affecting the Board's composition, size or manner of election.

16. Each Regulated Entity's chief compliance officer, as defined in Rule 38a–1(a)(4), will prepare an annual report for its Board that evaluates (and documents the basis of that evaluation) the Regulated Entity's compliance with the terms and conditions of the application and the procedures established to achieve such compliance.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

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BILLING CODE 8011–01–P

[11] Applicants are not requesting and the staff is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93676; File No. SR–MIAX–2021–58]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of a Proposed Rule Change To Adopt Exchange Rule 532, Order and Quote Price Protection Mechanisms and Risk Controls

November 29, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 16, 2021, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to adopt new Exchange Rule 532, Order and Quote Price Protection Mechanisms and Risk Controls; amend Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Rule 100, Definitions; and amend Exchange Rule 518, Complex Orders.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new Exchange Rule 532, Order and Quote Price Protection Mechanisms and Risk Controls. The Exchange proposes to adopt a new Managed Protection Override feature, a new Max Put Price Protection feature, and a new MIAX Strategy Price Protection (''MSPP'') in new proposed Rule 532.

The Exchange proposes to relocate and amend paragraph (a), Vertical Spread Variance (''VSV'') Price Protection; paragraph (b), Calendar Spread Variance (''CSV'') Price Protection; and paragraph (c) VSV and CSV Price Protection, from Interpretations and Policies .05 of Exchange Rule 518 to new proposed Rule 532 as described below. Additionally, the Exchange proposes to adopt a new Butterfly Spread Variance (''BSV'') Price Protection to proposed section (b)(2) of new proposed Rule 532.

The Exchange proposes to relocate paragraph (d), Implied Away Best Bid or Offer (''ixABBO'') Price Protection; paragraph (f), Complex MIAX Options Price Collar Protection; and paragraph (g), Market Maker Single Side Protection, from Interpretations and Policies .05 of Exchange Rule 518 to new proposed Rule 532 in their entirety and without modification as section (b)(6), Complex MIAX Options Price Collar Protection; section (b)(7), Implied Away Best Bid or Offer (''ixABBO'') Price Protection; and section (b)(8), Market Maker Single Side Protection.

The Exchange proposes to amend Exchange Rule 100, Definitions to insert a clarifying term to the definition of ''Book.''

The Exchange proposes to relabel paragraph (e) of Interpretations and Policies .05 of Exchange Rule 518 to paragraph (a), and to make a number of non-substantive changes to update internal cross references throughout Exchange Rule 518 that have changed as a result of the proposed changes contained herein.

Background

The Exchange began trading complex orders [4] in October, 2016.[5] As part of its effort to continue to build out its complex order market segment the Exchange has continued to add order types [6] and functionality. To encourage Members [7] to send complex orders to the Exchange the Exchange has implemented numerous risk protections specifically tailored to complex orders. The Exchange is now proposing to modify Exchange Rule 518, Complex Orders, to relocate and consolidate certain risk protection functionality in new proposed Exchange Rule 532, Order and Quote Price Protection Mechanisms and Risk Controls, and to adopt additional risk protection functionality as described below.

Proposal

Managed Protection Override

The Exchange proposes to adopt a new Managed Protection Override feature which will work in conjunction with certain risk protections on the Exchange. If a Member enables the Managed Protection Override then all risk protections connected to the Managed Protection Override feature are engaged. When a risk protection connected to the Managed Protection Override feature is triggered, and the Managed Protection Override feature is enabled, the order subject to the risk protection will be cancelled.

The Managed Protection Override will be available for the following risk protections: Vertical Spread Variance (''VSV'') Price Protection, Calendar Spread Variance (''CSV'') Price Protection, new proposed Butterfly Spread Variance (''BSV'') Price Protection, Parity Price Protection, and new proposed Max Put Price Protection.

Currently, when the Vertical Spread Variance (''VSV'') Price Protection and the Calendar Spread Variance (''CSV'') Price Protection are triggered the default behavior is to manage the order in accordance to Exchange Rule 518(c)(4).[8] Additionally, when the Parity Price Protection is triggered the default behavior is to place the order on the Strategy Book [9] at its parity protected price.[10] The Exchange believes that offering Members the option to have their orders either managed by the Exchange or cancelled gives Members greater flexibility and control over their orders while retaining risk protection functionality.

Max Put Price Protection (''MPPP'')

The Exchange proposes to adopt a new price protection for Put options [11] by establishing a maximum price at which a Put option may trade.[12] To

[4] A ''complex order'' is any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the ''legs'' or ''components'' of the complex order), for the same account, in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purposes of executing a particular investment strategy. Mini-options may only be part of a complex order that includes other mini-options. Only those complex orders in the classes designated by the Exchange and communicated to Members via Regulatory Circular with no more than the applicable number of legs, as determined by the Exchange on a class-by-class basis and communicated to Members via Regulatory Circular, are eligible for processing. *See* Exchange Rule 518(a)(5).

[5] For a complete description of the trading of complex orders on the Exchange, *see* Exchange Rule 518. *See also,* Securities Exchange Act Release No. 79072 (October 7, 2016), 81 FR 71131 (October 14, 2016) (SR–MIAX–2016–26).

[6] *See* Securities Exchange Act Release Nos. 89085 (June 17, 2020), 85 FR 37719 (June 23, 2020) (SR–MIAX–2020–16) (Proposal to adopt new Complex Attributable Order); 89212 (July 1, 2020), 85 FR 41075 (July 8, 2020) (SR–MIAX–2020–20) (Proposal to adopt new Complex Auction-on-Arrival-Only ''cAOAO'' order type).

[7] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] *See* Interpretations and Policies .05(c) of Exchange Rule 518.

[9] The ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(17).

[10] *See* Interpretations and Policies .01(g) of Exchange Rule 518.

[11] The term ''put'' means an option contract under which the holder of the option has the right, in accordance to the terms and provisions of the option, to sell to the Clearing Corporation the number of units of the underlying security covered by the option contract. *See* Exchange Rule 100.

[12] The Exchange notes that the Cboe Exchange offers a similar Buy Order Put Protection which provides that if a User enters a buy limit order for a put with, or if a buy market order (or unexecuted portion) for a put would execute at, a price higher than or equal to the strike price of the option, the System cancels or rejects the order (or unexecuted portion) or quote. This check does not apply to adjusted series or bulk messages. *See* Cboe Exchange Rule 5.34(a)(3).

determine the maximum price the Exchange will add a pre-set value, the Put Price Variance (''PPV''),[13] to the strike price of the Put option. The pre-set value will be determined by the Exchange and communicated to Members via Regulatory Circular. Put bid orders priced through the maximum value (bids higher than the maximum value) will trade up to, and including, the maximum value, and then will be managed at the limit of the allowable range, or optionally cancelled if the Managed Protection Override feature is enabled. Put offer orders priced higher than the maximum value will be rejected. A bid quote will trade up to, and including, the maximum value, then will be managed at the limit of the allowable range, or in the case of a bid eQuote, will be cancelled. An offer quote received that is higher than the maximum price will be displayed.[14]

Example Max Put Price Protection for a Buy Market Order

An order to Buy 10 XYZ Jan 5 Put @ Market is received.

The current market is:

MBBO [15] 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10

Max Put Price Protection = (Strike + PPV) = $5.10

Because the Buy Order is priced through the Max Put Price Protection of $5.10, the order is subject to management and posted to the order book at $5.10.

MBBO 5.10 (10) × 5.50 (10)

Example Max Put Price Protection for a Sell Limit Order

An Order to Sell 10 XYZ Jan 5 Put @ $5.25 is received.

The current market is:

MBBO 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10
Put Option = XYZ Jan 5 Put
Max Put Price Protection = (Strike + PPV) = $5.10

Because the Sell Order is priced higher than the Max Put Price Protection of $5.10, the order is rejected.

Example Max Put Price Protection for a Buy Quote

A Quote to Buy 10 XYZ Jan 5 Put @ 5.50 is received.

The current market is:

MBBO 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10
Put Option = XYZ Jan 5 Put
Max Put Price Protection = (Strike + PPV) = $5.10

Because the Buy Quote is priced through the Max Put Price Protection of $5.10, the quote posted to the order book and managed at $5.10.

MBBO 5.10 (10) × 5.50 (10)

Example Max Put Price Protection for a Sell Quote

A Quote to Sell 10 XYZ Jan 5 Put @ $5.25 is received.

The current market is:

MBBO 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10
Put Option = XYZ Jan 5 Put
Max Put Price Protection = (Strike + PPV) = $5.10

Although the Sell Quote is priced higher than the Max Put Price Protection of $5.10, sell Quotes priced higher than the Max Put Price Protection are not rejected and therefore it is posted to the order book at $5.25.

MBBO 5.10 (10) × 5.25 (10)

The Exchange believes that offering Members the option to have orders either managed by the Exchange or cancelled when a risk protection is triggered gives Members greater flexibility and control over their orders while retaining the risk protection functionality.

Definitions

The Exchange proposes to include a ''Definitions'' section as paragraph (b)(1) in Rule 532. For the purposes of proposed paragraph (b) the Exchange will adopt the following definition of a Butterfly Spread in section (b)(1)(i): A ''Butterfly Spread'' is a three legged Complex Order with two legs to buy (sell) the same number of calls [16] (puts) and one leg is to sell (buy) twice the number of calls (puts), all legs have the same expiration; the strike price of each leg is equidistant from the next sequential strike price; and all legs overlie the same security.[17]

The Exchange also proposes to relocate the definition of Calendar Spread and Vertical Spread from Interpretations and Policies .05(b) and .05(a) of Exchange Rule 518 respectively, to proposed section (b)(1)(ii) and (iii) of proposed Rule 532 respectively. The definition of a Calendar Spread is a complex strategy consisting of one call (put) option and the sale of another call (put) option overlaying the same security that have different expirations but the same strike price. The definition of a Vertical Spread is a complex strategy consisting of the purchase of one call (put) option and the sale of another call (put) option overlying the same security that have the same expiration but different strike prices. The Exchange notes its definition of a Calendar Spread and a Vertical Spread is not changing under this proposal.

Butterfly Spread Price Variance (''BSV'') Price Protection

The Exchange proposes to adopt a new price protection for Butterfly Spreads as section (b)(2) of new proposed Rule 532. A butterfly spread is comprised of three legs which have the same expiration date, and are of the same type, either calls or puts, and are at equal strike intervals. The upper and lower strikes are each a buy (sell) and the middle strike is a sell (buy). The ratio of a butterfly spread will always be +1 −2 +1 or −1 +2 −1.

Butterfly Spread Example

Buy 1 XYZ April 50 Call
Sell 2 XYZ April 55 Calls
Buy 1 FYX April 60 Call

The Exchange will establish a price protection for Butterfly Spreads by establishing a Butterfly Spread Variance. The minimum value of a Butterfly Spread is zero and the maximum value is capped at the

[13] The proposed pre-set value for the Put Price Variance will be $0.10 to align to other similar price protections on the Exchange. The Exchange believes this value provides an adequate price range for executions while offering price protection against potentially erroneous executions. *See* MIAX Regulatory Circular 2016–47, MIAX Complex Order Price Protection Pre-set Values (October 20, 2016) available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_RC_2016_47.pdf,* which establishes a $0.10 pre-set value for Vertical Spreads and Calendar Spreads.

[14] Orders and quotes are handled differently as orders may only be submitted by Electronic Exchange Members and quotes may only be submitted by Market Makers. The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100. The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[15] The term ''MBBO'' means the best bid or offer on the Simple Order Book on the Exchange. *See* Exchange Rule 518(a)(13). The ''Simple Order Book'' is the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 518(a)(15).

[16] The term ''call'' means an option contract under which the holder of the option has the right, in accordance with the terms of the option, to purchase from the Clearing Corporation the number of units of the underlying security covered by the option contract. *See* Exchange Rule 100.

[17] The Exchange notes that its proposed definition of a Butterfly Spread is substantially similar to the definition of a Butterfly Spread used by at least one other options exchange. *See* Nasdaq ISE, Options 3 Options Trading Rules, Section 16. Complex Order Risk Protections, (b)(3).

absolute value of the difference between the closest strikes (the upper strike price minus the middle strike price or the middle strike price minus the lower strike price). To establish the maximum and minimum trading values, a configurable pre-set value is added to the maximum spread value and subtracted from the minimum spread value. The pre-set value will be determined by the Exchange and communicated to Members via Regulatory Circular.[18] The minimum and maximum spread values are used together to create an allowable trading range for the Butterfly Spread. Liquidity priced through the allowable trading range (bids higher than the maximum value or offers lower than the minimum value) will trade up to and including the maximum value for bids or down to and including the minimum value for offers, and then will be managed at the limit of the allowable trading range, or cancelled if the Managed Protection Override is enabled. Liquidity priced outside the allowable trading range (offers higher than the maximum value or bids lower than the minimum value) will be rejected.

Example

Butterfly Spread: Buy 1 April 50 Call, Sell 2 April 55 Calls, Buy 1 April 60 Call.

April 50 Call MBBO: $11.00 × $16.00
April 55 Call MBBO: $6.00 × $11.00
April 60 Call MBBO: $1.00 × $6.00

The maximum spread value is absolute value of the difference between the closest strikes or $5.00 (60.00 − 55.00 or 55.00 − 50.00). The minimum spread value is zero. If the pre-set value is $0.10 the maximum allowable price is then $5.10 and the minimum allowable price is then $0.10. A strategy order to buy at $5.15 will be managed on the Strategy Book at $5.10.

Calendar Spread Variance (''CSV'') Price Protection

The Exchange proposes to (i) relocate the Calendar Spread Variance (''CSV'') Price Protection from Rule 518; (ii) make a clarifying change to the rule text; and (iii) amend the rule text to enable the operation of the Managed Protection Override. Specifically, the Exchange proposes to relocate the Calendar Spread Variance (''CSV'') Price Protection from Interpretations and Policies .05(b) of Rule 518 to paragraph (b)(3) of new proposed Rule 532. Additionally, the Exchange proposes to amend the rule text of proposed subparagraph (b)(3)(iv) to provide that if the execution price of a complex order would be outside the limit set forth in proposed subparagraph (i)[19] of proposed Rule 532(b)(3), such complex order will trade down to, and including, the minimum value. This proposed change clarifies the operation of the rule and harmonizes the operation of the rule to that of the Vertical Spread Variance (''VSV'') and Butterfly Spread Variance (''BSV'') Price Protections. Remaining interest will then be placed on the Strategy Book and managed to the appropriate trading price limit as described in Rule 518(c)(4), or cancelled if the Managed Protection Override is enabled. Orders to buy below the minimum trading price limit will be rejected by the System.[20]

Vertical Spread Variance (''VSV'') Price Protection

The Exchange proposes to (i) relocate Vertical Spread Variance (''VSV'') Price Protection from Rule 518; (ii) make a clarifying change to the rule text; and (iii) amend the rule text to enable the operation of the Managed Protection Override. Specifically, the Exchange proposes to relocate the Vertical Spread Variance (''VSV'') Price Protection from Interpretations and Policies .05(a) of Rule 518 to paragraph (b)(4) of new proposed Rule 532. Additionally, the Exchange proposes to amend the rule text of proposed subparagraph (b)(4)(iii) to provide that if the execution price of a complex order would be outside the limits set forth in proposed subparagraph (i)[21] of proposed Rule 532(b)(4), such complex order will trade up to, and including, the maximum value for bids or down to, and including, the minimum value for offers. This proposed change clarifies the operation of the rule and harmonizes the operation of the rule to that of the Calendar Spread Variance (''CSV'') and Butterfly Spread Variance (''BSV'') Price Protections. Remaining interest will then be placed on the Strategy Book and managed to an appropriate trading price limit as described in Rule 518(c)(4), or cancelled if the Managed Protection Override is enabled. Orders to buy below the minimum trading price limit and orders to sell above the maximum trading price limit will be rejected by the System.

MIAX Strategy Price Protection (''MSPP'')

The Exchange now proposes to introduce a MIAX Strategy Price Protection (''MSPP'') which will establish a maximum protected price for buy orders and a minimum protected price for sell orders. To determine the maximum price for a buy order the Exchange will add a pre-set value, the MIAX Strategy Price Protection Variance (''MSPPV''),[22] to the offer side value of the cNBBO.[23] To determine the minimum protected price for sell orders the Exchange will subtract the MSPPV value from the bid side value of the cNBBO. The MSPPV value will be determined by the Exchange and communicated to Members via Regulatory Circular. For market orders[24] the functional limit will be the MSPP. All Day[25] and GTC[26] complex orders are eligible for the MIAX Strategy Price Protection. cIOC orders,[27] cAOC orders,[28] cIOC eQuotes,[29] and cAOC

[18] The Exchange proposes to use a pre-set value of $0.10 for Butterfly Spreads to align to the pre-set value which is used on the Exchange for Calendar Spreads and Vertical Spreads. *See* supra note 12.

[19] The Exchange notes that proposed subparagraph (i) is identical to current paragraph (1) of Interpretations and Policies .05(b) of Exchange Rule 518.

[20] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[21] The Exchange notes that proposed subparagraph (i) is identical to current paragraph (1) of Interpretations and Policies .05(a) of Exchange Rule 518.

[22] The Exchange proposes to use a pre-set value of $2.50 for the MIAX Strategy Price Protection Variance (''MSPPV''). The Exchange believes this value provides an adequate price range for executions while offering price protection against potentially erroneous executions.

[23] The cNBBO is calculated using the NBBO for each component of a complex strategy to establish the best net bid and offer for a complex strategy. For stock-option orders, the cNBBO for a complex strategy will be calculated using the NBBO in the individual option component(s) and the NBBO in the stock component. *See* Exchange Rule 518(a)(2).

[24] A market order is an order to buy or sell a stated number of option contracts at the best price available at the time of execution. *See* Exchange Rule 516(a).

[25] A Day Limit Order is an order to buy or sell which, if not executed, expires at the end of trading in the security on the day on which it was entered. *See* Exchange Rule 516(k).

[26] A Good 'til Cancelled or ''GTC'' Order is an order to buy or sell which remains in effect until it is either executed, cancelled or the underlying option expires. *See* Exchange Rule 516(l).

[27] A Complex Immediate-or-Cancel or ''cIOC'' order is a complex order that is to be executed in whole or in part upon receipt. Any portion not so executed is cancelled. *See* Exchange Rule 518(b)(4).

[28] A Complex Auction-or-Cancel or ''cAOC'' order is a complex limit order used to provide liquidity during a specific Complex Auction with a time in force that corresponds with that event. cAOC orders are not displayed to any market participant, and are not eligible for trading outside of the event. A cAOC order with a size greater than the aggregate auctioned size (as defined in Rule 518(d)(4)) will be capped for allocation purposes at the aggregate auctioned size. *See* Exchange Rule 518(b)(3).

[29] A ''Complex Immediate or Cancel eQuote'' or ''cIOC eQuote,'' which is a complex eQuote with a time-in-force of IOC that may be matched with another complex quote or complex order for an execution to occur in whole or in part upon receipt into the System. cIOC eQuotes will not: (i) Be executed against individual orders and quotes

eQuotes,[30] are not eligible for the MIAX Strategy Price Protection,[31] nor are crossing orders.[32] The MIAX Strategy Price Protection is an additional price protection feature provided to all Members of the Exchange.

If the MSPP is priced less aggressively than the limit price of a complex order (*i.e.,* the MSPP is less than the complex order's bid price for a buy order, or the MSPP is greater than the complex order's offer price for a sell order) the order will be (i) displayed and/or executed up to, and including, its MSPP for buy orders; or (ii) displayed and/or executed down to, and including, its MSPP for sell orders. Any unexecuted portion of such a complex order will be cancelled.

If the MSPP is priced equal to, or more aggressively than, the limit price of a complex order (*i.e.,* the MSPP is greater than the complex order's bid price for a buy order, of [sic] the MSPP is less than the complex order's offer price for a sell order) the order will be (i) displayed and/or executed up to, and including, its limit price for buy orders; or (ii) displayed and/or executed down to, and including, its limit price for sell orders. Any unexecuted portion of such a complex order: (A) Will be subject to the cLEP as described in subsection (e) of Exchange Rule 518; (B) may be submitted, if eligible, to the managed interest process described in Exchange Rule 518(c)(4); or (C) may be placed on the Strategy Book at its limit price.

The MSPP is designed to work in conjunction with other features on the Exchange such as the Complex Liquidity Exposure (''cLEP'') Process. The Exchange introduced the Complex Liquidity Exposure Process (cLEP) in 2018.[33] The cLEP process was designed for complex orders and complex eQuotes that violate their Complex MIAX Price Collar (''MPC) price.[34] The MPC price protection feature is an Exchange-wide mechanism under which a complex order or complex eQuote to sell will not be displayed or executed at a price that is lower than the opposite side cNBBO bid at the time the MPC is assigned by the System (*i.e.,* upon receipt or upon opening) by more than a specific dollar amount expressed in $0.01 increments (the ''MPC Setting''), and under which a complex order or eQuote to buy will not be displayed or executed at a price that is higher than the opposite side cNBBO offer at the time the MPC is assigned by the System by more than the MPC Setting (each the ''MPC Price'').[35] The MPC Price is established (i) upon receipt of the complex order or eQuote during free trading, or (ii) if the complex order or eQuote is not received during free trading, at the opening (or reopening following a halt) of trading in the complex strategy; or (iii) upon evaluation of the Strategy Book by the System when a wide market condition, as described in Interpretations and Policies .05(e)(1) of this Rule, no longer exists.[36] Once established the MPC Price will not change during the life of the complex order or eQuote. If the MPC Price is priced less aggressively than the limit price of the complex order or eQuote (*i.e.,* the MPC Price is less than the complex order or eQuote's bid price for a buy, or the MPC Price is greater than the complex order or eQuote's offer price for a sell), or if the complex order is a market order, the complex order or eQuote will be displayed and/or executed up to its MPC Price.[37]

A complex order or complex eQuote that would violate its MPC Price begins a cLEP Auction.[38] The System will post the complex order or eQuote to the Strategy Book at its MPC Price and begin the cLEP Auction by broadcasting a liquidity exposure message to all subscribers of the Exchange's data feeds.[39] Remaining liquidity with an original limit price that is (i) less aggressive (lower for a buy order or eQuote, or higher for a sell order or eQuote) than or equal to the MPC Price will be handled in accordance with subsection (c)(2)(ii)–(v) of Rule 518, or (ii) more aggressive than the MPC Price will be subject to the Reevaluation Process.[40]

The Reevaluation process occurs at the conclusion of a cLEP Auction where the System will calculate the next potential MPC Price for remaining liquidity with an original limit price more aggressive than the existing MPC Price. The next MPC Price will be calculated as the MPC Price plus (minus) the next MPC increment for buy (sell) orders (the ''New MPC Price''). Liquidity with an original limit price equal to or less aggressive than the New MPC Price is no longer subject to the MPC price protection. Liquidity with an original limit price more aggressive than the New MPC Price (or market order liquidity) is subject to the MPC price protection feature using the New MPC Price. In certain scenarios this could lead to a cycle of cLEP Auctions and ever increasing MPC price protection prices.

The operation of the MIAX Strategy Price Protection feature during a cLEP Auction can be seen in the following example.

Example

MPC: 0.25

The Exchange has one order (Order 1) resting on its Strategy Book: +1 component A, −1 component B:

The current market is:

MBBO component A: 4.00 (10) × 6.00 (10)

MBBO component B: 1.00 (10) × 2.50 (10)

NBBO[41] component A: 4.05 (10) × 4.15 (10)

NBBO component B: 2.30 (10) × 2.40 (10)

resting on the Simple Order Book; (ii) be eligible to initiate a Complex Auction or join a Complex Auction in progress; (iii) rest on the Strategy Book; or (iv) be displayed. Any portion of a cIOC eQuote that is not executed is immediately cancelled. *See* paragraph (c)(2) of Interpretations and Policies .02 of Exchange Rule 518.

[30] A ''Complex Auction or Cancel eQuote'' or ''cAOC eQuote,'' which is an eQuote submitted by a Market Maker that is used to provide liquidity during a specific Complex Auction with a time in force that corresponds with the duration of the Complex Auction. A cAOC eQuote with a size greater than the aggregate auctioned size (as defined in Rule 518(d)(4)) will be capped for allocation purposes at the aggregate auctioned size. cAOC eQuotes will not: (i) Be executed against individual orders and quotes resting on the Simple Order Book; (ii) be eligible to initiate a Complex Auction, but may join a Complex Auction in progress; (iii) rest on the Strategy Book; or (iv) be displayed. *See* paragraph (c)(1) of Interpretations and Policies .02 of Exchange Rule 518.

[31] The Exchange does not believe that these order types require the additional price protection afforded by the MSPP as these orders and quotes do not rest on the Strategy Book but are either executed immediately or cancelled. *See supra* notes 26, 27, 28, and 29.

[32] The Exchange does not believe that crossing orders require the additional price protection afforded by the MSPP as the execution price of these orders is pre-established. A Complex Customer Cross or ''cC2C'' Order is comprised of one Priority Customer complex order to buy and one Priority Customer complex order to sell at the same price and for the same quantity. Trading of cC2C Orders is governed by Rule 515(h)(3). *See* Exchange Rule 518(b)(5). A Complex Qualified Contingent Cross or ''cQCC'' Order is comprised of an originating complex order to buy or sell where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, as defined in Rule 516, Interpretations and Policies .01, coupled with a contra-side complex order or orders totaling an equal number of contracts. Trading of cQCC Orders is governed by Rule 515(h)(4). *See* Exchange Rule 518(b)(6).

[33] *See* Securities Exchange Act Release No. 85155 (February 15, 2019), 84 FR 5739 (February 22, 2019) (SR–MIAX–2018–36).

[34] The Exchange notes that there are no changes to the Complex MIAX Price Collar functionality under this proposal.

[35] *See* Exchange Rule 518.05(f).

[36] *See* Exchange Rule 518.05(f)(3).

[37] *See* Exchange Rule 518.05(f)(5).

[38] *See* Exchange Rule 518(e).

[39] *Id.*

[40] *Id.*

[41] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from the appropriate Securities Information Processor (''SIP''). *See* Exchange Rule 518(a)(14).

cMBBO: [42] 1.50 (10) × 5.00 (10)
cNBBO: 1.65 (10) × 1.85 (10)

The price protection is:
MSPPV: 2.50
Buy MSPPV: 1.85 + .2.50 = 4.35
Sell MSPPV: 1.65 − 2.50 = − .85

Order 1 to sell 10 at 1.90 is received and updates the cMBBO.

cMBBO: 1.50 (10) × 1.90 (10)

The Exchange receives a new order (Order 2) to buy 30 at the Market. For Market Orders the functional limit is the MSPP or 4.35.

Order 2 buys 10 from Order 1 at $1.90 and initiates the Complex Liquidity Exposure Process: Order 2 reprices to its MPC protected price of $2.10 (cNBO of 1.85 + 0.25) and is posted at that price on the Strategy Book and the cLEP Auction begins.

During the cLEP Auction the Exchange receives a new order (Order 3) to sell 10 at 2.10. This order locks the current same side Book Price of $2.10. At the end of the auction, Order 3 sells 10 to Order 2 at $2.10, filling Order 3.

Order 2 reprices to the next MPC protected price of $2.35 (initial MPC of 2.10 + 0.25) and is posted at that price on the Strategy Book and the next cLEP Auction begins.

During the next cLEP Auction the Exchange does not receive any interest to sell. At the end of the auction Order 2 is reevaluated and reprices to the next MPC protected price of 2.60 (previous MPC of 2.35 + 0.25) and is posted at that price on the Strategy Book and the next cLEP Auction begins.

During all subsequent cLEP Auctions the Exchange does not receive any interest to sell. At the end of each subsequent auction, Order 2 is reevaluated and repriced to the next MPC protected price as seen below until the MSPP protected price is equal to or less than the MPC protected price.

3rd MPC evaluation 2.60 + 0.25 = 2.85
4th MPC evaluation 2.85 + 0.25 = 3.10
5th MPC evaluation 3.10 + 0.25 = 3.35
6th MPC evaluation 3.35 + 0.25 = 3.60
7th MPC evaluation 3.60 + 0.25 = 3.85
8th MPC evaluation 3.85 + 0.25 = 4.10
9th MPC evaluation 4.10 + 0.25 = 4.35

At the end of the final auction, because the MSPP protected price of 4.35 is equal to the MPC protected price of 4.35, Order 2 is not repriced to the next MPC and is cancelled subject to MSPP.

cMBBO: 4.35 (10) × 5.00 (10)

The Exchange proposes to amend Exchange Rule 518(e), Reevaluation, to account for the introduction of a protected price in the cLEP process. The proposed rule text will provide that, at the conclusion of a cLEP Auction, the System will calculate the next potential MPC Price for remaining liquidity with an original limit price or protected price more aggressive than the existing MPC Price. The next MPC Price will be calculated as the MPC Price plus (minus) the next MPC increment for buy (sell) orders (the ''New MPC Price''). The System will initiate a cLEP Auction for liquidity that would execute or post at a price that would violate its New MPC Price. Liquidity with an original limit price or protected price less aggressive (lower for a buy order or eQuote, or higher for a sell order or eQuote) than or equal to the New MPC Price will be posted to the Strategy Book at its original limit price or handled in accordance with subsection (c)(2)(ii)–(v) of this Rule. The cLEP process will continue until no liquidity remains with an original limit price that is more aggressive than its MPC Price. At the conclusion of the cLEP process, any liquidity that has not been executed will be posted to the Strategy Book at its original limit price.

The Exchange also proposes to amend Rule 518(e), Allocation at the Conclusion of a Complex Liquidity Exposure Auction, to provide that orders and quotes executed in a cLEP Auction will be allocated first in price priority based upon their original limit price, orders subject to MSPP are allocated using their protected price, and thereafter in accordance with the Complex Auction allocation procedures described in subsection (d)(7)(i)–(vi) of this Rule.

Parity Price Protection

The Exchange proposes to amend paragraph (g), Parity Price Protection, of Interpretations and Policies .01 of Exchange Rule 518, to provide that Married-Put and Buy-Write interest to sell (sell put and sell stock; or sell call and buy stock) that is priced below the parity protected price for the strategy will be placed on the Strategy Book at the parity protected price for the strategy, or cancelled if the Managed Protection Override is enabled. This provision allows the Parity Price Protection functionality to operate in conjunction with the Managed Protection Override feature which cancels an order when its price protection feature is triggered. The Exchange believes that offering Members the option to have orders either managed by the Exchange or cancelled when a risk protection is triggered gives Members greater flexibility and control over their orders while retaining the risk protection functionality.

Miscellaneous

The Exchange proposes to rename paragraph (e), Wide Market Conditions, SMAT Events and Halts, of Interpretations and Policies .05 of Exchange Rule 518, to new paragraph (a), as a result of the removal of the preceding paragraphs (a), (b), (c), and (d) from Interpretations and Policies .05 of Exchange Rule 518, which have been relocated to new proposed Rule 532. Additionally, the Exchange proposes to make a number of non-substantive changes in Rule 518 to correct internal cross references that have changed as a result of this proposal.

The Exchange also proposes to amend the definition of ''Book'' in Exchange Rule 100 by adding the clarifying term ''simple'' to the current definition. The Exchange proposes to define the term ''Book'' to mean the electronic book of simple buy and sell orders and quotes maintained by the System. When the Exchange introduced complex orders the Exchange defined the ''Strategy Book'' [43] as the Exchange's electronic book of complex orders and complex quotes. Additionally, the Exchange defined the ''Simple Order Book'' [44] as the Exchange's regular electronic book of orders and quotes in Rule 518. The Exchange believes its proposal to amend the definition provided in Exchange Rule 100 adds clarity to the definition regarding which book of orders and quotes is being referenced.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [45] in general, and furthers the objectives of Section 6(b)(5) of the Act [46] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

[42] The cMBBO is calculated using the MBBO for each component of a complex strategy to establish the best net bid and offer for a complex strategy on the Exchange.

[43] *See* Exchange Rule 518(a)(17).

[44] *See* Exchange Rule 518(a)(15).

[45] 15 U.S.C. 78f(b).

[46] 15 U.S.C. 78f(b)(5).

Managed Protection Override

The Exchange believes that the Managed Protection Override feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing a mechanism by which Members may determine the way their orders are handled when a risk protection is triggered. The Exchange believes that it has an effective way to manage orders on the Exchange so that they do not execute at potentially erroneous prices, however the Exchange believes that giving Members the option to have their orders cancelled if a risk protection is triggered protects investors and the public interest. Members can make a decision on what to do with their order based on the then current market conditions and may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanisms of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

Max Put Price Protection

The Exchange believes that the Max Put Price Protection feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing a risk protection mechanism to prevent trades from occurring at potentially unwanted or erroneous prices. Additionally, the Exchange believes that making this risk protection feature eligible for the Managed Protection Override feature benefits Members as it gives them the option to have their order cancelled if the Max Put Price protection is triggered and the Managed Protection Override feature is enabled. Cancelling orders back to Members allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

Butterfly Spread Price Variance (''BSV'') Price Protection

The Exchange believes that the Butterfly Spread Price Variance (''BSV'') Price Protection feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing a risk protection mechanism that will establish minimum and maximum trading values to prevent an order from trading at a potentially unwanted or erroneous price.

Additionally, the Exchange believes that making the Butterfly Spread Price Variance (''BSV'') Price Protection eligible for the Managed Protection Override feature benefits Members as it gives them the option to have their order cancelled if the Butterfly Spread Price Variance Price Protection is triggered and the Managed Protection Override feature is enabled. Cancelling orders back to Members allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

Calendar Spread Variance (''CSV'') Price Protection

The Exchange believes that amending the Calendar Spread Price Variance (''CSV'') Price Protection feature to enable the Managed Protection Override feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing Members the option of having the Exchange manage their order when a price protection is triggered, or having their order cancelled when a price protection is triggered, if the Managed Protection Override is enabled. The Exchange believes cancelling an order in this scenario benefits Members as it allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

The Exchange believes amending the rule text to clarify the operation of the rule and to harmonize the rule text to that of the Vertical Spread Variance (''VSV'') and Butterfly Spread Variance (''BSV'') Price Protections promotes the protection of investors by having similar rule text and similar behavior for similar price protections which provides clarity and consistency within the Exchange's rulebook. A clear and concise rulebook benefits investors and the public interest as it reduces the chance for confusion regarding the operation of price protection functionality.

Vertical Spread Variance (''VSV'') Price Protection

The Exchange believes that amending the Vertical Spread Price Variance (''VSV'') Price Protection feature to enable the Managed Protection Override feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing Members the option of having the Exchange manage their order when a price protection is triggered, or having their order cancelled, when a price protection is triggered, if the Managed Protection Override is enabled. The Exchange believes cancelling an order in this scenario benefits Members as it allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the

option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

The Exchange believes amending the rule text to clarify the operation of the rule and to harmonize the rule text to that of the Calendar Spread Variance (''CSV'') and Butterfly Spread Variance (''BSV'') Price Protections promotes the protection of investors by having similar rule text and similar behavior for similar price protections which provides clarity and consistency within the Exchange's rulebook. A clear and concise rulebook benefits investors and the public interest as it reduces the chance for confusion regarding the operation of price protection functionality.

MIAX Strategy Price Protection (''MSPP'')

The Exchange believes that the adoption of the MIAX Strategy Price Protection (''MSPP'') promotes just and equitable principles of trade, and facilitates transactions in securities, remove [sic] impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest, by providing an order price protection that establishes a minimum and maximum trading value to prevent potentially unwanted or erroneous executions from occurring. The Exchange believes that when the MSPP is priced less aggressively than the limit price of the complex order that executing the order, up to an including its MSPP for buy orders, or down to and including its MSPP for sell orders, and cancelling any unexecuted portion of the order, protects investors and the public interest. Cancelling orders back to Members allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

Parity Price Protection

The Exchange believes that amending Interpretations and Policies .01(g), Parity Price Protection, of Exchange Rule 518, to operate in conjunction with the Managed Protection Override feature promotes just and equitable principles of trade, and facilitates transactions in securities, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest, by providing Members greater flexibility and control over their orders if the Parity Price Protection is triggered. The Exchange believes that making this risk protection feature eligible for the Managed Protection Override feature benefits Members as it gives them the option to have their order cancelled if the Parity Price Protection is triggered and the Managed Protection Override feature is enabled. Cancelling orders back to Members allows them to make a decision on what to do with their order based on the then current market conditions and a Member may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

Miscellaneous

The Exchange believes that amending the definition of ''Book'' promotes just and equitable principles of trade, fosters cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing a clarifying term to the existing definition. In particular, the Exchange believes that the proposed change will provide greater clarity to Members and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

The Exchange believes the proposed change to correct internal cross references within the Exchange's Rulebook promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system because the proposal ensures that the Exchange's rules are accurate. The Exchange notes that the proposed changes to correct internal cross references and to make minor non-substantive edits does not alter the application of each rule. As such, the proposed amendments would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and national exchange system. In particular, the Exchange believes that the proposed rule changes will provide greater clarity to Members and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

The Exchange believes this proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing new price protection features for MIAX Members. Additionally, the description of the System's functionality is designed to promote just and equitable principles of trade by providing a clear and accurate description to all participants of how the price protection process is applied and should assist investors in making decisions concerning their orders. Further, the Exchange believes that the price protection features and functionality provides market participants with an appropriate level of risk protection to their orders and contributes to the maintenance of a fair and orderly market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Specifically, the Exchange does not believe that the proposed changes will impose any burden on intra-market competition as the rules of the Exchange apply equally to all MIAX participants. The price protections are available for any MIAX Member that submits orders or quotes to the Exchange. Any MIAX Member that submits a complex order to the Exchange will benefit from the risk protections proposed herein. Further any MIAX Member that seeks to buy or sell a put will be afforded the MAX Put

Price protection. Additionally, any Member may elect to enable the Managed Protection Override feature to allow the Exchange to cancel their orders when a risk protection is triggered.

In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal is intended to protect investors by providing additional price protection functionality and further enhancements and transparency to the Exchange's risk protections. The Exchange's proposal may promote inter-market competition as the Exchange's proposal adds additional price protection features and functionality that may attract additional order flow to the Exchange, thereby promoting inter-market competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–58 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2021–58. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2021–58, and should be submitted on or before December 27, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–26241 Filed 12–2–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93677; File No. SR–CBOE–2021–068]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Adopt a Modified Trading Schedule for Holidays

November 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 15, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to adopt a modified trading schedule for holidays. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a modified trading schedule for holidays observed by the Exchange and amend and conform various rules relating to the proposed holiday trading sessions, as described more fully below. Particularly, the Exchange proposes to (i) adopt an additional Global Trading Hours (''GTH'')[3] trading session that

[47] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange's rules provide that the Exchange may designate as eligible for trading during GTH any exclusively listed index option designated for trading under Chapter 4, Section B. If the Exchange designates a class of index options as eligible for trading during GTH, FLEX Options with the same underlying index are also deemed eligible for

Continued

would immediately precede domestic holidays and (ii) start the GTH session that immediately follows a holiday at 8:15 p.m. on the holiday.[4] The proposed holiday schedule would provide expanded access to trade SPX and VIX options, which are designed to help enable investors to hedge or gain exposure to the broad U.S. market and global equity volatility.

By way of background, the Exchange currently offers two trading sessions.[5] Regular Trading Hours (''RTH'') and GTH. Rule 5.1 currently sets forth the trading hours for the Exchange's RTH and GTH trading sessions, as well as the trading schedule for holidays observed by the Exchange. Particularly, RTH for transactions in equity options (including options on individual stocks, ETFs, ETNs, and other securities) are the normal business days and hours set forth in the rules of the primary market currently trading the securities underlying the options, except for options on ETFs, ETNs, Index Portfolio Shares, Index Portfolio Receipts, and Trust Issued Receipts the Exchange designates to remain open for trading beyond 4:00 p.m.[6] but in no case later than 4:15 p.m.[7] RTH for transactions in index options are from 9:30 a.m. to 4:15 p.m., subject to certain exceptions.[8]

Currently, the GTH session begins at 3:00 a.m. and ends at 9:15 a.m. on Monday through Friday.[9] Effective November 21, 2021, the GTH session will begin at 8:15 p.m. (previous day) and end at 9:15 a.m. on Monday through Friday.[10] However, effective November 21, 2021, any GTH session that follows a holiday listed under Rule 5.1(d) will instead begin at 12:00 a.m. on the calendar day immediately following the day the holiday is observed and end at 9:15 a.m., unless the holiday is observed on a Friday, in which case the subsequent GTH session will begin at 8:15 p.m. (Sunday) and will end at 9:15 a.m. (Monday).[11] Transactions effected during the GTH session will have the same trade date as the RTH session that immediately follows it.[12]

Additionally, there are several holidays on which the Exchange is currently not open for business.[13] For any holiday observed by the Exchange that falls on a Saturday, the Exchange is not open for business on the preceding Friday, and when any holiday observed by the Exchange falls on a Sunday, the Exchange is not open for business on the following Monday, unless unusual business conditions exist at the time. Currently, if the Exchange is not open for RTH on a day, including holidays, then it will not be open for GTH on that same day.[14]

The Exchange notes that it originally adopted the GTH trading session due to global demand from investors to trade SPX and VIX options, as alternatives for hedging and other investment purposes, particularly as a complementary investment tool to VIX futures.[15] Given that SPX and VIX options only traded during regular trading hours prior to the adoption of the GTH session, it was historically difficult for U.S. investors that traded in non-U.S. markets to use these products as part of their global investment strategies. Accordingly, the Exchange adopted the GTH session to meet that demand and allow market participants to engage in trading these options (SPX and VIX) in conjunction with trading VIX futures on Cboe Futures Exchange, LLC (''CFE'') during extended hours.[16] Currently, VIX futures are open for trading on CFE nearly 23 hours a day, 5 days a week.[17]

The Exchange also recently proposed to extend the GTH trading session in order to provide global market participants with expanded access to trade the products offered during GTH.[18] In particular, the Exchange proposed to lengthen the current GTH session to help meet growing investor demand for the ability to manage risk more efficiently, react to global macroeconomic events as they are happening and adjust SPX and VIX options positions nearly around the clock. Additionally, the proposed expanded hours overlap with the Asia Pacific markets, thereby offering a new segment of global market participants the opportunity to trade GTH products in their local time. The Exchange now proposes to also adopt a modified holiday trading hours schedule to provide global market participants the ability to trade during GTH sessions that overlap with U.S. domestic holidays. Particularly, the Exchange believes this proposal allows market participants to respond to international market conditions that may occur during the time the U.S. markets are closed due to a domestic holiday notwithstanding that global markets are still operating. The proposed change also further maximizes the overlap in time that SPX and VIX are open alongside the related futures contracts, as futures markets, including CFE, follow a modified holiday trading hours schedule that aligns with the Exchange's proposal.[19]

Trading Hours

The Exchange first proposes to amend Rule 5.1(c), which sets forth the trading hours for the GTH session. Specifically, the Exchange proposes to update Rule 5.1(c) to add a reference to the holiday hours set forth in Rule 5.1(d) (as discussed more fully below), as an exception to the otherwise codified GTH hours set forth under Rule 5.1(c). The Exchange also proposes to eliminate the language that provides that a GTH session following a holiday will begin at 12:00 a.m. (unless the holiday is observed on a Friday, in which case the GTH session begins at 8:15 p.m. on Sunday). Particularly, the Exchange proposes to allow the GTH session that immediately follows a holiday to start at the same time as GTH sessions on non-holidays (*i.e.,* start at 8:15 p.m.).

The Exchange next proposes to amend Rule 5.1(d) to adopt modified trading schedules for domestic[20] and

trading during GTH. Currently, only SPX, VIX and XSP are approved for trading during GTH. Although eligible, XSP is not currently listed for trading during GTH.

[4] If the holiday is observed on a Friday, GTH currently begins (and will continue to begin) at 8:15 p.m. on the following Sunday.

[5] The term ''trading session'' means the hours during which the Exchange is open for trading for Regular Trading Hours or Global Trading Hours (each of which may referred to as a trading session). Unless otherwise specified in the Rules or the context otherwise indicates, all Rules apply in the same manner during each trading session. *See* Rule 1.1 (Definitions).

[6] All times referenced herein are Eastern Standard Time.

[7] *See* Rule 5.1(b)(1).

[8] *See* Rule 5.1(b)(2).

[9] *See* Rule 5.1(c).

[10] *See* also Securities Exchange Act Release No. 34–93403 (October 22, 2021), 86 FR 59824 (October 28, 2021) (SR–CBOE–2021–061). The Exchange notes that currently, [sic].

[11] *Id.*

[12] Transactions effected between 8:15 p.m. to 11:59 p.m. would be considered to have the trade date of the following business day. For example, any transactions effected during the GTH session that begins at 8:15 p.m. on Tuesday, November 23 will be considered to have the trade date of Wednesday, November 24 regardless of whether the trades were effected between 8:15 p.m. and 11:59 p.m. on Tuesday, November 23 or between 12:00 a.m. and 9:15 a.m. on Wednesday November 24.

[13] *See* Rule 5.1(d). Currently, the Exchange is not open for business on: New Year's Day, Martin Luther King, Jr. Day, Presidents' Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, or Christmas Day.

[14] *See* Cboe Rule 1.1, definition of ''Business Day'' and ''Trading Day''.

[15] *See* Securities Exchange Act Release No. 34–73017 (September 8, 2014), 79 FR 54758 (September 12, 2014) (SR–CBOE–2014–062).

[16] *Id.*

[17] *See* CFE Rule 1202(b).

[18] *See* Securities Exchange Act Release No. 34–73017 (September 8, 2014), 79 FR 54758 (September 12, 2014) (SR–CBOE–2014–062).

[19] For example, the Exchange notes that CFE follows a holiday schedule that includes an extended trading hours session for VIX future that begin at 6:00 p.m. on the calendar day preceding a domestic holiday through 11:30 a.m. on the holiday. *See* Rule 1202(b).

[20] Domestic holidays include Martin Luther King, Jr. Day, Presidents' Day, Memorial Day,

international [21] holidays. First, the Exchange proposes to adopt Rule 5.1(d)(1), which would outline the trading hours schedule for domestic holidays and provide specifically that for Martin Luther King, Jr. Day, Presidents' Day, Memorial Day, Independence Day, Labor Day, and Thanksgiving Day (*i.e.,* domestic holidays), the trading day following the holiday will consist of the following three trading sessions: (i) A GTH session from 8:15 p.m. on the calendar day preceding the holiday to 11:30 a.m. on the holiday, (ii) a GTH session from 8:15 p.m. on the holiday, or if the holiday is on a Friday, on the Sunday following the holiday, to 9:15 a.m. on the trading day and (iii) a RTH session on the trading day. Proposed Rule 5.1(d)(1) would also make clear that there will continue to be no RTH session on the day a domestic holiday is observed.

The Exchange notes the proposed hours of operation for the GTH session immediately preceding a RTH session that is closed due to a domestic holiday overlaps with the hours of operation of many international markets, which do not observe U.S. domestic holidays and are therefore still open at this time. For example, markets in Asia begin trading as early as 8:00 p.m. Eastern Standard Time and many European markets close at 11:30 a.m. Eastern Standard Time. Additionally, the proposed schedule is similar to the holiday schedule followed by futures markets (which also closes at 11:30 a.m. on holidays), thereby maximizing the overlap in time that SPX and VIX are open alongside related futures contracts.[22] As noted above, there will also be a GTH trading session that starts on the holiday at 8:15 p.m. (instead of 12:00 a.m. next day) and proceeds as normal until 9:15 a.m. the following trading day (for non-Friday domestic holidays). This proposed change also provides global market participants an additional opportunity to trade in their local time and when their respective market, that does not observe U.S. domestic holidays, may still be operating.

As noted above, these two GTH trading sessions are not considered to occur on separate trading days and are considered part of the next trading day (*i.e.,* both GTH sessions will have the trade date of the trading day following the holiday).[23] As an example, the holiday GTH session preceding Memorial Day will start at 8:15 p.m. on the Sunday prior to Memorial Day and end at 11:30 a.m. on Memorial Day. The market will then be closed at 11:30 a.m. on Memorial Day (Monday) (*i.e.,* there will be no RTH session on Memorial Day). The next GTH trading session will begin at 8:15 p.m. on Memorial Day and proceed as normal until 9:15 a.m. on Tuesday, which will be followed by a normal RTH session that begins as 9:30 a.m. on Tuesday. All trading from Sunday night through Tuesday RTH market close is considered to be part of the Tuesday trading day. The following also illustrates how the holiday schedule applies for U.S. domestic holidays that are observed on a Friday. For example, if Independence Day is observed on a Friday, the trading day following the Friday holiday (Monday Trading Day) will consist of three trading sessions: (1) A GTH session open from 8:15 p.m. on the Thursday preceding Independence Day to 11:30 a.m. on Independence Day, (2) a GTH session from 8:15 p.m. on the Sunday following Independence Day to 9:15 a.m. on the following Monday and (3) a RTH session from 9:30 a.m. to 4:15 p.m. on Monday. All trading from Thursday night through Friday, and from Sunday night through Monday RTH market close is considered to be part of the Monday trading day.

The Exchange next proposes to adopt Rule 5.1(d)(2) which would outline the trading hours schedule for international holidays and provide specifically that for Good Friday, Christmas Day and New Year's Day (*i.e.,* international holidays), the trading day following the holiday will consist of the following two trading sessions: (i) A GTH session from 8:15 p.m. on the holiday, or if the holiday is observed on a Friday, on the Sunday following the holiday, to 9:15 a.m. on the trading day and (ii) a RTH session on the trading day. Proposed Rule 5.1(d)(2) would also make clear that there will continue to be no RTH session on the day an international holiday is observed nor a GTH session that immediately precedes the day an international holiday is observed. The Exchange does not propose to adopt a GTH trading session that immediately precedes an international holiday, as these holidays, unlike domestic holidays, are observed not just by U.S. residents, but by many global market participants. Therefore, many international markets are also closed in observance of these international holidays. Futures markets similarly do not provide an extended trading hours session that precede certain international holidays.[24] Just like regular GTH trading sessions, a GTH trading session that starts on an international holiday at 8:15 p.m., will be considered part of the next trading day. The following illustrates the international holiday schedule using Good Friday as an example. Particularly, there will be no GTH session immediately preceding Good Friday (*i.e.,* no GTH session that starts on Thursday). Rather, the market will be closed from RTH market close on the Thursday preceding Good Friday until the GTH session that starts at 8:15 p.m. on the Sunday following Good Friday. All trading from Sunday night through RTH market close on the following Monday is for a trading day of Monday.[25]

Definitions

In connection with the proposed modified holiday trading schedule, the Exchange proposes to amend the definition of ''business day'' and ''trading day'' under Rule 1.1 (Definitions). Effective November 21, 2021, ''business day'' and ''trading day'' will be defined as a day on which the Exchange is open for trading during RTH and includes the RTH session and the GTH session that immediately precedes it. Effective November 21, 2021, the definition will also provide that if the Exchange is not open for RTH on a day, then it will not be open for GTH immediately preceding what would have otherwise been the RTH session on that day. In light of the proposed modified holiday schedule for GTH discussed above, the Exchange proposes to update the definition of ''business day'' and ''trading day''. Specifically, the Exchange proposes to eliminate the following language ''[i]f the Exchange is not open for Regular Trading Hours on a day, then it will not be open for Global Trading Hours on

Independence Day, Labor Day and Thanksgiving Day.

[21] International holidays include Good Friday, Christmas Day and New Year's Day.

[22] *See, e.g.,* CFE Rule 1202.

[23] Pursuant to Rule 6.4 (Reporting of Trades to OCC), all transactions made on the Exchange during these sessions will continue to be submitted for clearance to the Options Clearing Corporation (''OCC'') in the same manner they are today. However, as noted, such trades will have the trade date of the trading day following the holiday.

[24] *See e.g.,* CFE Rule 1202, which provides, among other things, that there will be no extended trading hours session preceding New Year's Day and Christmas Day.

[25] As a further example, if Christmas Day (December 25) is on a Tuesday, there will be no GTH session that begins the preceding Monday at 8:15 p.m. The Trading Day following Christmas Day would be Wednesday, December 26 and would consist of two trading sessions: (1) A GTH session from 8:15 p.m. on Christmas Day to 9:15 a.m. on Wednesday and (2) a regular RTH session from 9:30 a.m. to 4:15 p.m. on the Wednesday following Christmas Day. All trading from Tuesday at 8:15 p.m. through RTH market close on Wednesday is considered to be part of the Wednesday trading day (*i.e.,* all transactions executed during these two sessions will have a trade date of December 26).

that day'' and in its place add language that clarifies that a business day or trading day that immediately follows a domestic holiday pursuant to Rule 5.1(d) includes the RTH session and the two GTH sessions that immediately precede it. The Exchange believes the proposed amendments to the definition add clarity and alleviate potential confusion in connection with the proposed changes to the trading hours on holidays.

Entry of Orders, Quotes and Cancellations

The Exchange lastly proposes to update Rule 5.7(e), which provides that after RTH market close, Users may cancel orders and quotes with Time-in-Force of Good-til-Cancelled (''GTC'') [26] or Good-til-Date (''GTD'') [27] that remain in the Book until 4:45 p.m. In light of the proposed holiday schedule for GTH sessions on domestic holidays (*i.e.,* GTH session will end at 11:30 a.m. on a domestic holiday (observed)), the Exchange proposes to update Rule 5.7(e) to provide that on such domestic holidays, users may cancel orders and quotes with Time-in-Force of GTC or GTD until 11:45 a.m. The Exchange notes that the proposed rule change would allow Users to cancel any GTC and GTD orders until 11:45 a.m. on domestic holidays, not just orders in All Sessions classes (*i.e.,* SPX and VIX). The Exchange believes the proposed rule change provides Users with additional flexibility to manage their orders in all classes that remain in the Book following the market close on holidays. In particularly, the Exchange notes that cancelling a RTH Only GTC or GTD order at 11:30 a.m. on a domestic holiday has the same effect as cancelling that order at 7:30 a.m. the following day—ultimately it accommodates the User's goal of cancelling an order prior to it potentially executing during the RTH Opening Process the following morning.

[26] *See* Rule 5.6(c). The terms ''Good-til-Cancelled'' and ''GTC'' mean, for an order so designated, if after entry into the System, the order is not fully executed, the order (or unexecuted portion) remains available for potential display or execution (with the same timestamp) unless cancelled by the entering User, or until the option expires, whichever comes first. Users may not designate bulk messages as GTC.

[27] *See* Rule 5.6(c). The terms ''Good-til-Date'' and ''GTD'' mean, for an order so designated, if after entry into the System, the order is not fully executed, the order (or unexecuted portion) remains available for potential display or execution (with the same timestamp) until a date and time specified by the entering User unless cancelled by the entering User. Users may not designate bulk messages as GTD. A User may not designate a GTD order as Direct to PAR.

Market-Maker Rules

Current Rule 5.50(a) (Market-Maker Appointments) provides that a Market-Maker's selected class appointment applies to classes during all trading sessions. In other words, if a Market-Maker selects an appointment in SPX options, for example, that appointment would apply during both GTH and RTH (and thus, the Market-Maker would have an appointment to make markets in SPX during GTH and RTH). As a result, the Market-Maker continuous quoting obligations set forth in Rule 5.52(d) applies to the class for an entire trading day (including both trading sessions). Pursuant to Rule 5.52(d), a Market-Maker must enter continuous bids and offers in 60% of the series of the Market-Maker's appointed classes, excluding any adjusted series, any intra-day add-on series on the day during which such series are added for trading, any Quarterly Option series, and any series with an expiration of greater than 270 days.[28] The Exchange calculates this requirement by taking the total number of seconds the Market-Maker disseminates quotes in each appointed class (excluding the series noted above) and dividing that time by the eligible total number of seconds each appointed class is open for trading that day. The Exchange also notes however, that pursuant to Rule 5.52(d)(2)(E), the obligations apply only when the Market-Maker is quoting in a particular class during a given trading day and the obligations are not applicable to an appointed class if a Market-Maker is not quoting in that appointed class. Accordingly, if a Market-Maker does not wish to quote during the proposed new GTH sessions (*i.e.,* 8:15 p.m. (day prior to holiday) to 11:30 a.m. (holiday) or 8:15 p.m. (holiday) to 11:59 p.m. holiday), then so long as the Market-Maker doesn't log in and quote during those hours, the time between 8:15 p.m. (day prior to holiday) and 11:30 a.m. (holiday) and between 8:15 p.m. and 11:59 p.m. (holiday) won't be considered when determining a Market-Maker's compliance with the quoting obligations. Accordingly, the adoption of a modified trading schedule on holidays will have a de minimis, if any, impact on a Market-Maker's continuous quoting obligations, as they may continue to choose when to actively quote and have their obligations to their appointed classes apply. Moreover, selecting an appointment in SPX or VIX options will be optional and within the discretion of a Market-Maker. Additionally, Market-Makers have the opportunity to quote during the holiday GTH trading hours (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading Permit or creating additional connections to the Exchange. Given this ease of access to the GTH holiday trading sessions, the Exchange believes Market-Makers may be encouraged to quote during the trading session, even as amended. The Exchange believes Market-Makers will continue to have an incentive to quote during the holiday GTH sessions given the significance of the SPX and VIX within the financial markets, the expected demand, and given that the related futures also trading during those hours (which may permit execution of certain hedging strategies). The Exchange believes continuing to extend a Market-Maker's appointment to GTH notwithstanding the proposed holiday trading hours will enhance liquidity during that trading session, which benefits all investors during those hours. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit and continues to maintain a balance of Market-Maker benefits and obligations.

[28] *See* Rule 5.52(d)(2).

The Exchange also does not anticipate any changes with respect to the current Lead-Market-Makers (''LMMs'') structure used today during GTH. More specifically, Rule 3.55 (LMMS) currently provides that the Exchange may approve one or more Market-Makers to act as LMMs in each class during GTH. Further, subparagraph (b) of Rule 5.55 (LMMs) provides that if a LMM is approved to act as an LMM during GTH, then the LMM must comply with the continuous quoting obligation and other obligations of Market-Makers set forth in Rule 5.52(d)(2) but does not have to comply with the obligations under Rule 5.55(a). Additionally, subparagraph (a)(2)(B)(iv) of Rule 5.32 (Order and Quote Book Processing, Display, Priority and Execution) provides that the DPM/LMM/PMM participation entitlement does not apply during GTH. LMMs appointed in the GTH holiday sessions will therefore continue to not be obligated to satisfy heightened continuous quoting and opening quoting standards during GTH, nor will they receive a benefit in exchange for satisfying an obligation (*i.e.,* LMMs do and will not receive a participation entitlement during GTH, including during holiday trading hours). The Exchange intends to adopt via a separate rule filing an incentive program that

provides appointed LMMs a rebate if they meet certain heightened continuous quoting standards during the GTH session, which includes GTH holiday sessions. The Exchange believes the such program will encourage LMMs to provide significant liquidity during GTH, including during the proposed holiday trading hours.

Discussion

The Exchange notes that the proposed rule change to adopt a modified holiday trading schedule makes no changes to the trading rules applicable to GTH. The GTH trading session, including GTH holiday sessions, will continue to be separate trading sessions from RTH and the rules that currently apply (or don't apply) to the current GTH session will continue to apply (or not apply) to the GTH holiday session.[29] The Exchange will continue to use the same servers and hardware during the GTH holiday sessions as it uses for RTH and GTH today. Further, TPHs may continue to use the same ports and connections to the Exchange for all trading sessions. The Book used during the GTH holiday sessions will also be the same Book used currently during RTH and GTH. The Exchange also notes the following:

- All TPHs will continue to be allowed to, but will not be required to, participate during GTH holiday trading hours.[30] As noted above, while a Market-Maker's appointment to an All Sessions class will apply to that class whether it quotes in series in that class or not during holiday trading hours, the Exchange believes any additional burden related to the application of a Market-Maker's quoting obligation to the additional time added to those hours will be de minimis. The Exchange believes even if a Market-Maker elects to not quote during GTH holiday trading hours, its ability to satisfy its continuous quoting obligation will not be substantially impacted given the few classes that will be listed for trading during GTH.
- The Exchange will continue to use the same connection lines, message formats, and feeds during RTH and GTH, including GTH holiday sessions.[31] TPHs may use the same ports and EFIDs [32] for each trading session.[33] Accordingly, the Exchange expects TPHs that want to trade during the holiday trading hours to have minimal preparation.
- The same opening process will continue to be used to open GTH.
- Order processing will operate in the same manner as it does during RTH and the current GTH session. There will be no changes to the ranking, display, or allocation algorithms rules.
- There will be no changes to the processes for clearing, settlement, exercise, and expiration.[34]
- The Exchange will report Exchange quotation and last sale information to the Options Price Reporting Authority (''OPRA'') pursuant to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (the ''OPRA Plan'') during the proposed additional holiday hours in the same manner it currently reports this information to OPRA during RTH and GTH today.[35] The Exchange will also continue to disseminate an opening quote and trade price through OPRA during the proposed additional holiday trading hours (as it does for RTH and GTH today). Therefore, all TPHs that elect to trade during the proposed holiday trading hours will have access to quote and last sale information during that trading session. Exchange proprietary data feeds will also continue to be disseminated during holiday trading hours using the same formats and delivery mechanisms with which the Exchange disseminates them during RTH and GTH today. Use of these proprietary data feeds during holiday trading hours will be optional (as they are today during RTH and GTH).[36]
- The same TPHs that are required to maintain connectivity to a backup trading facility during RTH and GTH today will be required to do so during the proposed holiday trading hours.[37] Because the same connections and servers will be used for all trading sessions, including any holiday trading hours, a TPH will not be required to take any additional action to comply with this requirement, regardless of whether the TPH chooses to trade during holiday trading hours.
- The Exchange will process all clearly erroneous trade breaks during holiday trading hours in the same manner it does during RTH and GTH today and will have Exchange officials available to do so.
- The Exchange will perform all necessary surveillance coverage during holiday trading hours.
- The Exchange may halt trading during GTH holiday sessions in the interests of a fair and orderly market in the same manner it may during RTH and GTH today pursuant to Rule 5.20. Among the factors that may be considered in making the foregoing determinations are whether there has been an activation of price limits on futures exchanges or the halt of trading in related futures with respect to index options.[38]
- Rule 5.22 (Market-wide Trading Halts due to Extraordinary Market Volatility) will continue to not apply during GTH, including the proposed GTH holiday sessions. Under Rule 5.22, the Exchange will halt trading in all classes whenever a market-wide trading halt (commonly known as a circuit breaker) is initiated in response to

[29] For example, business conduct rules in Chapter 8 and rules related to doing business with the public in Chapter 9 will continue to apply during the GTH holiday session. Additionally, a broker-dealer's due diligence and best execution obligations apply during the GTH holiday session. As there will still be no open outcry trading on the floor during GTH, Chapter 5, Section G will continue not to apply as such rules pertain to manual order handling and open-outcry trading.

[30] In order to participate in GTH, even as amended, a Trading Permit Holder (''TPH'') must have a letter of guarantee from a Clearing TPH that is properly authorized by the Options Clearing Corporation (''OCC'') to operate during the GTH session. *See* Cboe Options Rule 3.61.

[31] The same telecommunications lines used by TPHs during RTH and/or GTH today may be used during GTH, even as extended, and these lines will be connected to the same application server at the Exchange during both trading sessions.

[32] The term ''EFID'' means an Executing Firm ID. The Exchange assigns an EFID to a TPH, which the System uses to identify the TPH and the clearing number for the execution of orders and quotes submitted to the System with that EFID.

[33] A TPH may elect to have separate ports or EFIDs for each trading session, but the Exchange will not require that.

[34] The Exchange has held discussions with the Options Clearing Corporation, which is responsible for clearance and settlement of all listed options transactions and has informed the Exchange that it will be able to clear and settle all transactions that occur on the Exchange during the proposed holiday trading hours subject to its existing requirements for transactions executed during extended and overnight trading sessions. *See* Exchange Act Release No. 74268 (February 12, 2015), 80 FR 8917 (February 19, 2015) (SR–OCC–2014–024) (approval of proposed rule change concerning extended and overnight trading sessions), which applies to both index options and index future products.

[35] The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are trading on the participant exchanges. The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder. *See* Securities Exchange Act Release No. 17638 (March 18, 1981). The full text of the OPRA Plan is available at *http://www.opraplan.com.* All operating U.S. options exchanges participate in the OPRA Plan. The Exchange will report its best bid and offer and executed trades to OPRA during the proposed additional holiday trading hours in the same manner that they are reported during RTH and GTH today.

[36] Any fees related to receipt of the OPRA data feed during GTH would be included on the OPRA fee schedule. Any fees related to receipt of the Exchange's proprietary data feeds during GTH will be included on the Exchange's fee schedule (and will be included in a separate rule filing) or the Exchange's market data website, as applicable.

[37] *See* Rule 5.24.

[38] *See* Rule 5.20(a)(6). As discussed above, futures markets already follow a modified holiday trading schedule similar to what the Exchange is proposing. As such, should a halt of trading in related futures occur during the time a GTH holiday session is open, then the Exchange may consider whether to halt during that session, just as it may do during regular GTH (and RTH) sessions.

extraordinary market conditions. Rule 5.22(b)(1) states that the Exchange will halt trading for 15 minutes if a Level 1 or Level 2 Market Decline occurs after 9:30 a.m. and up to and including 3:25 p.m. (or 12:25 p.m. for an early scheduled close). Additionally, the Exchange will not halt trading if a Level 1 or Level 2 Market Decline occurs after 3:25 p.m. (or 12:25 p.m., if applicable). Rule 5.22(b)(2) states that the Exchange will halt trading until the next trading day if a Level 3 Market Decline occurs. The Exchange notes that Rule 5.22(b)(1) will continue not to apply during the proposed GTH holiday sessions, just as it does not apply during GTH today, as the beginning of the GTH holiday session will occur past the 15-minute halt window for a Level 1 or Level 2 Market Decline. Rule 5.22(b)(2) will also not apply to the GTH holiday session, as the GTH holiday sessions are still considered a different (*i.e.,* the next) trading day than the preceding RTH session (even though a GTH holiday session may begin on the same calendar day as such a halt). As such, if a Level 3 Market Decline occurs at any time during the RTH session immediately preceding a holiday, the Exchange will halt trading in SPX and VIX only until the start of the GTH holiday session. The Exchange believes that it is appropriate to continue to not apply Rule 5.22(b) because, even if stock trading was halted at the close of the previous trading day, the condition that led to the halt is likely to have been resolved by the time the GTH holiday session starts given the length of time between the close of the previous trading day and the proposed start time of GTH holiday session (approximately 4 hours). Moreover, current Rule 5.20(a) continues to allow the Exchange to consider unusual conditions or circumstances when determining whether to halt trading during GTH. To the extent a circuit breaker caused a stock market to be closed at the end of the prior trading day, the Exchange could consider, for example, whether it received notice from stock exchanges that trading was expected to resume (or not) the next trading day (after the holiday) in determining whether to halt trading during a GTH holiday session. Because the stock markets would not begin trading until after GTH opens, the Exchange believes it should be able to open a GTH holiday session rather than waiting up to a few days to see whether stock markets open to allow investors to participate in GTH if the Exchange believe such trading can occur in a fair and orderly manner based on then-existing circumstances, not circumstances that existed many hours earlier.

The Exchange understands that systems and other issues may arise and is committed to resolving those issues as quickly as possible, including during the new GTH holiday trading hours. Thus, the Exchange will have appropriate staff on-site and otherwise available as necessary during the proposed GTH holiday sessions to handle any technical and support issues that may arise during those hours. Additionally, the Exchange will have personnel available to address any trading issues that may arise during the additional GTH trading hours. The Exchange is also committed to fulfilling its obligations as a self-regulatory organization at all times, including during GTH, and will have appropriately trained, qualified regulatory staff in place during GTH holiday sessions to the extent it deems necessary to satisfy those obligations. The Exchange believes its surveillance procedures are adequate to properly monitor trading during the proposed GTH holiday sessions but notes if additional changes are needed in the future, it will revise such procedures to the extent necessary.

Implementation Date

The Exchange will announce the implementation date of the proposed rule change in accordance with Rule 1.5. The Exchange also notes that it first announced its proposal to adopt a modified GTH holiday schedule to market-participants via a Trade Desk notice earlier this year.[39] Since then, the Exchange has issued numerous updated notices, FAQs and detailed technical specifications.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[40] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[41] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[42] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change to adopt a modified holiday schedule will remove impediments to and perfect the mechanism of a free and open market and a national market system and will not significantly affect the protection of investors or the public interest. Particularly, the proposed rule change provides an enhanced investment opportunity within the options trading industry that is consistent with the continued globalization of the securities markets and closer aligns the Exchange's trading hours with extended trading hours of futures exchanges and also market hours of other geographic regions. The adoption of a modified holiday trading schedule is a competitive initiative designed to improve the Exchange's marketplace for the benefit of investors and allow the Exchange to provide a competitive marketplace for market participants to trade certain products for an additional period of time outside of RTH. More specifically, the adoption of GTH holiday sessions are designed to increase the overlap in time that SPX and VIX options are open alongside the related futures contracts and further aims to provide global market participants with expanded access to trade the products offered during GTH. As discussed above, the proposed modified holiday trading schedule is designed to better help meet growing investor demand for the ability to manage risk more efficiently, react to global macroeconomic events as they are happening and adjust SPX and VIX options positions nearly around the clock. Indeed, the proposal allows market participants operating in geographic locations that do not observe U.S. domestic holidays to respond to international market conditions that may occur during such holidays. The proposed rule change also provides a mechanism for the Exchange to more effectively compete with exchanges located outside of the United States. Global markets have become increasingly interdependent and linked,

[39] *See* Exchange Notice C2021032501 ''Cboe Options Exchange Releases Technical Specifications in Support of Extended Global Trading Hours''.

[40] 15 U.S.C. 78f(b).

[41] 15 U.S.C. 78f(b)(5).

[42] *Id.*

both psychologically and through improved communications technology. This has been accompanied by an increased desire among investors to have access to U.S.-listed exchange products outside of regular trading hours, and the Exchange believes this desire extends to its exclusively listed products. Indeed, market participants in the Asia Pacific region and Europe have expressed their interest in having the ability to participate in the GTH session during their market hours, which coincide with the proposed holiday trading schedule. As described above, markets in Asia begin trading as early as 8:00 p.m. Eastern Standard Time and many European markets close at 11:30 a.m. Eastern Standard Time. Accordingly, the proposed GTH holiday session provides market participants an additional opportunity to trade in their local time when their respective market (that does not observe U.S. domestic holidays) is still operating. The Exchange therefore believes that the proposed rule change is reasonably designed to provide an appropriate mechanism for additional trading hours available outside of its current RTH and GTH sessions, while providing for appropriate Exchange oversight pursuant to the Act, trade reporting, and surveillance.

The Exchange also notes that it, along with some of its affiliated options exchanges, already allow for trading outside of the hours of RTH (*i.e.,* during the current GTH trading session).[43] Furthermore, the Commission has authorized U.S. stock exchanges to be open for trading outside of regular trading hours.[44] Additionally, as noted above, futures exchanges also operate during the hours proposed to be adopted, including the Exchange's affiliate, CFE, which is open during the holiday hours the Exchange proposes to adopt.[45]

As described in detail above, the Exchange's trading rules that apply to GTH today will continue to apply during the proposed GTH holiday trading hours, which rules have all been previously filed with the Commission as being consistent with the goals of the Act. Rules that will continue to apply during the proposed holiday trading hours include rules that protect public customers, impose best execution requirements on TPHs, and prohibit acts and practices that are inconsistent with just and equitable principles of trade as well as fraudulent and manipulative practices. The Exchange's rules will also continue to provide opportunities for price improvement during the proposed holiday trading hours and applies the same allocation and priority rules that are available to the Exchange during RTH and GTH today. The Exchange believes, therefore, that the rules that will apply during the proposed holiday trading hours will continue to promote just and equitable principles of trade and prevent fraudulent and manipulative acts.

The proposed rule change clearly identifies the ways in which trading during the proposed holiday hours will be different from trading during current GTH (such as clarifying the trading sessions that will be considered part of the trading day following a holiday). This ensures that investors are aware of any differences relating to the proposed additional trading hours. Additionally, the Exchange notes that it will continue to require that disclosures be made to customers describing potential risks, which will continue to further protect investors from any additional risks related to trading during GTH.[46] The Exchange believes that, with these disclosures, GTH remains appropriate and beneficial. The All Sessions order[47] and RTH Only order[48] will continue to protect investors by permitting investors who wish only to trade during RTH from having orders or quotes execute outside of the RTH session, including during the proposed holiday GTH trading hours. Consistent with the goal of investor protection, the Exchange will not allow market orders during the proposed holiday GTH trading hours due to the expected increased volatility and decreased liquidity during these hours, just as it does not currently allow such orders during GTH today for the same reasons.

Additionally, the Exchange believes that the proposed rule change will foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, as the Exchange will ensure that adequate staffing is available during the proposed additional GTH holiday hours (as it does during current GTH hours) to provide appropriate trading support during those hours, as well as Exchange officials to make any necessary determinations under the rules during GTH (such as trading halts and trade nullification for obvious errors). The Exchange is also committed to continuing to fulfill its obligations as a self-regulatory organization at all times, including during the proposed holiday hours. The Exchange believes its surveillance procedures are adequate to properly monitor trading during the proposed holiday trading hours. Clearing and settlement processes will be the same for transactions executed during the proposed holiday GTH trading hours as they are for transactions executing during RTH or GTH trading session today.

The proposed rule change further removes impediments to a free and open market and does not unfairly discriminate among market participants, as all TPHs with access to the Exchange may trade during the proposed holiday trading hours using the same connection lines, message formats data feeds, and EFIDs they use during RTH and GTH today, minimizing any preparation efforts necessary to participate during the proposed hours. TPHs will continue not be required to trade during GTH.

Additionally, as discussed above, while the proposed rule change increases the total time during which a Market-Maker with an appointment has the ability to quote in a selected class, the Exchange believes this increase has a de minimis, if any, impact on Market-Makers given that a Market-Maker's compliance with its continuous quoting obligation is based on all classes in which it has an appointment in the aggregate and based only when a Market-Maker is quoting it its appointed classes. Indeed, as noted above, if a Market-Maker who quotes during the GTH session today does not wish to quote during the proposed holiday GTH trading hours, then so long as such Market-Maker does not log into the system and quote during those hours (or whatever other time it wishes to begin quoting), there will be no impact with respect to the Market-Maker's ability to satisfy its continuous quoting obligations. Selecting an appointment in SPX and/or VIX options will continue to

[43] *See* Cboe Options Rule 5.1, C2 Rule 5.1 and Cboe EDGX Rule 21.2.

[44] *See e.g.,* Cboe BZX Exchange, Inc. Rule 1.5, which provides for an After Hours Trading Session which is a trading session from 4:00 p.m.–8:00 p.m. and follows the Regular Trading Hours session which takes place between 9:30 a.m. and 4:00 p.m. *See also* Exchange Act Release No. 59963 (May 21, 2009), 74 FR 25787 (May 29, 2009) (SR–BATS–2009–012) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend BATS Rules to Offer an After Hours Trading Session).

[45] *See, e.g.,* CFE Rule 1202, which outlines the trading schedule for futures on the Cboe Volatility Index and includes holiday trading sessions that begin at 6:00 p.m. the day prior to a holiday and ends at 11:30 a.m. on the holiday and another extending trading hours session that begins at 6:00 p.m. on the holiday.

[46] *See* Cboe Options Rule 9.20.

[47] An All Sessions order is an order a User designates as eligible to trade during both GTH and RTH. *See* Cboe Options Rule 5.6(c).

[48] An RTH Only order is an order a User designates as eligible to trade only during RTH or not designated as All Sessions. *See* Cboe Options Rule 5.6(c).

be optional and within the discretion of a Market-Maker. Additionally, Market-Makers continue to have the opportunity to quote during GTH and the proposed holiday GTH trading hours (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading Permit or creating additional connections to the Exchange. The Exchange believes Market-Makers will have an incentive to quote in SPX and VIX during the holiday GTH trading hours given the significance of these products within the financial markets, the expected demand, and given that the related futures are also trading during those hours on holidays (which may permit execution of certain hedging strategies). The Exchange believes continuing to extend a Market-Maker's appointment to the GTH holiday trading hours will enhance liquidity during that time, which benefits all investors during those hours. The Exchange believes that any slight additional burden of extending the continuous quoting obligation to the additional hours being added in the eligible classes would be outweighed by the Exchange's efforts to add liquidity during the proposed holiday GTH trading session in All Sessions classes, the minimal preparation a Market-Maker may require to participate in the holiday GTH trading session, and the benefits to investors that may result from that liquidity. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit and continues to maintain a balance of Market-Maker benefits and obligations.

The proposed rule change is also consistent with Section 11A of the Act and Regulation NMS thereunder, because it continues to provide for the dissemination of transaction and quotation information during GTH, including holiday GTH trading hours, through OPRA, pursuant to the OPRA Plan, which the Commission approved and indicated to be consistent with the Act. While Section 11A and Regulation NMS contemplate an integrated system for trading securities, they also envision competition between markets, and innovation that provides marketplace benefits to attract order flow to an exchange does not result in unfair competition if other markets are free to compete in the same manner.[49] As discussed, the Exchange, as well as other options exchanges, already offer trading sessions outside of regular trading hours.[50]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change to adopt a modified holiday trading schedule will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because all TPHs will be able, but not be required, to participate during the additional trading hours, and will be able to do so using the same connectivity as they use during RTH and GTH today. As discussed, participation in GTH, including the proposed modified holiday trading schedule, will be voluntary and within the discretion of TPHs. While the proposed rule change increases the total time during which a Market-Maker with either a SPX and/or VIX appointment may be able quote, the Exchange believes the proposal will have a de minimis, if any, impact on a Market-Maker's continuous quoting obligations, as they may continue to choose when to actively quote and have their obligations to their appointed classes apply. Furthermore, selecting an appointment in these options classes will be optional and within the discretion of a Market-Maker. Additionally, Market-Makers continue to have the opportunity to quote during GTH and any holiday trading hours (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading Permit or creating additional connections to the Exchange. The Exchange believes that extending the continuous quoting obligation to the additional trading hours being added is also outweighed by the Exchange's efforts to add liquidity during the entire GTH trading session in All Sessions classes, the minimal preparation a Market-Maker may require to participate in the GTH trading session, and the benefits to investors that may result from that liquidity. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit and continues to maintain a balance of Market-Maker benefits and obligations.

The Exchange does not believe that the proposed rule change to adopt a modified holiday schedule will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed rule change is a competitive initiative that will benefit the marketplace and investors. Additionally, all options exchanges are free to compete in the same manner. The Exchange further believes that the same level of competition among options exchanges will continue during RTH. Because the Exchange will continue to make only exclusively listed products available for trading during GTH, including GTH holiday trading hours, and because any All Sessions orders that do not trade during GTH will be eligible to trade during the RTH trading sessions in the same manner as all other orders submitted during RTH, the proposed rule change will have no effect on the national best prices or trading during RTH. The Exchange also believes the proposed rule change could further increase its competitive position outside of the United States by providing investors with an additional investment vehicle with respect to their global trading strategies during times that better correspond with parts of regular trading hours outside of the United States.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

[49] *See* Exchange Act Release Nos. 73704 (November 28, 2014), 79 FR 72044 (December 4, 2014) (SR–CBOE–2014–062) (approval of proposed rule change for Cboe Options to extend its trading hours outside of Regular Trading Hours); and 29237 (May 24, 1991), 46 FR 24853 (May 31, 1991) (SR–NYSE–1990–052 and SR–NYSE–1990–053) (approval of proposed rule change for NYSE to extend its trading hours outside of Regular Trading Hours). The Exchange also notes that no other U.S. options exchange provides for trading SPX or VIX options outside of RTH, so there is currently no need for intermarket linkage during GTH, including GTH holiday trading hours. If another Cboe Affiliated Exchange lists any options authorized to trade during GTH outside of RTH, trading of such options on the Exchange would comply with linkage rules.

[50] *See, e.g.,* Cboe Options Rule 5.1, C2 Rule 5.1 and Cboe EDGX. Rule 21.2.

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2021–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2021–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2021–068 and should be submitted on or before December 27, 2021.

[51] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[51]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–26244 Filed 12–2–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93674; File No. SR–Phlx–2021–69]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Juneteenth National Independence Day as an Exchange Holiday and Give the Exchange the Authority To Halt or Suspend Trading or Close Exchange Facilities for Certain Unanticipated Closures

November 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on November 17, 2021, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 1030, within General 3, titled ''Member Access to the Exchange,'' to make Juneteenth National Independence Day a holiday of the Exchange memorialize all current Exchange holidays within General 3, Rule 1030, and to add a provision to permit the Exchange the authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a new Rule 1030, within General 3, titled ''Member Access to the Exchange,'' to make Juneteenth National Independence Day a holiday. The Exchange also proposes to memorialize all current holidays within General 3, Rule 1030, as well as add a provision to permit the Exchange authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures.

Today, the Exchange observes the following holidays: New Year's Day, Martin Luther King, Jr. Day, Presidents' Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day.[3] Equity 2, Section 8 (Normal Business Hours) provides, ''The System operates from 8:00 a.m. to 5:00 p.m. Eastern. Time on each business day, unless modified by the Exchange.'' [4]

At this time, the Exchange also proposes to observe Juneteenth National Independence Day, which was designated a legal public holiday on June 17, 2021.[5] Consistent with broad industry sentiment [6] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[7] the Exchange proposes to

[3] *See https://www.nasdaq.com/market-activity/stock-market-holiday-calendar.*

[4] Additionally, Phlx Options 3, Section 1 (Hours of Business) provides, ''The Board of Directors shall determine by resolution the hours during which business may be transacted on the Exchange.''

[5] Public Law 117–17.

[6] *See, e.g. https://www.wsj.com/articles/wall-street-moves-to-close-markets-for-juneteenth-in-2022-11626376243#:~:text=Stock%20and%20bond%20markets%20are,on%20a%20Sunday%20next%20year.*

[7] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/#US.*

add ''Juneteenth National Independence Day'' to the proposed list of holidays within General 3, Rule 1030(a). As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year, in addition to the other annual holidays noted within proposed General 3, Rule 1030(a).

As is the case today for those annual holidays currently observed, when a holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday and when any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the succeeding Monday, unless unusual business conditions exist at the time.[8] Proposed General 3, Rule 1030(a) would provide,

The Exchange will be open for the transaction of business on business days. The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, Juneteenth National Independence Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day. When a holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday and when any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the succeeding Monday, unless unusual business conditions exist at the time.

When determining whether unusual business conditions exist in connection with the observance of a holiday on the preceding Friday or following Monday, or not observing the holiday, the Exchange would coordinate with the securities industry. Proposed General 3, Rule 1030(a) is similar to Cboe BYX Exchange, Inc. (''CBOE BYX'') Rule 11.1(b) and Cboe Exchange, Inc. (''Cboe'') Rules 5.1(d) and 5.23(d). The Exchange believes memorializing these annual holidays within its rules will bring additional clarity to those observed holidays.

Next, the Exchange proposes to add rule text within proposed General 3, Rule 1030(b), similar to CBOE BYX Rule 11.1(c), which states, ''The Chief Executive Officer of the Exchange shall have the power to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly markets, the protection of investors, or otherwise in the public interest including special circumstances such as (1) actual or threatened physical danger, severe climatic conditions, civil unrest, terrorism, acts of war, or loss or interruption of facilities utilized by the Exchange, (2) a request by a governmental agency or official, or (3) a period of mourning or recognition for a person or event. No such action shall continue longer than a period of two days, or as soon thereafter as a quorum of the Board of Directors can be assembled, unless the Board approves the continuation of such suspension.'' While the Exchange would continue to submit a proposed rule change to the Commission to amend the annual holidays within General 3, Rule 1030(a), the Exchange proposes to give the Exchange the authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures. Unanticipated closures are typically the result of natural disasters, ad hoc National Holidays, disruptions of infrastructure, and other unpredictable events that would cause the Exchange to close for business. The Exchange would not utilize this authority routinely, rather the authority is reserved for extraordinary circumstances where there would not be sufficient time for the Exchange to file to amend its rules. The Exchange notes that it would coordinate with the industry in determining closures for these events.[9] The Exchange believes that it is necessary to have such authority in the aforementioned cases as there may not be sufficient time to file a proposed rule change. Additionally, these unanticipated closures would not be recognized on an annual basis, rather these types of closures would be ad hoc closures. The Exchange would provide notice to members and member organizations of these unanticipated closures in addition to continuing to post its annual holiday schedule on its website.

Finally, the Exchange proposes to add rule text at the end of General 3, Section 1030(b) which states, ''The powers granted to the Chief Executive Officer within paragraph (b) do not apply to paragraph (a) or any other rule within the Exchange's Rulebook.'' The power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph. The powers of the Chief Executive Officer do not extend to paragraph (a) of General 3, Section 1030 or to any other provision in the Rulebook, including but not limited to Options 3, Section 1 or Equity 2, Section 8.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by memorializing its current holidays within General 3, Rule 1030(a) and also providing the manner in which the Exchange would handle holidays that fell on a Saturday or Sunday, unless unusual business conditions exist. Today, the Exchange coordinates with the securities industry with respect to annual holidays.

Further, the Exchange's proposal to observe the Juneteenth National Independence Day as an annual holiday is consistent with the Act. Similar to other holidays listed within proposed General 3, Rule 1030(a), the rule text addresses what day would be taken off if June 19 fell on a Saturday or Sunday. The proposed rule also accounts for unusual business conditions that may alter the observance of an annual holiday or affect the day the holiday is observed. The Exchange notes that when determining whether to utilize the unusual business conditions provision, the Exchange would continue to coordinate with the securities industry.

The proposed rule promotes clarity and transparency by providing the list of current annual holidays, as well as the proposed new Juneteenth National Independence Day holiday, within its Rules. The proposed changes do not raise any new or novel issues. For these reasons, the Exchange believes that these aspects of the proposal are consistent with the Act.

Further, the Exchange's proposal to permit the Chief Executive Officer to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly

[8] For example, New Year's Day 2022 would not be observed because January 1, 2022 falls on a Saturday and typically the last day of the preceding year remains a full business day.

[9] The Options Clearing Corporation (''OCC'') has issued a guide for such events. *See* OCC's Market Closing Guide (*https://www.theocc.com/getmedia/8d6a36c6-1aa4-4984-9333-d7b0a6a09be7/unscheduled-market-closings-guide.pdf*). *See also* DTCC Reference Guide: Unscheduled Closing of Exchanges and Markets for Clearing Agencies (*https://www.dtcc.com/~/media/Files/Downloads/%20issues/Unscheduled_Close.pdf*).

[10] 15 U.S.C. 78f(b)

[11] 15 U.S.C. 78f(b)(5).

markets, the protection of investors, or otherwise in the public interest including certain specified special circumstances is consistent with the Act as the provision would permit the Exchange to act in coordination with other exchanges within the securities industry to close, as necessary, for natural disasters, ad hoc National Holidays, disruptions of infrastructure, and other unpredictable events. The Exchange would not utilize this authority routinely, rather the authority is reserved for extraordinary circumstances [12] where there would not be sufficient time for the Exchange to file to amend its rules. With this proposal, the Exchange's process of filing a proposed rule change for any new annual holidays it determines to add to the list of holidays within General 3, Rule 1030(a) would remain unchanged. The proposed authority would permit the Exchange to close the market on an ad hoc basis for an extraordinary event without the need to file a proposed rule change; these unanticipated closures would not be recognized on an annual basis. Today, the Exchange would utilize emergency authority to close its market as a result of an extraordinary circumstance.[13] This amendment removes impediments to and perfects the mechanism of a free and open market and a national market system by allowing the Exchange to halt or suspend trading or close Exchange facilities for unanticipated circumstances by providing notice to members and member organizations in addition to continuing to post its annual holiday schedule on its website.

The Exchange's proposal to add rule text at the end of General 3, Section 1030(b) to make clear the power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph is consistent with the Act as that rule text will clarify the scope of the Chief Executive Officer's powers. Making clear the powers of the Chief Executive Officer adds greater transparency to the proposed rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Memorializing its current holidays within General 3, Rule 1030(a) and describing the way holidays are observed today that fall on a Saturday or Sunday, unless unusual business conditions exist, does not impose an undue burden on competition, rather the proposal brings clarity to the Exchange's Rules. Moreover, adding Juneteenth National Independence Day to its list of annual holidays within General 3, Rule 1030(a) will not impose any burden on competition as the holiday aligns with broad industry sentiment [14] and the approach recommended by SIFMA. The Exchange would continue to coordinate with the securities industry regarding the observation of annual holidays.

Further, the Exchange's proposed changes to General 3, Rule 1030(b) to permit the Chief Executive Officer to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly markets, the protection of investors, or otherwise in the public interest including certain specified special circumstances does not impose an undue burden on competition. The proposed authority would permit the Exchange to close on an ad hoc basis for an extraordinary event without the need to file a rule change by providing notice to members and member organizations of these unanticipated closures. This would allow the Exchange to continue to coordinate with the securities industry for unanticipated closures. These proposed changes are not designed to address any competitive issues and are consistent with existing rules of other exchanges.[15]

The Exchange's proposal to add rule text at the end of General 3, Section 1030(b) to make clear the power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph does not impose an undue burden on competition, rather, the rule text will make clear the powers of the Chief Executive Officer thereby adding greater transparency to the proposed rule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [16] and subparagraph (f)(6) of Rule 19b–4 thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2021–69 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2021–69. This file

[12] The special circumstances noted in proposed Rule 1030(b) include, (1) actual or threatened physical danger, severe climatic conditions, civil unrest, terrorism, acts of war, or loss or interruption of facilities utilized by the Exchange, (2) a request by a governmental agency or official, or (3) a period of mourning or recognition for a person or event.

[13] *See* Phlx By-Law 7.5.

[14] *See* note 6 above.

[15] *See* Cboe BYX Rule 11.1(b) and (c) and Cboe Rules 5.1(d) and 5.23(d).

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2021–69 and should be submitted on or before December 27, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–26240 Filed 12–2–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rules 17h–1T and 17h–2T; SEC File No. 270–359, OMB Control No. 3235–0410

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rules 17h–1T and 17h–2T (17 CFR 240.17h–1T and 17 CFR 240.17h–2T), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17h–1T requires a covered broker-dealer to maintain and preserve records and other information concerning certain entities that are associated with the broker-dealer. This requirement extends to the financial and securities activities of the holding company, affiliates and subsidiaries of the broker-dealer that are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Rule 17h–2T requires a covered broker-dealer to file with the Commission quarterly reports and a cumulative year-end report concerning the information required to be maintained and preserved under Rule 17h–1T.

The collection of information required by Rules 17h–1T and 17h–2T, collectively referred to as the ''risk assessment rules'', is necessary to enable the Commission to monitor the activities of a broker-dealer affiliate whose business activities are reasonably likely to have a material impact on the financial and operational condition of the broker-dealer. Without this information, the Commission would be unable to assess the potentially damaging impact of the affiliate's activities on the broker-dealer.

There are currently 235 respondents that must comply with Rules 17h–1T and 17h–2T. Each of these 235 respondents are estimated to require 10 hours per year to maintain the records required under Rule 17h–1T, for an aggregate estimated annual burden of 2,350 hours (235 respondents × 10 hours). In addition, each of these 235 respondents must make five annual responses under Rule 17h–2T. These five responses are estimated to require 14 hours per respondent per year for an aggregate estimated annual burden of 3,290 hours (235 respondents × 14 hours).

In addition, new respondents must draft an organizational chart required under Rule 17h–1T and establish a system for complying with the risk assessment rules. The staff estimates that drafting the required organizational chart requires one hour and establishing a system for complying with the risk assessment rules requires three hours. Based on the reduction in the number of filers in recent years, the staff estimates there will be zero new respondents, and thus, a corresponding estimated burden of zero hours for new respondents. Thus, the total compliance burden per year is approximately 5,640 burden hours (2,350 hours + 3,290 hours).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: November 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–26246 Filed 12–2–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93675; File No. SR–NASDAQ–2021–093]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Include Juneteenth National Independence Day as a Holiday

November 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 17, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 1030, within General 3, titled ''Member Access to the Exchange,'' to make Juneteenth National Independence Day a holiday of the Exchange, to memorialize all current Exchange holidays within General 3, Rule 1030, and to add a provision to permit the Exchange the authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a new Rule 1030, within General 3, titled ''Member Access to the Exchange,'' to make Juneteenth National Independence Day a holiday of the Exchange as well as its Affiliated Markets.[3] The Exchange also proposes to memorialize all current holidays within General 3, Rule 1030, as well as add a provision to permit the Exchange the authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures.

Today, the Exchange observes the following holidays: New Year's Day, Martin Luther King, Jr. Day, Presidents' Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day.[4] Nasdaq Equity 2, Section 8 (Normal Business Hours) provides, ''The System operates from 4:00 a.m. to 8:00 p.m. Eastern. Time on each business day, unless modified by Nasdaq.'' [5]

At this time, the Exchange also proposes to observe Juneteenth National Independence Day, which was designated a legal public holiday on June 17, 2021.[6] Consistent with broad industry sentiment [7] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[8] the Exchange proposes to add ''Juneteenth National Independence Day'' to the proposed list of holidays within General 3, Rule 1030(a). As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year, in addition to the other annual holidays noted within proposed General 3, Rule 1030(a).

As is the case today for those annual holidays currently observed, when a holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday and when any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the succeeding Monday, unless unusual business conditions exist at the time.[9] Proposed General 3, Rule 1030(a) would provide,

The Exchange will be open for the transaction of business on business days. The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, Juneteenth National Independence Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day. When a holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday and when any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the succeeding Monday, unless unusual business conditions exist at the time.

When determining whether unusual business conditions exist in connection with the observance of a holiday on the preceding Friday or following Monday, or not observing the holiday, the Exchange and its Affiliated Markets would coordinate with the securities industry. Proposed General 3, Rule 1030(a) is similar to Cboe BYX Exchange, Inc. (''CBOE BYX'') Rule 11.1(b) and Cboe Exchange, Inc. (''Cboe'') Rules 5.1(d) and 5.23(d). The Exchange believes memorializing these annual holidays within the rules of Nasdaq and its Affiliated Markets will bring additional clarity to those observed holidays.

Next, the Exchange proposes to add rule text within proposed General 3, Rule 1030(b), similar to CBOE BYX Rule 11.1(c), which states, ''The Chief Executive Officer of the Exchange shall have the power to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly markets, the protection of investors, or otherwise in the public interest including special circumstances such as (1) actual or threatened physical danger, severe climatic conditions, civil unrest, terrorism, acts of war, or loss or interruption of facilities utilized by the Exchange, (2) a request by a governmental agency or official, or (3) a period of mourning or recognition for a person or event. No such action shall continue longer than a period of two days, or as soon thereafter as a quorum of the Board of Directors can be assembled, unless the Board approves the continuation of such suspension.'' While the Exchange would continue to submit a proposed rule change to the Commission to amend the annual holidays within General 3, Rule 1030(a), the Exchange proposes to give the Exchange the authority to halt or suspend trading or close Exchange facilities for certain unanticipated closures. Unanticipated closures are typically the result of natural disasters,

[3] The Affiliated Markets include BX, ISE, GEMX, and MRX. Nasdaq Phlx LLC rules do not currently incorporate by reference the Nasdaq General 3 rules. Phlx will separately file a similar rule change.

[4] *See https://www.nasdaq.com/market-activity/stock-market-holiday-calendar.*

[5] Additionally, NOM Options 3, Section 1 (Days and Hours of Business) provides at subsection (c), ''NOM shall not be open for business on any holiday observed by The Nasdaq Stock Market, LLC.'' Separately the Exchange notes that BX has similar rules at Equity 2, Section 8 and Options 3, Section 1(c). ISE, GEMX and MRX Options 3, Section 1(e) delineate the list of holidays noted above. ISE, GEMX, and MRX will separately file to remove Options 3, Section 1(e) as that rule text would be redundant once this filing becomes effective as ISE, GEMX, and MRX rules incorporate by reference Nasdaq General 3.

[6] Public Law 117–17.

[7] *See, e.g. https://www.wsj.com/articles/wall-street-moves-to-close-markets-for-juneteenth-in-2022-11626376243#:~:text=Stock%20and%20bond%20markets%20are,on%20a%20Sunday%20next%20year.*

[8] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/#US.*

[9] For example, New Year's Day 2022 would not be observed because January 1, 2022 falls on a Saturday and typically the last day of the preceding year remains a full business day.

ad hoc National Holidays, disruptions of infrastructure, and other unpredictable events that would cause the Exchange to close for business. The Exchange would not utilize this authority routinely, rather the authority is reserved for extraordinary circumstances where there would not be sufficient time for the Exchange to file to amend its rules. The Exchange notes that it would coordinate with the industry in determining closures for these events.[10] The Exchange believes that it is necessary to have such authority in the aforementioned cases as there may not be sufficient time to file a proposed rule change. Additionally, these unanticipated closures would not be recognized on an annual basis, rather these types of closures would be ad hoc closures. The Exchange would provide notice to members of these unanticipated closures in addition to continuing to post its annual holiday schedule on its website.

Finally, the Exchange proposes to add rule text at the end of General 3, Section 1030(b) which states, ''The powers granted to the Chief Executive Officer within paragraph (b) do not apply to paragraph (a) or any other rule within the Exchange's Rulebook.'' The power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph. The powers of the Chief Executive Officer do not extend to paragraph (a) of General 3, Section 1030 or to any other provision in the Rulebook, including but not limited to Options 3, Section 1 or Equity 2, Section 8.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by memorializing its current holidays within General 3, Rule 1030(a) and also providing the manner in which the Exchange would handle holidays that fell on a Saturday or Sunday, unless unusual business conditions exist. Today, the Exchange and its Affiliated Markets coordinate with the securities industry with respect to annual holidays.

Further, the Exchange's proposal to observe the Juneteenth National Independence Day as an annual holiday is consistent with the Act. Similar to other holidays listed within proposed General 3, Rule 1030(a), the rule text addresses what day would be taken off if June 19 fell on a Saturday or Sunday. The proposed rule also accounts for unusual business conditions that may alter the observance of an annual holiday or affect the day the holiday is observed. The Exchange notes that when determining whether to utilize the unusual business conditions provision, the Exchange and its Affiliated Markets would continue to coordinate with the securities industry.

The proposed rule promotes clarity and transparency by providing the list of current annual holidays of Nasdaq and its Affiliated Markets, as well as the proposed new Juneteenth National Independence Day holiday, within its Rules. The proposed changes do not raise any new or novel issues. For these reasons, the Exchange believes that these aspects of the proposal are consistent with the Act.

Further, the Exchange's proposal to permit the Chief Executive Officer to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly markets, the protection of investors, or otherwise in the public interest including special circumstances is consistent with the Act as the provision would permit Nasdaq and its Affiliated Markets to act in coordination with other exchanges within the securities industry to close, as necessary, for natural disasters, ad hoc National Holidays, disruptions of infrastructure, and other unpredictable events. The Exchange would not utilize this authority routinely, rather the authority is reserved for certain specified extraordinary circumstances [13] where there would not be sufficient time for the Exchange to file to amend its rules. With this proposal, the Exchange's process of filing a proposed rule change for any new annual holidays it determines to add to the list of holidays within General 3, Rule 1030(a) would remain unchanged. The proposed authority would permit Nasdaq and its Affiliated Markets to close the market on an ad hoc basis for an extraordinary event without the need to file a proposed rule change; these unanticipated closures would not be recognized on an annual basis. Today, the Exchange would utilize emergency authority to close for business for unanticipated closures.[14] This amendment removes impediments to and perfects the mechanism of a free and open market and a national market system by allowing the Exchange and its Affiliated Markets to halt or suspend trading or close Exchange facilities for unanticipated circumstances by providing notice to members in addition to continuing to post its annual holiday schedule on its website.

The Exchange's proposal to add rule text at the end of General 3, Section 1030(b) to make clear the power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph is consistent with the Act as that rule text will clarify the scope of the Chief Executive Officer's powers. Making clear the powers of the Chief Executive Officer adds greater transparency to the proposed rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Memorializing its current holidays within General 3, Rule 1030(a) and describing the way holidays are observed that fall on a Saturday or Sunday, unless unusual business conditions exist, does not impose an undue burden on competition, rather the proposal brings clarity to the Exchange's Rules. Moreover, adding Juneteenth National Independence Day to its list of annual holidays within General 3, Rule 1030(a) will not impose any burden on competition as the holiday aligns with broad industry sentiment [15] and the approach recommended by SIFMA. The Exchange and its Affiliated Markets would continue to coordinate with the securities industry regarding the observation of annual holidays.

[10] The Options Clearing Corporation (''OCC'') has issued a guide for such events. *See* OCC's Market Closing Guide (*https://www.theocc.com/getmedia/8d6a36c6-1aa4-4984-9333-d7b0a6a09be7/unscheduled-market-closings-guide.pdf*). *See also* DTCC Reference Guide: Unscheduled Closing of Exchanges and Markets for Clearing Agencies (*https://www.dtcc.com/~/media/Files/Downloads/%20issues/Unscheduled_Close.pdf*).

[11] 15 U.S.C. 78

[12] 15 U.S.C. 78f(b)(5).

[13] The special circumstances noted in proposed Rule 1030(b) include, (1) actual or threatened physical danger, severe climatic conditions, civil unrest, terrorism, acts of war, or loss or interruption of facilities utilized by the Exchange, (2) a request by a governmental agency or official, or (3) a period of mourning or recognition for a person or event.

[14] *See* Nasdaq By-Law Article IX, Section 5, Authority to Take Action Under Emergency or Extraordinary Market Conditions.

[15] *See* note 7 above.

Further, the Exchange's proposed changes to General 3, Rule 1030(b) to permit the Chief Executive Officer to halt, suspend trading in any and all securities traded on the Exchange, to close some or all Exchange facilities, and to determine the duration of any such halt, suspension, or closing, when he or she deems such action necessary for the maintenance of fair and orderly markets, the protection of investors, or otherwise in the public interest including certain specified special circumstances does not impose an undue burden on competition. The proposed authority would permit Nasdaq and its Affiliated Markets to close on an ad hoc basis for an extraordinary event without the need to file a rule change by providing notice to members of these unanticipated closures. This would allow the Exchange to continue to coordinate with the securities industry for unanticipated closures. These proposed changes are not designed to address any competitive issues and are consistent with existing rules of other exchanges.[16]

The Exchange's proposal to add rule text at the end of General 3, Section 1030(b) to make clear the power of the Chief Executive Officer to halt, suspend or close facilities of the Exchange within paragraph (b) applies only to the circumstances noted within that paragraph does not impose an undue burden on competition, rather, the rule text will make clear the powers of the Chief Executive Officer thereby adding greater transparency to the proposed rule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[17] and subparagraph (f)(6) of Rule 19b–4 thereunder.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2021–093 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–093. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2021–093 and should be submitted on or before December 27, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–26242 Filed 12–2–21; 8:45 am]

BILLING CODE 8011–01–P

[16] *See* Cboe BYX Rule 11.1(b) and (c) and Cboe Rules 5.1(d) and 5.23(d).

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2021–0027]

Agency Information Collection Activities: New Emergency Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a new, emergency information collection.

SSA is asking OMB for approval of this information collection seven days after the date of publication of this **Federal Register** Notice, independent of public comment, due to its emergency nature. However, we still welcome comment on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. We will consider any comments if we ultimately seek to extend this information collection beyond the standard six-month emergency approval. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA.

Comments: https://www.reginfo.gov/public/do/PRAMain. Submit your

comments online referencing Docket ID Number [SSA–2021–0027].

(SSA) Social Security Administration, OLCA, Attn: Director, Office of Regulations and Reports Clearance, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.* Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAMain,* referencing Docket ID Number [SSA–2021–0027]. We recommend submitting comments via this link as the fastest way for them to reach us.

SSA is submitting the information collection below to OMB for clearance. If you wish to submit comments, we recommend you do so no later than January 3, 2022. However, please be aware that due to the emergency nature of this collection, SSA will be seeking OMB clearance in advance of this date. Individuals may obtain copies of this OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

COVID–19 Symptoms Screener for In-Person Hearings—20 CFR 404.929, 404.933, 416.1429, 416.1433, 418.1350, and 422.203—0960–NEW. Following a temporary pause on in-person service, such as in-person hearings due to the COVID–19 pandemic, SSA will soon restart in-person hearings on a limited basis. When SSA resumes these limited in-person hearings, we will ask participating members of the public to complete a brief COVID–19 symptoms screener questionnaire within 24 hours of their hearings.

Background

During the recent COVID–19 pandemic, SSA conducted its services almost exclusively online or by telephone, to protect the health of both the public and our employees. We took these measures in accordance with relevant Centers for Disease Control COVID–19 pandemic guidance, and to comply with existing Occupational Safety and Health Act provisions regarding workplace safety.

While in-person hearings have not been available since March 2020, claimants or their appointed representatives who wished to appeal a redetermination could choose to participate in an online video hearing or phone hearing instead. We would like to soon resume in-person hearings on a limited-capacity basis. Initially, we plan to keep the number of in-person hearings to an average of three separate hearings per hearings office per day, to ensure the continued health and safety of the public and SSA employees. The number of in-person hearings per hearing office may be revised over the course of reentry.

Need for Information Collection; Collection Methodology; How Information Will Be Used

Because of COVID–19 health and safety considerations, we plan to require all members of the public entering an SSA hearing office to participate in an in-person hearing to complete a brief screener questionnaire designed to identify COVID–19 symptoms. A link to the questionnaire will be provided in the mailed notice of scheduled hearings. People participating in a hearing can complete and submit the questionnaire online within 24 hours before the start of the hearing. If hearings participants do not wish to use the internet, they can call the hearings office where the hearing is scheduled and complete the questionnaire over the phone.

The questionnaire will ask questions relating to personal experience of any COVID symptoms; exposure to someone diagnosed with COVID; or travel by means other than land travel, such as car, bus, ferry, or train. SSA will use the screener responses to determine if the in-person hearings participant is ''cleared'' or ''not cleared'' to enter an SSA hearing office. If participants answer ''no'' to all questions, they are ''cleared'' to participate. If they answer ''yes'' to any part of the screener, they will be ''not cleared.'' Persons who are not cleared may seek to be rescheduled for the next in-person hearing date that at least 14 days after the COVID–19 symptoms first presented, or 14 days after they tested positive for COVID–19.

Alternatives to Completing the Information Collection

Although completion of the questionnaire will be required for an in-person hearing, it is not required for other modalities of appeals hearings. One may choose an online video hearing or telephone hearing as an alternative to an in-person hearing. Claimants may obtain Social Security payments regardless of the hearing method they choose.

Type of Request: New (temporary, emergency) information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars)*	Average wait time in hearing office (minutes)**	Total annual opportunity cost (dollars)***
COVID Screener Questionnaire.	179,580 (164 hearing offices × 3 hearings per office per day × 2 persons per hearing × 182.5 days, which is the duration of the emergency information collection request (ICR)).	1	10	29,930 (179,580 respondents × 10 completion minutes/60 minutes per burden hour).	$19.01*	10**	$1,934,496*** (29,930 response hours + 71,832 office wait time hours = 101,762 total hours. Then multiply 101,762 hours × $19.01).

*We based this figure on averaging both the average disability insurance (DI) payments based on SSA's current fiscal year (FY) 2021 data (*https://www.ssa.gov/legislation/2021FactSheet.pdf*), and the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

**We based this figure on the average FY 2021 wait times for hearing offices, based on SSA's current management information data.

***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: November 17, 2021.

Naomi Sipple,

Reports Clearance Officer, Office of Legislation and Congressional Affairs, Social Security Administration.

[FR Doc. 2021–26376 Filed 12–2–21; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Airport Compliance Program

AGENCY: Federal Aviation Administration, Department of Transportation.

ACTION: Notice of availability of FAA Order 5190.6B, Change 1, *Airport Compliance Manual.*

This notice announces the availability of revisions to five chapters of FAA Order 5190.6B, *Airport Compliance Manual,* originally issued in September 2009. Order 5190.6B provides guidance to FAA employees on the implementation of the FAA's airport compliance program. Under the program, the FAA has the responsibility to assure airport sponsors comply with certain obligations that arise from FAA grant agreements and from deeds of property conveyance for airport use. The FAA is undertaking this update to ensure Order 5190.6B is accurate and consistent with current law and practice. As FAA updates Order 5190.6B, revised chapters will be available electronically at: *https://www.faa.gov/airports/resources/publications/orders/compliance_5190_6/.*

The FAA will identify the date of the update on each page of the Order.

The updated Order will be identified as FAA Order 5190.6B, Change 1. Each change will be numbered until the entire Order is updated. When this is complete, the new Order will be 5190.6C.

At this time, the FAA has completed revisions to five chapters. The revised chapters can be found at: *https://www.faa.gov/airports/resources/publications/orders/compliance_5190_6/.*

The updated chapters include: Chapter 1, *Scope and Authority;* Chapter 9, *Unjust Discrimination between Aeronautical Users;* Chapter 10, *Reasonable Commercial Minimum Standards;* Chapter 11, *Self-Service;* and Chapter 23, *Reversions of Airport Property.* Each of the five chapters has been updated to remain current with Federal statutes, correct or update references to regulations, orders or other authorities, and make editorial changes. The FAA will revise the remaining chapters in the Order to reflect statutory changes, update or correct references to authorities, or make editorial changes. The FAA will provide electronic notice on its website, a summary of the changes to each chapter, and electronically update the Order.

DATES: Revisions to Chapters 1, 9, 10, 11, and 23 of FAA Order 5190.6 are effective upon the date of publication of this notice. Subsequent revisions to chapters will be posted electronically at: *https://www.faa.gov/airports/resources/publications/orders/compliance_5190_6/.*

FOR FURTHER INFORMATION CONTACT: Lorraine Herson-Jones, Manager, Airport Compliance Division, ACO–100, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–3085; facsimile: (202) 267–4629.

Availability of Documents: FAA Order 5190.6BB, Change 1 is available on the FAA website at: *https://www.faa.gov/airports/resources/publications/orders/compliance_5190_6/.*

You can get an electronic copy of the Order and all other documents in this docket using the internet by:

(1) Visiting FAA's Regulations and Policies web page: *https://www.faa.gov/regulations_policies*

—or—

(2) Accessing the Government Printing Office's web page: *http://www.govinfo.gov/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Airport Compliance and Management Analysis, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–3085. Make sure to identify the FAA Order number being requested.

SUPPLEMENTARY INFORMATION:

Background

The FAA administers several grant programs for airports, including the Airport Improvement Program (AIP), established by the Airport and Airway Improvement Act of 1982 as amended, 49 U.S.C. 47101 *et seq.,* (AAIA).[1] Section 47107 requires the Secretary of Transportation to obtain certain assurances from an airport operator as a condition of receiving a grant under the AIP. The FAA implements this requirement with a standard set of grant assurances for airport sponsors which can be viewed on the FAA Airports website at: *https://www.faa.gov/airports/aip/grant_assurances/.*

The FAA has issued a series of compliance manuals for the administration of the AIP and its predecessor grant programs. Order 5190.6, Airport Compliance Requirements, was issued on August 24, 1973. Order 5190.6 was canceled and replaced by Order 5190.6A, Airport Compliance Requirements, on October 2, 1989. Order 5190.6A was replaced by Order 5190.6B on September 30, 2009. Each of these orders respectively, while in effect, has served as the handbook or manual for FAA employees responsible for monitoring and enforcing the compliance of airport sponsors with obligations to the Federal government. Those obligations most commonly arise from conditions or assurances contained in agreements with the FAA for grants in aid to airports. In addition to grant obligations, an airport sponsor may also have Federal obligations under a deed of property transferred under the Surplus Property Act of 1944, as amended, 49 U.S.C. 47151–47153, or the Federal Airports Act of 1946, as amended, 49 U.S.C. 47125, or property acquired with Federal funds.

Since 2009, there have been changes to the laws and policies relating to the Federal obligations of airport sponsors and revisions to the procedures for investigating and resolving complaints that allege noncompliance. The Office of Airport Compliance and Management Analysis has worked closely with industry stakeholders since the Order was last updated in 2009 to gain the best understanding of issues of concern. Where applicable, the changes in this updated Order reflect feedback from industry stakeholders. Stakeholders may contact the Office of Airport Compliance and Management Analysis with additional concerns so that they may be considered for future updates to the Order. To incorporate any changes and provide the most useful and current program guidance to FAA employees, the Office of Airport Compliance and Management Analysis is undertaking a review of the Order and will publish updates as the chapter reviews are completed. The updated FAA Order 5190.6B will be located on the FAA website. Concurrent with this notice, the FAA has uploaded the first revised chapters to the Order, referred to as Order 5190.6B, Change 1. These are: Chapter 1, *Scope and Authority;* Chapter 9, *Unjust Discrimination between Aeronautical Users;* Chapter 10, *Reasonable Commercial Minimum Standards;* Chapter 11, *Self-Service;* and Chapter 23, *Reversions of Airport Property.*

The FAA considered comments received to Order 5190.6B and updates to Chapters 1, 9, 10, 11, and 23 reflect the major issues raised. Updates to the Order's appendices also are included with this update.

[1] FAA also administers CARES, CRSSA and ARPA grants. These new grant programs are beyond the scope of this guidance. For more information, see *https://www.faa.gov/airports/airport_rescue_grants/.*

Summary of Changes to Order 5190.6B

- After review of public comments and experience since 2009 with using Order 5190.B, the FAA is updating the Order starting with Chapters 1, 9, 10, 11, and 23 of the Order.
- Many of these changes are editorial and intended to clarify language based on suggestions received in public comments or recommendations from FAA employees.
- In other cases, the Order has been updated to align with new or revisions to Federal statutes, regulations, or orders which have been enacted or revised since 2009.
- Edits and additions to the revised chapters are intended to provide accurate and useful guidance on airport compliance policy for FAA employees and not to adopt significant changes in compliance policy. A summary of the changes will be posted on the FAA website as future chapters are revised.

In addition to updating these five chapters listed above, the agency has revised several of the appendices to Order 5190.6B. The changes update citations and documents to provide current versions, delete obsolete references, and include more recent sample documents. As part of the updates, Appendices E–1, F–3, G–1, and S have been removed.

Future Updates to Order

The FAA is continuing its review of all chapters of Order 5190.6B and will publish updates to the Order as it completes each review. Chapters may be updated individually or in related groups. These updates will reflect statutory, administrative, or clerical changes. It is intended that the Order will continue to be updated periodically as changes in statutes, regulations, or orders occur.

The most current version of the updated chapters will be maintained at: *https://www.faa.gov/airports/resources/publications/orders/compliance_5190_6/.*

Each chapter will contain the date of its most recent update.

Notice of Availability

FAA Order 5190.6B.1, *Airport Compliance Manual,* with the updated Chapters 1, 9, 10, 11 and 23, is available at the locations listed in the ''Availability of Documents'' section of this notice.

Issued in Washington, DC.

Kevin C. Willis,

Director, FAA, Office of Airport Compliance and Management Analysis.

[FR Doc. 2021–25936 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2021–0140]

U.S. DOT Strategic Plan

ACTION: Notice of request for public comment (RFC).

SUMMARY: The Office of the Secretary of Transportation invites the public to comment on the draft DOT Strategic Framework, which includes draft strategic goals and strategic objectives to accomplish each strategic goal. The strategic goals and strategic objectives will be included in the U.S. Department of Transportation (DOT) Strategic Plan for fiscal years (FY) 2022–2026.

DATES: Comments must be received within 14 days from posting of this notice. DOT will consider comments filed after this date to the extent practicable.

ADDRESSES: Written comments may be submitted electronically or via U.S. mail. Respondents are encouraged to submit comments electronically to ensure timely receipt. Please include your name, title, organization, postal address, telephone number, and email address.

- *Electronic Submission:* Go to *http://www.regulations.gov.* Search by using the docket number (provided above). Follow the instructions for submitting comments on the electronic docket site.
- *Email: dotstrategicplanning@dot.gov.* Please include the full body of your comments in the text of the electronic message and as an attachment.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room PL–401, Washington, DC 20590–0001.
- *Instructions:* All submissions must include the agency name and docket numbers.

FOR FURTHER INFORMATION CONTACT: Juli Huynh, Director, Office of Policy Coordination and Development, Office of the Assistant Secretary for Transportation Policy, *dotstrategicplanning@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Government Performance and Results Act (GPRA) of 1993, as amended by the GPRA Modernization Act of 2010 (Pub. L. 111–352), requires that Federal agencies revise and update their strategic plan at the beginning of each new presidential term, and in doing so, solicit input from interested stakeholders. The draft DOT Strategic Framework reflects the Secretary's priorities for achieving DOT's mission through six strategic goals:

- *Safety:* Make our transportation system safer for all people. Work toward a future where transportation-related serious injuries and fatalities are eliminated.
- *Economic Strength & Global Competitiveness:* Grow an inclusive and sustainable economy. Invest in our transportation system to provide American workers and businesses reliable and efficient access to good-paying jobs, resources, and markets.
- *Equity:* Reduce inequities. Support and engage people and communities to promote safe, affordable, accessible, and multimodal access to opportunities and services while reducing transportation-related disparities and adverse community impacts and health effects.
- *Climate & Sustainability:* Tackle the climate crisis by ensuring that transportation plays a central role in the solution. Substantially reduce greenhouse gas emissions and transportation-related pollution and build more resilient and sustainable transportation systems to benefit and protect communities.
- *Transformation:* Design for the future. Invest in purpose-driven research and innovation to meet the challenge of the present and modernize a transportation system of the future that serves everyone today and in the decades to come.
- *Organizational Excellence:* Strengthen our world class organization. Advance the Department's mission by establishing policies, processes, and an inclusive and innovative culture to effectively serve communities and responsibly steward the public's resources.

These strategic goals are supported by strategic objectives that reflect the outcomes DOT is seeking to achieve. The DOT's draft strategic goals and objectives are detailed in the draft DOT Strategic Framework, which can be accessed at *https://www.transportation.gov/dot-strategic-plan.*

Written Comments: The U.S. DOT invites the public to provide comments to inform the development of the U.S. DOT Strategic Plan for FY 2022–26. In particular, comments may respond to any or all of the following questions:

1. What strategies or priorities should the U.S. DOT adopt to achieve the Department's strategic goals and objectives?

2. How should U.S. DOT measure progress towards those priorities?

3. What emerging challenges or opportunities in transportation warrant

additional U.S. DOT activities or investments?

4. How can U.S. DOT best coordinate its activities with Federal, State, local, tribal, labor, private sector, academic, non-profit, international and other stakeholders?

5. How can U.S. DOT best utilize additional programs and authorities in the Infrastructure Investment and Jobs Act to accomplish the goals laid out in the strategic plan?

The Department anticipates that the final U.S. DOT Strategic Plan for FY 2022–2026 will be posted on the DOT website in February 2022.

Public Comment: DOT will consider input and revise the draft DOT Strategic Plan as appropriate.

Signed in Washington, DC, on November 29, 2021.

Christopher Coes,

Principal Deputy Assistant Secretary for Transportation Policy.

[FR Doc. 2021–26266 Filed 12–2–21; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, notice is hereby given that the Department of Veterans Affairs (VA) proposes to establish a new system of records entitled, ''Federal Case Management Tool'' (FCMT). FCMT is a web-based application that supports VA and the Department of Defense (DoD) with the effective management and tracking of Veteran and Service member beneficiaries at all levels of the continuum of care.

DATES: Comments on this new system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the new system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to ''Federal Case Management Tool (FCMT)—VA'' (202VA005Q). Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Freda Perry, Project Manager, Federal Case Management Tool (FCMT), Office of Information & Technology, Department of Veterans Affairs, 810 Vermont Avenue NW, (005QF3), Washington, DC 20420, (202) 802–7882, and *Freda.Perry2@va.gov;* Paul Zeien, Director, Education Veterans Readiness and Employment Product Line—EVREPL (FCMT), Office of Information & Technology, Department of Veterans Affairs, 5000 S 5th Avenue, Hines, IL 60141, (708) 483–5432 and *Paul.Zeien@va.gov.*

SUPPLEMENTARY INFORMATION: The Department is establishing a new system of records entitled ''Federal Case Management Tool (FCMT),'' as it was previously connected to the Veterans Tracking Application (VTA)/Federal Case Management Tool (FCMT) (160VA005Q3) system of records, originally published in the **Federal Register** on April 19, 2012, and amended on Aril 15, 2014. Due to the separation of Federal Case Management Tool (FCMT) from Veterans Tracking Application (VTA), the VTA/FCMT system of records was again amended on March 8, 2020, and republished as Veterans Tracking Application (163CA005Q3), a standalone application that now falls under the product line ''Eligibility and Enrollment (E&E)'' at VHA. Accordingly, FCMT is being established as a new system of records encompassing a standalone application that now falls under ''Education Veterans Readiness and Employment Product Line (EVREPL)''.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Neil C. Evans, M.D., Chief Officer, Connected Care, Performing the Delegable Duties of the Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on October 21, 2021 for publication.

Dated: November 30, 2021.

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

Federal Case Management Tool (FCMT)—VA (202VA005Q)

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Systems of records are generally maintained on information systems owned, operated by, or operated on behalf of the Department. The primary FCMT system is in the Microsoft Government Community Cloud (GCC), a government-authorized cloud-service provider, with Microsoft Global Foundation Services (GFS) Datacenters in Boydton, Virginia; Des Moines, Iowa; Dallas, Texas; and Phoenix, Arizona. For security reasons, Microsoft does not disclose the physical location of the data centers. For more information, please refer to the JAB FedRAMP ATO for Microsoft Dynamics CRM.

SYSTEM MANAGER(S):

Paul Zeien, Director—Education Veterans Readiness and Employment Product Line—EVREPL (FCMT), Office of Information & Technology, Department of Veterans Affairs, 5000 S 5th Avenue, Hines, IL 60141 (708) 483–5432 and *Paul.Zeien@va.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintaining this system is Title 38 U.S.C. 5106.

PURPOSE(S) OF THE SYSTEM:

The purpose of the FCMT is to track the initial arrival of a Service member into the VA and DoD health care systems and their subsequent movement among VA health facilities, as well as monitor benefits application and administration details. This history includes all benefit award details to include application dates, award decisions, dates, and amounts.

The records and information may be used for analysis to produce various management, workload tracking, and follow-up reports for our Veterans; to track and evaluate the ordering and delivery of services and patient care; for the planning, distribution and utilization of resources; and to allocate clinical and administrative support to patient medical care.

In addition, the data may be used to assist in workload allocation for patient treatment services including provider panel management, nursing care, clinic

appointments, surgery, prescription processing, diagnostic and therapeutic procedures; to plan and schedule training activities for employees; for audits, reviews and investigations conducted by the network directors office and VA Central Office; for quality assurance audits, reviews and investigations; for law enforcement investigations; and for personnel management, evaluation and employee ratings, and performance evaluations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

These records include information on Service Members (SM) and Veterans as described for the Federal Recovery Coordinator Program (FRCP), severely injured/visually severely impaired (SI/VSI), Case Management for Veterans Benefits Administration (VBA), Veterans Health Administration (VHA) Liaison, and Chapter 63 Special Outreach programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include identifying information (*e.g.,* name, contact information, Social Security number), association to dependents, cross reference to other names used, military service participation and status information (branch of service, rank, enter on duty date, release from active duty date, military occupations, type of duty), reason and nature of active duty separation (completion of commitment, disability, hardship, etc.), combat/environmental exposures (combat pay, combat awards, theater location), combat deployments (period of deployment, location/country), Guard/Reserve activations (type of activation), military casualty/disabilities (line of duty death, physical examination board status, serious/very serious injury status, recovery plans, DoD rated disabilities), benefit participation, eligibility and usage, and VA compensation (rating, award amount).

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by VA Department of Defense Identity Repository (VADIR) for the Department of Defense and Department of Veterans Affairs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. Congress

VA may disclose information to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. Data Breach Response and Remediation, for VA

VA may disclose information to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records, (2) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. Data Breach Response and Remediation, for Another Federal Agency

VA may disclose information to another Federal agency or Federal entity, when VA determines that information is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. Law Enforcement

VA may disclose information that, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, to a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

5. DoJ for Litigation or Administrative Proceeding

VA may disclose information to the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her official capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components, is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

6. Contractors

VA may disclose information to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. OPM

VA may disclose information to the Office of Personnel Management (OPM) in connection with the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations.

8. EEOC

VA may disclose information to the Equal Employment Opportunity Commission (EEOC) in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

9. FLRA

VA may disclose information to the Federal Labor Relations Authority (FLRA) in connection with: The investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised; matters before the Federal Service Impasses Panel; and the investigation of representation petitions and the conduct or supervision of representation elections.

10. MSPB

VA may disclose information to the Merit Systems Protection Board (MSPB) and the Office of the Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

11. NARA

VA may disclose information to NARA in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

12. Federal Agencies, for Research

VA may disclose information to a Federal agency for the purpose of

conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency.

13. Federal Agencies, for Computer Matches

VA may disclose information from this system to other federal agencies for the purpose of conducting computer matches to obtain information to determine or verify eligibility of veterans receiving VA benefits or medical care under Title 38, U.S.C.

14. Federal Agencies, Courts, Litigants, for Litigation or Administrative Proceedings

VA may disclose information to another federal agency, court, or party in litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding.

15. Governmental Agencies, Health Organizations, for Claimants' Benefits

VA may disclose information to Federal, state, and local government agencies and national health organizations as reasonably necessary to assist in the development of programs that will be beneficial to claimants, to protect their rights under law, and assure that they are receiving all benefits to which they are entitled.

16. Health Care Providers, for Referral by VA

VA may disclose information to: (1) A federal agency or health care provider when VA refers a patient for medical and other health services, or authorizes a patient to obtain such services and the information is needed by the federal agency or health care provider to perform the services; or (2) a federal agency or to health care provider under the provisions of 38 U.S.C. 513, 7409, 8111, or 8153, when treatment is rendered by VA under the terms of such contract or agreement or the issuance of an authorization, and the information is needed for purposes of medical treatment or follow-up, determination of eligibility for benefits, or recovery by VA of the costs of the treatment.

17. Health Care Provider, for Referral to VA

VA may disclose information to a non-VA health care provider when that health care provider has referred the individual to VA for medical or other health services.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are transmitted between approved VA and DoD office/systems and FCMT over secure telecommunications (*i.e.,* SFTP, secure web services) using approved encryption technologies. Records (or information contained in records) are maintained in electronic format in the FCMT database. Information from FCMT is disseminated in three ways: (1) Approved VA and DoD systems electronically request and receive data from FCMT over the internal VA and DoD network; (2) data is provided over the secure telecommunications between FCMT and approved VA and DoD office/systems for reconciliation of records; (3) periodic electronic data extracts of subsets of information contained in FCMT are provided to approved VA and DoD offices/systems over the internal VA network and DoD network. FCMT is currently on the Microsoft Government Community Cloud and all backups are located there as well.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved using name, claim file number, social security number, date of birth, and other unique identifiers belonging to the individual to whom the information pertains.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are electronically imaged and established by VA as the official record, its paper contents (with the exception of documents that are on hold due to pending litigation, and service treatment records and other documents that are the property of DoD), are reclassified as *duplicate—non record keeping—copies* of the official record, and will be destroyed in accordance with Records Control Schedule VB–1, Part 1 Section XIII, Item 13–052.100 as authorized by NARA. All paper documentation that is not the property of VA (*e.g.,* DoD-owned documentation) is currently stored by VA after scanning, pending a policy determination as to its final disposition. All documentation being held pursuant to active litigation is held in its native format during the pendency of the litigation. All FCMT records are stored on a secure VA server, pending permanent transfer to NARA where they will be maintained as historical records. Once an electronic record has been transferred into NARA custody, the record will be fully purged and deleted from the VA system in accordance with governing records control schedules using commercial off the shelf (COTS) software designed for the purpose. Once purged, the record will be unavailable on the VA system, and will only be accessible through NARA.

Prior to destruction of any paper source documentation reclassified as *duplicate copies,* VA engages in a comprehensive and multi-layered quality control and validation program to ensure material that has been electronically imaged is completely and accurately uploaded into the VBMS eFolder. To guarantee the integrity and completeness of the record, VA engages in industry-best practices, using state-of-the-art equipment, random sampling, independent audit, and 100% VA review throughout the claims adjudication process. Historically, VA's success rate in ensuring the accuracy and completeness of the electronic record routinely and consistently exceeds 99%. Furthermore, no paper document is ever destroyed while any related claim or appeal for VA benefits is still pending. VA waits 3 years after the final adjudication of any claim or appeal before destroying the paper duplicate copies that have been scanned into the FCMT. As noted, the electronic image of the paper document is retained indefinitely as a permanent record either by VA or NARA.

Decisions to destroy VR&E paper counseling records are to be made in accordance with Records Control Schedule (RCS), RCS VB–1, Part I, Field in Section VII, dated January 31, 2014. Automated storage media containing temporary working information are retained until a claim is decided, and then destroyed. All other automated storage media are retained and disposed of in accordance with disposition authorization approved by NARA. Education file folders in paper are retained at the servicing Regional Processing Office. Education paper folders may be destroyed in accordance with the times set forth in the VBA Records Management, Records Control Schedule VB–1, Part 1, Section VII, as authorized by NARA.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

1. Physical Security: The primary FCMT system is in the Microsoft Government Community Cloud (GCC), and the backup disaster recovery system is located on the Government Community Cloud as well. Access to data processing centers is generally restricted to center employees, custodial personnel, Federal Protective Service, and other security personnel. Access to computer rooms is restricted to authorized operational personnel through electronic passage technology. All other persons needing access to computer rooms are escorted.

2. System Security: Access to the VA network is protected by the usage of ''PIV''. Once on the VA network, separate ID and password credentials are required to gain access to the FCMT

server and/or database. Access to the server and/or database is granted to only a limited number of system administrators and database administrators. In addition, FCMT has undergone certification and accreditation. Users of FCMT access the system via AccessVA. Users must also register through FCMT and obtain a FCMT Account. Within the VTA system, users are designated a role which determines their access to specific data. Based on a risk assessment that followed National Institute of Standards and Technology Vulnerability and Threat Guidelines, the system is considered stable and operational. FCMT is in a minor application under the BAM CRM Authority to Operate (ATO). The system is in the process of requesting a stand-alone Authority to Operate (ATO) as a major application.

RECORD ACCESS PROCEDURES:

Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, and describe the records sought in sufficient detail to enable VA personnel to locate them with a reasonable amount of effort.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above. A request to contest or amend records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Generalized notice is provided by the publication of this notice. For specific notice, see Record Access Procedure, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None, this is a new SORN.

[FR Doc. 2021–26257 Filed 12–2–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXX]

Agency Information Collection Activity Under OMB Review: VA Form 26–0967, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion, and VA Form 26–0967a, Specially Adaptive Housing Assistive Technology Grants Criteria and Responses

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–XXXX.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Agency Information Collection Activity under OMB Review: VA Form 26–0967, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion, and VA Form 26–0967a, Specially Adaptive Housing Assistive Technology Grants Criteria and Responses.

OMB Control Number: 2900–XXXX.

Type of Review: New.

Abstract: The proposed regulations would require applicants to submit VA Form 26–0967, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion. These regulations would also require applicants to provide statements addressing six scoring criteria for grant awards as part of their application. The information will be used by Loan Guaranty personnel in deciding whether an applicant meets the requirements and satisfies the scoring criteria for award of an SAH Assistive Technology grant under 38 U.S.C. 2108. 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.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 86 FR 17891on April 6, 2021, page 17891.

Affected Public: Individuals or Households.

Estimated Annual Burden: 40.

Estimated Average Burden per Respondent: 2 hours.

Frequency of Response: One time.

Estimated Number of Respondents: 20.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–26265 Filed 12–2–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

VA National Academic Affiliations Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app. 2, that the VA National Academic Affiliations Council (NAAC) will meet via conference call on December 7, from 1:00 p.m. to 3:00 p.m. EST. The meeting session is open to the public.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On December 7, 2021, the Council will receive briefs on VA initiatives that influence trainees and the academic mission. The Council will receive public comments from 2:50 p.m. to 2:55 p.m. EST.

Interested persons may attend and/or present oral statements to the Council. The dial in number to attend the conference call is: 646–828–7666. At the prompt, enter meeting ID 161 604 9930,

then press #. The meeting passcode is 124088, then press #. Individuals seeking to present oral statements are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting or at any time, by email to *Larissa.Emory@va.gov,* or by mail to Larissa A. Emory PMP, CBP, MS, Designated Federal Officer, Office of Academic Affiliations (14AA), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Ms. Emory via email or by phone at (915) 269–0465.

Dated: November 30, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–26252 Filed 12–2–21; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 86 Friday,
No. 230 December 3, 2021

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 129
Laboratory Accreditation for Analyses of Foods; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 129

[Docket No. FDA–2019–N–3325]

RIN 0910–AH31

Laboratory Accreditation for Analyses of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to establish a program for the testing of food in certain circumstances by accredited laboratories, as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Establishing this program will help FDA improve the safety of the U.S. food supply and protect U.S. consumers by helping ensure that certain food testing of importance to public health is conducted subject to appropriate oversight and in accordance with appropriate model standards to produce reliable and valid test results.

DATES: This rule is effective February 1, 2022. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 1, 2022.

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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Stacie Hammack, Chemist, Food and Feed Laboratory Operations, Office of Regulatory Affairs, Food and Drug Administration, 60 8th Street NE, Atlanta, GA 30309, 301–796–5817; *Stacie.Hammack@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown Street, North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

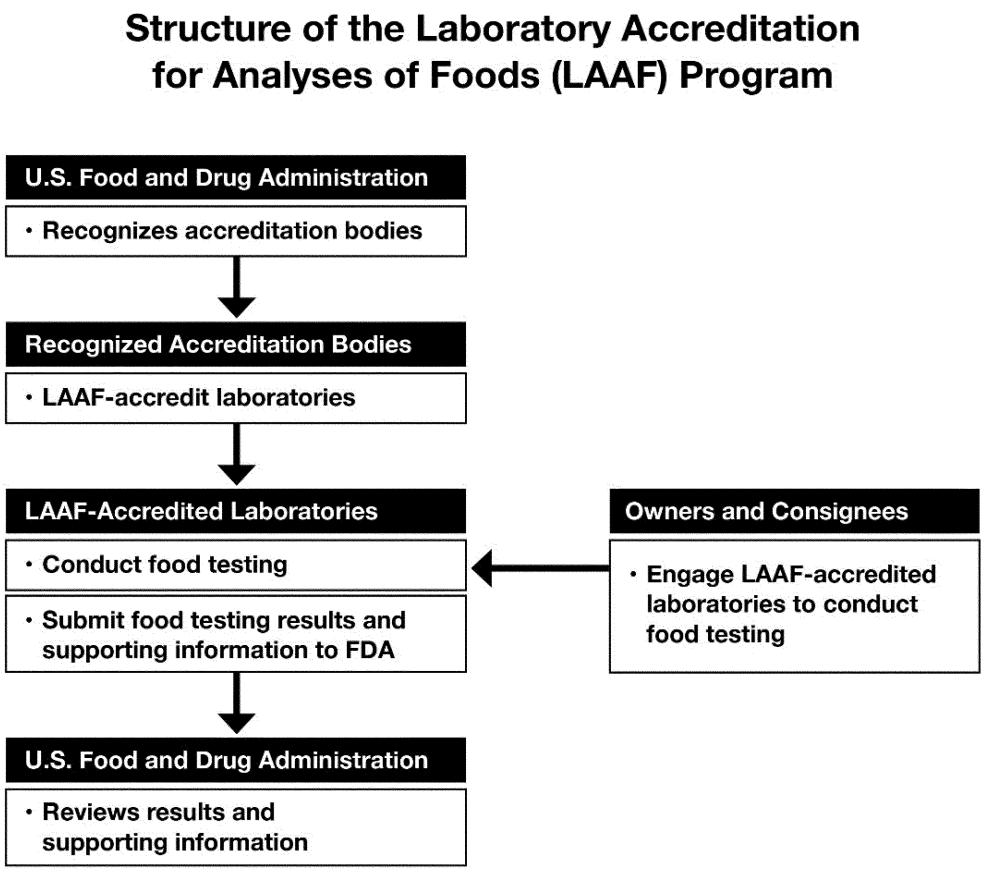
I. Executive Summary

A. Purpose and Coverage of the Final Rule

This rule is part of FDA's implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), through which the Agency intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. In this document we establish the Laboratory Accreditation for Analyses of Foods (LAAF) program as required by FSMA section 202(a), which added section 422 to the FD&C Act (21 U.S.C. 350k). Under the LAAF program, FDA will recognize accreditation bodies that will accredit laboratories to the standards established in this final rule. Laboratories accredited to the LAAF standard (''LAAF-accredited laboratories'') are authorized to conduct certain food testing as described in this rule.

The program structure is portrayed in the following diagram:[1]

[1] For a description of how the program structure diagram has been revised, see (Response 11).



You are subject to this rule if you are an accreditation body seeking recognition to accredit laboratories under this subpart, a recognized accreditation body, a laboratory seeking accreditation to conduct food testing under this subpart, or an accredited laboratory conducting food testing under this subpart. This rule also applies to owners or consignees that must have certain food testing conducted by a laboratory accredited under this subpart. Although participation in this program is voluntary for accreditation bodies and laboratories, only recognized accreditation bodies may accredit laboratories to conduct the testing of food covered under this subpart.

This program for the testing of food by accredited laboratories establishes oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate. Establishing this program will substantially improve our capability to protect U.S. consumers from unsafe food.

B. Summary of the Major Provisions of the Final Rule

This rule contains model standards that laboratories must meet in order to participate and conduct certain food testing covered by this subpart. The rule will establish a publicly available registry listing accreditation bodies and laboratories that have been recognized or accredited under this program. Results of food testing conducted by laboratories under the program must be sent directly to FDA. Laboratories accredited under this program (''LAAF-accredited laboratories'') are required to submit to FDA analytical reports as specified in this final rule.

This rule contains eligibility requirements for accreditation bodies to qualify for FDA recognition and requirements that accreditation bodies must meet once recognized, such as requirements related to assessing and overseeing laboratories, conflicts of interest, reporting, and records. The rule contains eligibility requirements for laboratories to qualify for LAAF-accreditation by a recognized accreditation body and requirements that laboratories must meet once LAAF-accredited, such as requirements related to conflicts of interest, analysis, reporting, and records. These requirements will help ensure the effectiveness of the recognized accreditation bodies and LAAF-accredited laboratories under this program. This rule contains procedures we will follow to recognize accreditation bodies under this program and procedures for accreditation bodies to follow to LAAF-accredit laboratories under this program. This rule contains regulatory procedures and requirements relating to our oversight of recognized accreditation bodies and LAAF-accredited laboratories.

This rule applies when food testing is conducted in certain circumstances. ''Food testing'' and ''testing of food'' include the analysis of human or animal food, as well as testing of the food growing or manufacturing environment (*i.e.,* ''environmental testing'').

C. Legal Authority

Section 422(a)(1)(A) the FD&C Act, which was added by section 202(a) of FSMA, directs us to establish a program for the testing of food by accredited laboratories. Therefore, section 422 of the FD&C Act provides FDA with authority for these final regulations, which outline requirements for participants in the program for the testing of food by LAAF-accredited laboratories. FDA also derives authority for these requirements from section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

The rule will require that testing of food in certain circumstances be performed by a laboratory that is LAAF-accredited by a recognized accreditation body, and for the testing results to be submitted directly to us. The costs of the rule primarily will be incurred by participating accreditation bodies, participating laboratories, shell egg producers, sprouts producers, bottled drinking water manufacturers, owners and consignees of certain import-related food, and FDA. Rarely, certain firms will have participating laboratories conduct tests for other reasons including as part of a corrective action plan after an order suspending registration, as part of evidence for a hearing prior to issuance of a mandatory recall order, as part of evidence for an appeal of an administrative detention order, and as required under a directed food laboratory order (formerly, a food testing order). We will incur costs to, among other things, establish and maintain the program for recognizing accreditation bodies that apply to participate in our program, evaluate participating accreditation bodies and review the performance of participating laboratories, and review associated documents and reports. The present value of the costs of the rule ranges from $38 million to $66 million when discounted by 7 percent over 10 years and from $43 million to $77 million when discounted by 3 percent over 10 years. Annualized costs over 10 years range from $5.8 million to $9.6 million when discounted by 7 percent, and from $5.9 million to $9.7 million when discounted by 3 percent.

The rule will generate some quantified and unquantified benefits. Quantified benefits include a reduction in the number of foodborne illnesses from fewer false negative test results for import-related food covered under the rule and for shell eggs, sprouts, and bottled drinking water testing covered under the rule. We anticipate cost savings from the clarification of the process for compiling, submitting, and reviewing analytical reports for import-related food covered under this rule, including reduced reporting burden. There would be less revenue lost from fewer false positive test results for import-related food covered under the rule and for tests of shell eggs, sprouts, and bottled drinking water testing covered under the rule. The present value of the benefits of the rule ranges from $46 million to $88 million when discounted at 7 percent over 10 years and ranges from $56 million to $106 million when discounted at 3 percent over 10 years. Annualized benefits over 10 years range from $6.6 million to $12.5 million when discounted by both 7 and 3 percent.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
AAVLD	American Association of Veterinary Laboratory Diagnosticians.
ANSI	American National Standards Institute.
AOAC	AOAC International.
APA	Administrative Procedure Act.
CFR	Code of Federal Regulations.
CPSC	Consumer Product Safety Commission.
CVM	Center for Veterinary Medicine.
DWPE	Detention Without Physical Examination.
EO	Executive Order.
E. coli	*Escherichia coli.*
FDA	United States Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOIA	Freedom of Information Act.
FR	Federal Register.
FRIA	Final Regulatory Impact Analysis.
FSMA	FDA Food Safety Modernization Act.
FSVP	Foreign Supplier Verification Program.
HACCP	Hazard Analysis and Critical Control Point.
IBR	Incorporation by Reference.
IEC	International Electrotechnical Commission.
ILAC	International Laboratory Accreditation Cooperation.
IOM	Investigations Operations Manual.
ISO	International Organization for Standardization.
LAAF	Laboratory Accreditation for Analyses of Foods.
MRA	Mutual Recognition Arrangement.
NIST	National Institute of Standards and Technology.
NRTE	Not Ready to Eat.
NTTAA	National Technology Transfer and Advancement Act of 1995.
OMB	Office of Management and Budget.
ORA	Office of Regulatory Affairs.
PLAP	Private Laboratory Analytical Package.
PRA	Paperwork Reduction Act of 1995.
PRIA	Preliminary Regulatory Impact Analysis.
SAHCODHA	Serious Adverse Health Consequences or Death to Humans or Animals.
U.S.C.	United States Code.
Vet-LIRN	Veterinary Laboratory Investigation and Response Network.
WTO	World Trade Organization.

III. Background

A. Need for the Regulation

FSMA is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system. FSMA provides us with new enforcement authorities designed to achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, FSMA gives us important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. In implementing FSMA, we prioritized the development of seven foundational rules that provide the framework for risk-based preventive controls and enhance our ability to oversee their implementation by industry for both domestic and imported food. We have finalized these foundational rules and begun their implementation while also developing additional programs required by FSMA, including this program for food testing by accredited laboratories.

FSMA, in establishing section 422 of the FD&C Act, underscores that food testing can play a role in detecting and responding to food safety problems. Section 422(b)(1) of the FD&C Act requires that food be tested by laboratories accredited to the standards we are establishing in this final rule in four circumstances:

- In response to a specific testing requirement under the FD&C Act or implementing regulations, when applied to address an identified or suspected food safety problem;
- As required by the Secretary of Health and Human Services (Secretary), as the Secretary deems appropriate, to address an identified or suspected food safety problem;
- In support of admission of an article of food under section 801(a) of the FD&C Act (21 U.S.C. 381(a)); and
- Under an import alert that requires successful consecutive tests.

With one exception, section 422(b)(2) of the FD&C Act requires the results of food testing conducted under section 422(b)(1) to be sent directly to FDA, thereby allowing FDA to review the test results.

Direct receipt of food testing results in these circumstances is of particular importance to the Agency and to public health. This rule applies to food testing conducted under specific testing requirements in the FD&C Act and implementing regulations that ''address an identified or suspected food safety problem'', and in directed food laboratory orders that we will issue ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' Further, owners and consignees often engage private laboratories to test their food products and submit the results of the testing, along with associated analysis and data, to us to show that the imported food complies with the FD&C Act. If we determine that the food testing results are valid and that they demonstrate the detained food product does not violate the FD&C Act, we will release the food from detention and allow it to proceed into the United States. We use the detention without physical examination (DWPE) procedure when there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative. Import alerts inform FDA field staff and the public that we have enough evidence to allow for DWPE of products that appear to be in violation of FDA laws and regulations. Concerns periodically have arisen regarding importers' manipulation or substitution of the samples a private laboratory tests, and practices such as ''testing into compliance,'' in which multiple samples from a shipment are tested, but only those results that would allow the shipment to enter the United States are submitted to us. See, *e.g.,* ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998 (statement of ''Former Customs Broker'') (Ref. 1, pages 26–34 and 137–140).

B. Summary of Comments to the Proposed Rule

We published a proposed rule for ''Laboratory Accreditation for Analyses of Foods'' (the proposed rule) in the **Federal Register** on November 4, 2019 (84 FR 59452). The comment period was extended twice (85 FR 11893 (February 28, 2020); 85 FR 19114 (April 6, 2020)). Upon close of the comment period on July 6, 2020, we had received approximately 70 comment submissions that covered almost every aspect of the proposed rule.

C. General Overview of the Final Rule

We have made changes in the final rule in response to public comments; these changes are discussed in greater detail in section V below. Additionally, we have revised the final rule to improve clarity and readability. We also have reorganized the final rule as described in the following table.

TABLE 1—SUMMARY OF SECTION NUMBERING CHANGES IN THE FINAL RULE

Final rule	Proposed rule
General provisions	General provisions
§ 1.1101 What documents are incorporated by reference in this subpart?	N/A.
§ 1.1102 What definitions apply to this subpart?	§ 1.1102 What definitions apply to this subpart?
§ 1.1103 Who is subject to this subpart?	§ 1.1103 Who is subject to this subpart?
General Requirements	General Requirements of this Subpart
§ 1.1107 When must food testing be conducted under this subpart?	§ 1.1107 Under what circumstances must food testing be conducted under this subpart by an accredited laboratory?
§ 1.1108 When and how will FDA issue a directed food laboratory order?	§ 1.1108 When and how will FDA issue a food testing order?
§ 1.1109 How will FDA make information about recognized accreditation bodies and LAAF-accredited laboratories available to the public?	§ 1.1109 How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public?

TABLE 1—SUMMARY OF SECTION NUMBERING CHANGES IN THE FINAL RULE—Continued

Final rule	Proposed rule
General provisions	General provisions
§ 1.1110 What are the general requirements for submitting information to FDA under this subpart?	N/A.
FDA Recognition of Accreditation Bodies	Recognition of Accreditation Bodies
§ 1.1113 What are the eligibility requirements for a recognized accreditation body?	§ 1.1113 What requirements must an accreditation body meet to be recognized by FDA? § 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?
§ 1.1114 How does an accreditation body apply to FDA for recognition or renewal of recognition?	§ 1.1128 How does an accreditation body apply to FDA for recognition or renewal of recognition?
§ 1.1115 How will FDA evaluate applications for recognition and renewal of recognition?	§ 1.1129 How will FDA review applications for recognition and applications for renewal of recognition?
§ 1.1116 What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition?	§ 1.1132 What must a recognized accreditation body do if it wants to voluntarily relinquish its recognition or does not want to renew its recognition?
§ 1.1117 How may an accreditation body request reinstatement of recognition?	§ 1.1133 How does an accreditation body request reinstatement of recognition?
Requirements for Recognized Accreditation Bodies	Requirements for Recognized Accreditation Bodies
N/A—(contents combined with § 1.1113)	§ 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?
§ 1.1119 What are the conflict of interest requirements for a recognized accreditation body?	§ 1.1119 What requirements apply to how a recognized accreditation body must protect against conflicts of interests?
§ 1.1120 How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories?	§ 1.1120 How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?
§ 1.1121 When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, reduce the scope of or withdraw the LAAF-accreditation of a laboratory?	§ 1.1121 What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant accreditation? § 1.1122(h) Appeals procedures.
§ 1.1122 What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation?	§ 1.1122 When must a recognized accreditation body withdraw or reduce the scope of the accreditation of a laboratory, and when may a recognized accreditation body put an accredited laboratory on probation?
§ 1.1123 What reports, notifications, and documentation must a recognized accreditation body submit to FDA?	§ 1.1123 What reports and notifications must a recognized accreditation body submit to FDA?
§ 1.1124 What are the records requirements for a recognized accreditation body?	§ 1.1124 What records requirements must a recognized accreditation body meet?
§ 1.1125 What are the internal audit requirements for a recognized accreditation body?	§ 1.1125 What internal audit requirements must a recognized accreditation body meet?
FDA Oversight of Recognized Accreditation Bodies	Procedures for Recognition of Accreditation Bodies
§ 1.1130 How will FDA oversee recognized accreditation bodies?	§ 1.1130 How will FDA oversee recognized accreditation bodies?
§ 1.1131 When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?	§ 1.1131 When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation?
LAAF-Accreditation of Laboratories	Accreditation of Laboratories
§ 1.1138 What are the eligibility requirements for a LAAF-accredited laboratory?	§ 1.1138 What requirements must a laboratory meet to become accredited by a recognized accreditation body? § 1.1146 What are the general requirements for accredited laboratories to remain accredited?
§ 1.1139 How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation?	§ 1.1158 How does a laboratory apply for accreditation or modification of its scope of accreditation by a recognized accreditation body?
§ 1.1140 What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation?	§ 1.1163 What if a laboratory wants to voluntarily relinquish its accreditation?
§ 1.1141 What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA?	§ 1.1164 What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition?
§ 1.1142 How does a laboratory request reinstatement of LAAF-accreditation?	§ 1.1165 How does a laboratory request reinstatement of accreditation?
Requirements for LAAF-Accredited Laboratories	Requirements for Accredited Laboratories
Content added to § 1.1138	§ 1.1146 What are the general requirements for accredited laboratories to remain accredited?
§ 1.1147 What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?	§ 1.1147 What impartiality and conflict of interest requirements must accredited laboratories meet?

TABLE 1—SUMMARY OF SECTION NUMBERING CHANGES IN THE FINAL RULE—Continued

Final rule	Proposed rule
General provisions	General provisions
Content moved to § 1.1138	§ 1.1148 What quality assurance requirements must accredited laboratories meet?
§ 1.1149 What oversight standards apply to sampling?	§ 1.1149 What oversight standards apply to sampling?
§ 1.1150 What are the requirements for analysis of samples by a LAAF-accredited laboratory?	§ 1.1150 What requirements apply to analysis of samples by an accredited laboratory?
§ 1.1151 What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart?	§ 1.1151 What requirements apply to the methods of analysis an accredited laboratory uses to conduct food testing under this subpart?
§ 1.1152 What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA?	§ 1.1152 What notifications, results, and reports must accredited laboratories submit to FDA?
§ 1.1153 What are the requirements for submitting abridged analytical reports?	N/A.
§ 1.1154 What other records requirements must a LAAF-accredited laboratory meet?	§ 1.1153 What other records requirements must an accredited laboratory meet?
FDA Oversight of LAAF-Accredited Laboratories	Procedures for Accreditation of Laboratories
§ 1.1159 How will FDA oversee LAAF-accredited laboratories?	§ 1.1159 How will FDA oversee accredited laboratories?
§ 1.1160 How will FDA review test results and analytical reports?	§ 1.1160 How will FDA review submitted test results and analytical reports?
§ 1.1161 When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?	§ 1.1161 When will FDA put an accredited laboratory on probation or revoke the accreditation of a laboratory?
§ 1.1162 What are the consequences if FDA puts a LAAF-accredited laboratory on probation or disqualifies a LAAF-accredited laboratory?	§ 1.1162 What are the consequences if FDA puts an accredited laboratory on probation or revokes the accreditation of a laboratory?
Requesting FDA Reconsideration or Regulatory Hearings of FDA Decisions Under This Subpart	Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under This Subpart
§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?	§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?
§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the accreditation body's recognition or disqualify a LAAF-accredited laboratory?	§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the recognized accreditation body's recognition or revoke the accredited laboratory's accreditation?
§ 1.1174 How does an owner or consignee request a regulatory hearing on a directed food laboratory order?	§ 1.1174 How does an owner or consignee request a regulatory hearing on a food testing order?
Electronic Records and Public Disclosure Requirements	Electronic Records and Public Disclosure Requirements under This Subpart
§ 1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?	§ 1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?
§ 1.1200 Are the records obtained by FDA under this subpart subject to public disclosure?	§ 1.1200 Are the records obtained by FDA under this subpart subject to public disclosure?

Also, in one location in the proposed rule we inadvertently misstated the title of this subpart (the third codified instruction, 84 FR 59452 at 59501). Throughout the final rule we correctly state the subpart title (''Laboratory Accreditation for Analyses of Foods'').

D. Incorporation by Reference

FDA is incorporating by reference two consensus standards, which were approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Both standards are widely accepted globally. The consensus standards may be examined at FDA's Dockets Management Staff (see **ADDRESSES**).

The standards listed below are available for purchase from the International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, +41 22 749 01 11, *central@iso.org* (*https://www.iso.org/store.html*) or from any other source from which the user is assured that the copy to be received is an accurate version of the standard.

ISO/IEC 17011:2017, Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second edition, November 2017 (Ref. 2). ISO/IEC 17011:2017 specifies the general standards for accreditation bodies assessing and accrediting conformity assessment bodies (''conformity assessment bodies'' are organizations providing testing, inspection, management system certification, personnel certification, or product certification). Its incorporation by reference should allow us to use a framework that is familiar to accreditation bodies and the laboratory industry.

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Third edition, November 2017 (Ref. 3). ISO/IEC 17025:2017 sets general standards for the competence of testing laboratories, including general management requirements such as impartiality and quality assurance. It is

very familiar to the testing laboratories that may be interested in applying to conduct food testing under this subpart.

IV. Legal Authority

We are issuing this final rule under the FD&C Act and FSMA. As noted, section 202(a) of FSMA, ''Laboratory Accreditation for Analyses of Foods'', amends the FD&C Act to create a new provision, section 422, under the same name. Section 422 of the FD&C Act directs us to establish a program for the testing of food by accredited laboratories and provides several requirements for the program.

Additionally, section 701(a) of the FD&C Act gives FDA the authority to publish regulations for the efficient enforcement of the FD&C Act. The requirements discussed in this final rule will allow FDA to efficiently enforce section 422 of the FD&C Act. Thus, our legal authority for this final rule is derived primarily from section 422 and section 701(a) of the FD&C Act. Further, we also note that this rule is consistent with section 404 of FSMA, which states that nothing in FSMA should be construed in a manner that is inconsistent with the agreement establishing the World Trade Organization (WTO) or any other treaty or international agreement to which the United States is a party.

Section 379j–31 of the FD&C Act (21 U.S.C. 743) is one of many statutory provisions that provide authority for FDA's regulations contained in part 1 (21 CFR part 1). We inadvertently omitted that citation from the authority citation in the proposed rule, but have included it in the final rule.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 70 comment submissions on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from consumers, food associations, accreditation bodies, laboratory associations, laboratories, consumer groups, and other organizations.

In the remainder of this document, we describe the comments that are within the scope of this rulemaking, respond to them, and explain any revisions we made to the proposed rule.

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.

Note that summaries of and responses to comments on the estimated costs and benefits of the proposed rule and other topics covered by the Preliminary Regulatory Impact Analysis (PRIA) may be found in the Final Regulatory Impact Analysis (FRIA) (Ref. 4).

B. General Comments

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. Further, several comments made overarching comments that pertain to the rule more generally, focusing on issues throughout the rule such as program structure, FDA's role, terminology, and implementation. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) We received many comments expressing general support for the proposed rule, most expressing the view that the LAAF program would help to ensure the safety of food. Some of these comments stress the importance of accurate and reliable food testing results, and the role of valid results in enhancing food safety. Some comments focus on the advantages of setting quality standards and establishing accountability for food testing laboratories. Some comments opine that the laboratory accreditation program will increase U.S. consumer confidence in the safety of the food supply. Other comments maintain that the program will result in fewer illnesses, thus reducing healthcare costs. Other comments express support for implementation of FSMA section 202 and the underlying goals of the laboratory accreditation program, *e.g.,* improved safety of imported food, trustworthy testing results. A few comments opine that the rule would lead to more efficient food imports by clarifying what information needs to be in a laboratory analytical report, which should in turn expedite FDA review of those reports. These comments assert that such efficiencies are particularly valuable when the imported food is perishable, such as produce. Some of these comments further suggest that a more efficient review process for FDA could allow FDA to focus its limited resources on imports that generally are not subject to testing under this subpart.

(Response 1) We appreciate the comments in support of the proposed rulemaking and moving forward to implement the LAAF program. We agree that the program established by the final rule will help ensure the safety of food and should increase U.S. consumer confidence in the food supply. We also agree that requiring analyses to be performed by LAAF-accredited laboratories that meet the standards set forth in the final rule will make tests consistently more accurate and prevent illnesses. Further, setting model standards for LAAF-accredited laboratories will improve the reliability and accountability of test results on which we rely to make regulatory decisions regarding certain foods.

We agree with comments predicting fewer illnesses as a result of this final rule. For additional discussion of the cost benefit analysis associated with this final rule, see section VII. We also agree there will be efficiencies gained for industry and FDA from clarifying the requirements in an analytical report and from the process that allows submission of abridged analytical reports.

(Comment 2) Some comments question whether the LAAF program established by this final rule would make a food safety impact because only a small fraction of food testing laboratories are likely to participate.

(Response 2) Although the laboratory accreditation rule does not set mandatory standards for all food testing laboratories, the program will make an important difference for the food testing subject to the rule, as the testing situations covered by the rule all involve heightened food safety concerns. Therefore, the food testing covered by the rule addresses the specific circumstances in which accurate and reliable test results are especially important to protect public health. We also anticipate that some owners or consignees who are not covered by the rule may choose to use a LAAF-accredited laboratory because these laboratories will have met the program standards; this would create a benefit incidental to the program. Finally, we expect that creating model laboratory standards based on ISO/IEC 17025:2017 accreditation may encourage other laboratories to work toward these standards, including accreditation.

(Comment 3) Some comments are generally supportive of the proposed rule but state that FDA already regulates food safety, and because it is unclear how much safer food would be as a result of the proposed rule, the resources necessary for this program may be better spent elsewhere. A subset

of these comments states that the proposed rule would make food safety regulations more complicated for small food businesses and would also burden small food businesses with additional costs.

(Response 3) As described in section 422 of the FD&C Act, this final rule will establish a program for the accreditation of laboratories the use of which will be required in certain circumstances where heightened food safety concerns exist. We estimate the benefits outweigh the costs of the rule. For additional information on the estimated costs and benefits of this final rule, see section VII and the FRIA (Ref. 4). As mentioned in the preceding response, there may be other benefits incidental to the LAAF program.

Some comments express concern that this rule may complicate the regulatory landscape for small business owners and consignees that are also subject to other food safety regulations. It is true that some small owners and consignees will be required to use a LAAF-accredited laboratory for the testing described in § 1.1107. However, this rule does not create new testing requirements; it merely requires certain tests that are already occurring to be conducted by a LAAF-accredited laboratory. Further, in some cases the regulation creating the underlying testing requirement addresses this issue in its application to small businesses. For example, § 1.1107(a)(1)(ii) provides that certain shell egg tests required by the egg safety rule (see part 118 (21 CFR part 118)) are covered by this final rule. However, the egg safety rule does not apply to producers with less than 3,000 laying hens at a particular farm (see § 118.1(a)). Accordingly, those small egg producers are unaffected by this provision of the final rule. We also expect that the online registry of LAAF-accredited laboratories, described in § 1.1109, will make it easy for all owners and consignees to locate laboratories LAAF-accredited to conduct the tests covered by this subpart.

Regarding the concern that this final rule will burden small owners and consignees with additional costs, see the discussion below in section VII and the FRIA (Ref. 4).

(Comment 4) Some comments express support for specific aspects of the proposed rule, including the provisions protecting against conflicts of interest, and state that the program would improve transparency and consistency in the food testing that falls within its scope. Some comments contend that there have been situations in which a food is described in terms such as ''safe'' based on biased testing conducted by the food's producer.

(Response 4) We appreciate the supportive comments regarding the conflict of interest provisions. FDA anticipates that the model laboratory standards being established in this final rule, as well as the program requirements for LAAF-accreditation of laboratories by recognized accreditation bodies, will increase the reliability of tests conducted under this subpart. Ensuring that both accreditation bodies and laboratories are free from conflicts of interest is critical to the integrity of food testing conducted under this subpart. For more information on the conflict of interest requirements applicable to recognized accreditation bodies, see the discussion of § 1.1119 below; for more information on the conflict of interest requirements applicable to LAAF-accredited laboratories, see the discussion of § 1.1147 below.

(Comment 5) Some comments support the establishment of laboratory standards and appreciate the transparency of the public registry that will list recognized accreditation bodies and LAAF-accredited laboratories but express concern that laboratories would conform to the standards only while being actively monitored by the Agency. These comments encourage the Agency to address this risk.

(Response 5) We acknowledge a hypothetical risk that LAAF-accredited laboratories might conform to standards only while being actively monitored by FDA; however, we believe that the model laboratory standards and reporting requirements we are establishing in this final rule, as well as oversight of LAAF-accredited laboratories by both recognized accreditation bodies and FDA, will adequately address this risk. For example, under this subpart, FDA will recognize accreditation bodies that will LAAF-accredit laboratories to conduct certain testing of food under this subpart. Recognized accreditation bodies' assessment of LAAF-accredited laboratories involves onsite and remote assessments as described in § 1.1120 of the rule. FDA may conduct an onsite or remote review of a LAAF-accredited laboratory at any reasonable time to review performance (see § 1.1159(c)). LAAF-accredited laboratories must submit quality control results with each analytical report (see §§ 1.1152(d)(8), 1.1153(c)(2)), so FDA will be able to review the quality control results to ensure that methods are performed correctly. Further, for LAAF-accredited laboratories that submit abridged analytical reports, FDA may audit these reports by requesting that additional documentation or a full analytical report be submitted within 72 hours of the request (see § 1.1153(d)(2)).

In sum, in this final rule, FDA is establishing requirements for accreditation bodies and laboratories that will provide sufficient oversight of LAAF-accredited laboratories such that we expect consistent quality test results to be the norm.

(Comment 6) A few comments philosophically disagree with defining and regulating food at all, and thus oppose the establishment of a program to require any laboratory testing of food.

(Response 6) Congress defined ''food'' in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) and by statute has authorized FDA to regulate food, including in section 422 of the FD&C Act, which directs FDA to establish this program.

(Comment 7) Some comments ask what effect the final rule will have on existing food testing laboratories. Other comments express a concern that some individuals may perceive that test results from laboratories not participating in the LAAF program are suspect or less valuable.

(Response 7) Food testing laboratories are not required to participate in this program; however, owners and consignees will be required to use a LAAF-accredited laboratory for the food testing covered by this rule, such as testing to support removal from import alert and the shell egg testing required by part 118 (see § 1.1107). Laboratories that wish to conduct the food testing covered by this rule will need to apply to a recognized accreditation body and must satisfy the standards established in this final rule in order to voluntarily participate in the program. A LAAF-accredited laboratory engaged by an owner or consignee to conduct the food testing covered by this final rule will conduct the test and send the results directly to FDA, in accordance with the requirements of this subpart.

Food testing laboratories that do not wish to conduct the testing described in § 1.1107 are not required to participate in the program.

We do not expect this program to decrease confidence in food laboratories that choose not to become LAAF-accredited, in part due to the very large number of food testing laboratories that exist and conduct all sorts of food testing for myriad customers and purposes. We view the program as beneficial to the food testing industry, as an explicit goal of the statute is to increase the number of qualified food testing laboratories. See section 422(a)(3) of the FD&C Act.

(Comment 8) Some comments advocate for expanded roles for the laboratories that participate in this program. Some of these comments suggest that LAAF-accredited laboratories could conduct tests for FDA's surveillance sampling program and argue that sufficient capacity exists in the United States for ISO/IEC 17025:2017-accredited laboratories to conduct all DWPE and FDA surveillance sampling and testing. Under the surveillance sampling program, FDA focuses its sampling and testing efforts on a few commodities at a time with the goals of keeping contaminated products from reaching consumers and facilitating a greater understanding of hazards. For more information on FDA's surveillance sampling, see *https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling.* These comments also suggest that FDA should create a program whereby private laboratories meet the standards of FDA laboratories, such that FDA could rely on those private laboratories for its testing needs and therefore focus its resources elsewhere. Finally, these comments suggest that independent accredited laboratories could also conduct sampling and testing on imported food, most of which is not sampled and tested by FDA prior to entry.

(Response 8) This final rule establishes the LAAF program, the scope of which is specified in FD&C Act section 422(b)(1) and described in § 1.1107. All the tests that will be conducted by LAAF-accredited laboratories are currently being conducted by non-FDA laboratories (*e.g.,* private laboratories). Expanding the scope of this program to include testing currently conducted by FDA laboratories, such as surveillance sampling, was not proposed because it is not contemplated by the statute. Any future expansion of this program will be accomplished via rulemaking and will include an opportunity for public comment.

(Comment 9) Some comments offer general support for this subpart, stating that it will improve the defensibility of the resulting test data by ensuring that all participating laboratories operate in accordance with a robust quality management system. These comments suggest that as we continue to develop the LAAF program, we consider two documents that were developed to improve the defensibility of human and animal food laboratory data: The Partnership for Food Protection document, ''Human and Animal Food Testing Laboratories Best Practices Manual,'' (Ref. 5) and the Association for Public Health Laboratories document, ''Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories'' (Ref. 6). The former document is based on ISO/IEC 17025:2017 and its purpose is to ''promote mutual acceptance and assurance of quality laboratory data shared among Federal, State, local, territorial, and tribal human and animal food regulatory agencies.'' (Ref. 5). The latter document, focused on unaccredited laboratories, provides information on the minimum elements of a quality management system.

(Response 9) FDA appreciates this support and information. As an active member of the Partnership for Food Protection initiative, FDA is particularly familiar with the former document. We consider both documents to be helpful resources for the intended audiences.

1. FDA's Role and Related Terminology

In the proposed rule, FDA sought to define ''accreditation'' to mean, ''a determination by a recognized accreditation body that a laboratory meets the applicable requirements *of this subpart* to conduct food testing under this subpart using one or more methods of analysis'' (emphasis added). We then proceeded to use the word ''accreditation'' to mean that a laboratory had been approved to conduct testing under this subpart. For example, we wrote that the proposed rule ''would establish certain model laboratory standards that accredited laboratories must meet to remain accredited'' (84 FR 59452 at 59478). By way of another example, we wrote that the proposed provision on duration of accreditation under this subpart, ''clarifies that an accredited laboratory's accreditation continues'' until there is a voluntary or involuntary separation from the program (id. at 59489).

Consequently, when we used phrases such as, ''FDA may revoke accreditation,'' we intended to communicate that FDA could cause the involuntary separation of a laboratory from this program. For example, we wrote that ''if we revoke the accreditation in whole of a laboratory, the laboratory would be immediately ineligible to conduct food testing under this rule'' (id. at 59491).

We did not propose to define the term ''assess.'' However, we generally used it interchangeably with ''evaluate.'' For example, we entitled one section, ''[h]ow must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?'' (Proposed § 1.1120, 84 FR 59452 at 59469). By way of additional examples, we also wrote, ''[a]s the ISO/IEC 17025 revision is still relatively new, FDA is not able to adequately assess the accreditation of entities that only conduct sampling at this time'' (id. at 59476); we said it was critical that we receive sufficient supporting information ''for us to understand the test results and to assess the validity of the underlying testing'' (id. at 59482) and we asserted authority to ''exercise some ability to oversee accredited laboratories, via requesting records and, if appropriate, conducting onsite assessments'' (id. at 59490).

(Comment 10) Numerous comments request that FDA address and clarify the roles and relationships among the Agency, recognized accreditation bodies, and LAAF-accredited laboratories under this subpart.

Several comments contend that the Agency should not use the words ''assess'' or ''accredit'' to describe Agency actions toward laboratories. Similarly, comments argued that FDA could not revoke a laboratory's ''accreditation.'' We understand several comments to be suggesting that the words ''accredit'' and ''assess'' have particular meaning in the accreditation body and laboratory community, and in the context of food testing, that meaning is always and necessarily related to the voluntary consensus standard ISO/IEC 17025:2017. For example, some comments state that FDA should limit its onsite ''assessments'' of laboratories to matters pertaining to this subpart. Comments explain that failure by FDA to use key terms as they are understood in the industry will lead to market confusion, *e.g.,* regarding the ISO/IEC 17025:2017 accreditation status of laboratories.

Some comments express concern that FDA may be under the impression that it can affect the ISO/IEC 17025:2017 accreditation of laboratories, either by ''assessing'' against the ISO/IEC 17025:2017 standard or by withdrawing a laboratory's ISO/IEC 17025:2017 accreditation. Comments argue that such a role is contrary to the Congressional intent underlying section 422 of the FD&C Act. Comments state that Congress did not intend for FDA to be an accreditation body. Some comments contend that FDA's role in the rule as proposed would be redundant of or ''above'' the role of the recognized accreditation bodies. Some comments express concern that FDA would be able to coerce a recognized accreditation body into withdrawing a laboratory's ISO/IEC 17025:2017 accreditation.

Some comments suggest that FDA's role should be administering a program that evaluates data or program integrity. Some comments suggest that FDA reframe its relationship with the laboratories in terms of an agreement to list and de-list the laboratories on our online registry. Some comments recommend that FDA grant each laboratory a license to conduct testing under this subpart. In this framework, comments state that FDA's role with regard to the laboratories would be limited to the review of test results and analytical reports submitted to FDA by the laboratories. Some comments suggest that FDA should perform some level of review, even if brief, of laboratory applications approved by recognized accreditation bodies. Finally, some comments offer to work with FDA to more clearly define roles and responsibilities under this program.

(Response 10) We agree that substantial revisions and considerable clarification are in order.

In proposing to define ''accreditation,'' to reflect a positive assessment by a recognized accreditation body *under this subpart,* we failed to sufficiently appreciate that in the context of food testing, many parties may perceive ''accreditation,'' to mean accreditation to ISO/IEC 17025:2017. Similarly, when we used the word, ''assess,'' we did not intend to communicate, ''assess against ISO/IEC 17025:2017.'' Instead, we used the word as consistent with its more general use: The Cambridge Dictionary defines ''assess'' as, ''to judge or decide the amount, value, quality, or importance of something.'' (Ref. 7).

Accordingly, it was not our intent to communicate that FDA had the authority to assess laboratories against the ISO/IEC 17025:2017 standard. For example, when we said in the proposed rule that we had the authority to conduct an ''onsite assessment'' of a laboratory participating in this program, we did not mean that our visit would be for the purpose of assessing against ISO/IEC 17025:2017. Nor did we intend to communicate that we had the authority to withdraw ISO/IEC 17025:2017 accreditation, or to pressure or demand an accreditation body to take such an action. We agree such a role would not be appropriate or consistent with section 422 of the FD&C Act.

To communicate our intent more effectively, we have taken several steps. First, we removed the definition of ''accreditation'' and no longer refer to laboratories that have been approved by a recognized accreditation body to conduct testing under this subpart as merely ''accredited.'' Instead, we use the more precise term ''LAAF-accredited,'' where ''LAAF'' is an acronym for the title of this subpart, ''Laboratory Accreditation for Analyses of Foods.'' We added a definition for ''LAAF-accreditation'' to § 1.1102. Where we do use the word, ''accredited'' in this final rule without further qualification, we generally mean accredited to ISO/IEC 17025:2017.

Second, we no longer use the verb ''assess'' to refer to an action that FDA takes regarding laboratories. We reserve the word ''assess'' to refer to the action a recognized accreditation body takes toward a laboratory. We employ the word ''evaluate'' to mean an activity FDA takes with regard to an accreditation body seeking to become recognized or already recognized under this subpart. Largely accepting the suggestion of some comments, we describe our relationship with regard to the laboratories under this subpart as ''reviewing'' the performance of LAAF-accredited laboratories.

Third, we do not use the word ''revoke'' in the final rule to mean an action FDA may take to remove a LAAF-accredited laboratory from this program. Instead, although an accreditation body may withdraw or reduce the scope of LAAF-accreditation, we say that FDA may ''disqualify'' a laboratory from conducting testing under this subpart. We note that although ''disqualify'' was used in the proposed rule in connection with permission to submit abridged analytical reports, we have revamped that process such that there is no longer a disqualification period. In the final rule, ''disqualify'' is used to describe the action FDA may take to remove a laboratory from the program; we say that FDA may ''disqualify a LAAF-accredited laboratory from submitting analytical reports under this subpart'' (see § 1.1161). For further information on the process related to submitting abridged analytical reports, see the discussion of § 1.1153 below at Response 124.

We agree in part with the comments suggesting that FDA perform some level of review of laboratory applications approved by recognized accreditation bodies. Although we have just explained that it is not appropriate for FDA to assess or accredit laboratories ourselves, we nevertheless have a responsibility to ensure that the laboratories we list on our website have been properly assessed by a recognized accreditation body. To that end, we will require the accreditation bodies to submit certain information to us concerning their assessment of a laboratory, including the resulting certificate listing the scope of LAAF-accreditation (see § 1.1123(d)). We decline the suggestion to reframe FDA's relationship with LAAF-accredited laboratories in terms of FDA granting a license to such laboratories, or in terms of entering into a listing agreement with the laboratories. We note that some comments suggest that such a construct could prove helpful in relation to FDA granting permission for certain laboratories to submit abridged analytical reports. Nevertheless, we have determined that such a construct would present complications (*e.g.,* could be legally cumbersome for the FDA to ''license'' laboratories) and is unnecessary to achieve the goals of this program.

We have implemented the revised terminology described here throughout the final rule. We also have tried to avoid describing the proposed rule using the now-discarded terminology (*e.g.,* FDA ''assessing'' a laboratory), even if that is the language we originally used in the proposed rule, because we wish to reduce confusion and communicate more clearly. We thank the commenters for their feedback on this important topic and we look forward to contributions of all interested shareholders as we implement the LAAF program.

2. Program Structure

(Comment 11) In the proposed rule, FDA proposed evaluating and recognizing accreditation bodies, and then those accreditation bodies would assess and LAAF-accredit laboratories. We received several comments on this proposed structure. Some comments express support because the rule relies on the current accreditation body-laboratory conformity assessment structure and leverages existing public-private partnerships in the United States.

Alternatively, some comments contend that the structure was unnecessary or ineffective. Some of these comments advocate that laboratories should simply send their analytical reports to FDA and the Agency would ensure the testing of food was properly conducted. Some comments contend that the only requirement should be that accreditation bodies are signatories to the International Laboratory Accreditation Cooperation (ILAC), and then let the accreditation bodies assess the laboratories for LAAF-accreditation, applying the accreditation bodies' usual standards. Some comments argue that FDA should not have any authority over accreditation bodies, because such authority would result in two entities overseeing the laboratories, which these

comments view as both confusing and intrusive.

(Response 11) The structure of the LAAF program is specified by the statute, per section 422(a)(1)(B) and (a)(2) of the FD&C Act. FDA will recognize accreditation bodies, which in turn will accredit laboratories. Further, there are advantages and efficiencies to relying on the structure of the existing conformity assessment industry (*i.e.,* accreditation bodies assess laboratories) for the structure of this program. For example, this familiarity may make it easier for these stakeholders to participate in the program. At the same time that we are glad to leverage widely accepted international voluntary consensus standards as foundational requirements, we are supplementing those standards with certain requirements that we have determined will help ensure the integrity of the testing under this program. As a reminder, all the testing that we are requiring be conducted by a LAAF-accredited laboratory is occurring in the context of increased food safety concern (see § 1.1107(a). For example, under § 1.1107(a)(4), testing to support the release of food detained at the border because it is or appears to be adulterated or misbranded, is covered by this rule. Accordingly, we have determined that it is appropriate to impose some requirements in addition to those of the international voluntary consensus standards.

Regarding the concern that FDA's exercise of authority over recognized accreditation bodies for purposes of this program will be confusing and intrusive, we have structured the program such that FDA evaluates the recognized accreditation bodies, and the accreditation bodies assess the laboratories against the model standards established in this rule, including conformity to ISO/IEC 17025:2017. FDA will not be assessing laboratory applicants.

As shown in section I.A. above, we have revised the program structure diagram from the proposed rule (see 84 FR 59452 at 59453) to reflect changes made in the final rule. The program structure diagram incorporates revised program terminology throughout (*i.e.,* ''LAAF-accredited''; see discussion at Response 10). We also include a second box representing FDA to better illustrate our roles of recognizing accreditation bodies and reviewing results and supporting information submitted by LAAF-accredited laboratories.

(Comment 12) Some comments opine that the framework of the proposed rule is inappropriate. These comments contend that it is not appropriate for FDA to oversee accreditation bodies because FDA is not an ILAC signatory. These comments further state that only accreditation bodies should oversee the laboratories they accredit and that therefore FDA's involvement would be both unnecessary and confusing. These comments recommend that FDA simply maintain a list of ILAC-signatory accreditation bodies, and have laboratories accredited by those listed accreditation bodies submit test results to us.

(Response 12) We disagree that the framework of the rule, and FDA's oversight of both recognized accreditation bodies and LAAF-accredited laboratories, is inappropriate. Section 422 of the FD&C Act directs FDA to establish this program and, in relevant part, provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary (see section 422(a)(2) of the FD&C Act). The Agency has established that being an ILAC signatory is a necessary, but not sufficient, condition to being recognized by FDA to LAAF-accredit laboratories. We have determined it necessary and appropriate to set additional standards for accreditation bodies, such as the conflict of interest requirements in § 1.1119. FDA must also evaluate the work of the accreditation bodies to ensure the integrity of the program. Further, the statute directs the Agency to periodically review a recognized accreditation body's compliance with the requirements of the program.

Similarly, section 422(a)(6) of the FD&C Act directs the Agency to develop model standards that a laboratory must meet to be LAAF-accredited to conduct testing under this subpart. We have adopted ISO/IEC 17025:2017 accreditation as a baseline requirement, but given the specific circumstances in which food testing is required to be conducted by a LAAF-accredited laboratory and since we use the results of such tests to inform regulatory decisions and protect public health, we have included FDA oversight of LAAF-accredited laboratories among the components of the program (see section 422(a)(6)(B) of the FD&C Act).

Therefore, FDA oversight of recognized accreditation bodies is not only appropriate, but it is also required by statute. Further, FDA has determined that oversight of LAAF-accredited laboratories submitting test results to FDA is appropriate given the Agency's use of the test results. The alternative framework proposed by the comment is not a viable option for a comprehensive and effective program that is sufficiently protective of public health.

(Comment 13) A few comments encourage FDA to reassess our proposal to place laboratories or accreditation bodies in probationary status, which is noted on the public registry, after finding one or more nonconformances. These comments suggest that we consider the variety of circumstances that may surround nonconformance, including that the entity may be in the process of actively addressing the nonconformance. The comments express a concern that publication of probationary status on the online registry may negatively and unfairly impact the entity, as the entity may be in the process of addressing the issue that resulted in a non-conformance.

(Response 13) We agree that entities should have an opportunity to address concerns before those concerns cause the entity to be placed on probation, particularly as probation will be noted on the online registry. Accordingly, we have revised the final rule such that generally an entity will be notified of deficiencies and provided an opportunity to take corrective action prior to being placed on suspension or probation. Consistent with our decision to incorporate by reference ISO/IEC 17011:2017 and ISO/IEC 17025:2017, we have decided to leverage the corrective action processes described in those standards to provide such an opportunity.

Under these ISO/IEC standards, the corrective action process requires the entity to do more than simply correct a non-conformity. Instead, the entity is required to consider the non-conformity from a process perspective, including identifying the cause of the non-conformity and considering whether internal process changes are needed to prevent its recurrence. FDA's view is that that this focus on looking for and addressing any systemic weaknesses in the entity's procedures, rather than simply remedying a single error or lapse, will serve to strengthen both the accreditation bodies and the laboratories that participate in this program, and therefore the LAAF program itself.

Section 1.1121(a) of the final rule states that if a recognized accreditation body observes a deficiency in a LAAF-accredited laboratory, the recognized accreditation body may require corrective action using the procedures described by ISO/IEC 17025:2017 section 8.7 (Ref. 3). Similarly, we have revised §§ 1.1131 and 1.1161 regarding FDA oversight actions regarding recognized accreditation bodies and LAAF-accredited laboratories, respectively, such that generally entities will be provided an opportunity to take

corrective action prior to being placed on probation.

Some problems may warrant immediate action by a recognized accreditation body to suspend, reduce the scope of, or withdraw the LAAF-accreditation of a laboratory or by FDA to immediately disqualify a LAAF-accredited laboratory. For additional information, see § 1.1121 (''When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, reduce the scope of, or withdraw the LAAF-accreditation of a laboratory?''); § 1.1131 (''When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?''); and § 1.1161 (''When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?'').

Finally, note that we have revised the final rule to refer to ''suspension'' of LAAF-accredited laboratories by recognized accreditation bodies instead of ''probation'' as proposed. The final rule retains and limits the term ''probation'' to refer to an action that FDA may take with respect to a recognized accreditation body or a LAAF-accredited laboratory in certain circumstances (see §§ 1.1131 and 1.1161). For more information on this terminology change, see Comments 58, 71, and 82 and Responses.

3. Implementation

(Comment 14) Several comments address implementation. In section VII of the proposed rule, we proposed that implementation would occur in a stepwise fashion; we would focus first on accreditation bodies and subsequently, laboratories. See 84 FR 59452 at 59495. We proposed that after the program attains sufficient laboratory capacity, we would publish a notice in the **Federal Register** giving 6 months' notice that owners and consignees would be required to use laboratories approved for participation in this program. All comments on this aspect of our proposal endorse a stepwise approach to implementation. These comments also agree with providing notice to affected entities via a **Federal Register** document. Some comments encourage the Agency to also issue **Federal Register** notices to announce when we will commence accepting applications from accreditation bodies, and when recognized accreditation bodies are able to start accepting applications from laboratories.

(Response 14) We appreciate comments supporting our proposed implementation steps. As we stated in the preamble to the proposed rule, implementation of the LAAF program will necessarily occur in a stepwise fashion. We will announce when accreditation bodies may apply for recognition. When we have recognized a sufficient number of accreditation bodies, we will announce that laboratories may apply to the recognized accreditation bodies for LAAF-accreditation. When we have sufficient LAAF-accredited laboratory capacity for the testing covered by § 1.1107, we will publish a document in the **Federal Register** giving owners and consignees 6 months' notice that they will be required to use a LAAF-accredited laboratory for such testing.

We decline to commit to publishing notices in the **Federal Register** to announce that we are ready to accept applications from accreditation bodies and that laboratories may apply to recognized accreditation bodies. There are a variety of methods to communicate effectively with stakeholders and the interested public; at the appropriate time we will determine which methods best advance the Agency's interest in transparency and the needs of the LAAF program.

(Comment 15) Some comments recommend that in addition to the stepwise approach discussed in the previous comment and response, we also take a phased-in approach to implementation. That means that FDA would only require testing under the rule for the various categories of tests described in § 1.1107 as sufficient laboratory capacity is attained for each. Some comments suggest that we refrain from requiring testing under the rule until we have achieved sufficient laboratory capacity for a majority of the tests covered by the rule.

Some comments maintain that there will be sufficient laboratory capacity for the DWPE-related testing covered by the final rule, because as we noted in the proposed rule, 10 laboratories that conduct the majority of such testing already are ISO/IEC17025-accredited (see 84 FR 59452 at 59457). These comments state that there are ''hundreds'' of ISO/IEC 17025-accredited independent food laboratories in the United States that potentially could participate in the program, which would expand capacity. These comments expect that the program we are establishing in this final rule would also increase incentives for ISO/IEC17025 accreditation and therefore expand capacity even further.

Some comments question whether, and some comments ask when, sufficient laboratory capacity will be reached for all the tests covered by this final rule. Other comments inquire how FDA will determine when sufficient laboratory capacity has been reached. Some comments urge that when FDA considers whether there is sufficient laboratory capacity, we take into account whether laboratories can perform the testing in a timely manner. Other comments suggest that when we consider capacity, we take into account laboratory location relative to owners and consignees. Some comments predict that it will take a long time to achieve sufficient laboratory capacity, and some comments request that we explain what will happen if sufficient laboratory capacity is not attained for a particular category of testing. Some comments encourage FDA to identify the LAAF-accredited laboratories publicly once sufficient capacity is reached.

Further, some comments express skepticism that the program would ever be able to attain sufficient capacity to implement the bottled drinking water followup testing covered by the rule (see § 1.1107(a)(1)(iii)). These comments state that such followup tests occur rarely and suggest that no water testing laboratory will find it worthwhile to participate in this program for the relatively little bottled drinking water followup testing business it might gain by doing so.

Other comments focus on laboratories that currently test shell eggs and maintain that many such laboratories are not currently ISO/IEC 17025-accredited. These comments question whether those laboratories would choose to become ISO/IEC 17025-accredited in order to participate in this program, as, according to these comments, such laboratories would be unlikely to test any commodities covered by this final rule other than shell eggs. These comments state it is unclear how quickly additional laboratories would be able to get approved for participation in the program and predict there could be a logistical problem of bottlenecking if sufficient laboratory capacity for a particular test is not attained. These comments encourage FDA to consult with the National Poultry Improvement Plan at the U.S. Department of Agriculture and other Agencies that have experience testing agricultural products. Finally, these comments ask that FDA allow adequate time for a sufficient number of laboratories to become LAAF-accredited to conduct the shell egg testing described in § 1.1107(a)(1)(ii) before we require owners and consignees to have those tests conducted under this program.

(Response 15) We agree that given the breadth of matrices and methods covered by the rule it may be necessary to separately consider whether sufficient laboratory capacity has been attained for the variety of tests described in § 1.1107. As discussed in the preceding comment and response, the first implementation step is for FDA to receive, review, and evaluate applications from accreditation bodies. Once we have recognized a sufficient number of accreditation bodies, we anticipate that many laboratories will be interested in becoming LAAF-accredited, but it is impossible for us to predict various relevant factors including how many laboratories will apply, the methods for which they will be successful, and the associated timeframes. Perhaps sufficient laboratory capacity will be promptly attained for all tests covered by the rule; that would allow us to issue a single **Federal Register** document notifying owners and consignees that in 6 months they must use a LAAF-accredited laboratory for all tests described in § 1.1107. That outcome is not assured, however, and therefore we may phase in implementation as suggested by some comments. To the extent that some comments suggest we wait to implement any of the rule until we have attained sufficient capacity for a majority of all the tests covered by the rule, we decline the suggestion due to the many variables that are not entirely within our control (the number of laboratories that apply as soon as they are able, the number and capacity of recognized accreditation bodies that will be assessing the initial laboratory applications, etc.).

We appreciate the comments contending that there will be more than sufficient laboratory capacity for all the testing under this rule. This program represents the least amount of change for those private laboratories that are already ISO/IEC 17025-accredited and have been conducting the tests that support admission of a food under section 801(a) of the FD&C Act and removal from DWPE under an import alert and sending their test results and associated analyses to FDA, some for many years. Further, as indicated by some comments, the data we analyzed for the proposed rule indicated that many of the laboratories that have been conducting tests to support admission of a food and removal from DWPE under import alerts are already ISO/IEC 17025-accredited; the cost for such laboratories to become LAAF-accredited is relatively low. We agree with comments maintaining that our reliance on ISO/IEC 17025 as a foundational requirement for LAAF-accreditation provides an incentive for laboratories to become ISO/IEC 17025-accredited and we note that an explicit goal of section 422 is to increase the number of laboratories qualified to conduct testing under this subpart (see section 422(a)(3) of the FD&C Act).

Determining whether the program has attained sufficient laboratory capacity may appear to be a simple comparison of the number of a particular type of test that is needed, to the number of laboratories LAAF-accredited for that method. The reality is far different. Test demand cannot be predicted with certainty; in part it is a result of the prevalence of circumstances presenting heightened food safety concerns (*e.g.,* the number and breadth of import alerts; how much food product is or appears to be violative when offered for import) and in part it is a result of business choices outside of our control or knowledge (*e.g.,* how much food subject to DWPE is offered for import; whether a shell egg producer's environment tests positive for *Salmonella* Enteritidis and whether the producer then chooses to test its shell eggs or divert them to treatment (see §§ 118.5(a)(2)(ii) and (b)(2)(ii); 118.6(a)(2)). Some laboratories are much bigger than others, and bigger laboratories presumably can conduct more tests than smaller laboratories, so simply knowing how many laboratories are LAAF-accredited for a given method does not present a complete picture of capacity. We acknowledge that location is a relevant factor in choosing a laboratory, in large part due to the time and cost implications of shipping samples to a laboratory that is relatively far away, but the degree to which this factor is relevant to laboratory capacity may vary depending on the test at issue (*e.g.,* size of sample, whether there are time and temperature requirements, the degree to which a product is perishable). Similarly, although timeliness may be an important factor for one sort of food test, it may be less critical in other food testing contexts. Other factors may also be relevant, and as noted above, it is infeasible for us to predict them all.

FDA is committed to implementing this program promptly and, as in other FSMA contexts, in a practical manner. In determining laboratory capacity we will take all relevant information and factors into account. We remain committed to providing owners and consignees 6 months' notice via a document in the **Federal Register** before requiring them to use a LAAF-accredited laboratory for the testing covered by this rule. We will not preclude the possibility that we may issue more than one **Federal Register** document as laboratory capacity is attained for various tests described in § 1.1107.

The publication of this final rule in the **Federal Register** arguably marks the beginning of the implementation of this program. Although we expect to reach sufficient laboratory capacity for all the tests covered by this rule, we decline the invitation of some comments to predict how long it will take to achieve that milestone. If sufficient laboratory capacity is not reached for a particular category or subcategory of the tests described in § 1.1107, then the immediate result would be that we not require owners and consignees to use a LAAF-accredited laboratory to conduct those particular tests.

We anticipate a sufficient number of LAAF-accredited laboratories for the bottled drinking water tests covered by this final rule (see § 1.1107(a)(1)(iii)). For a related discussion, please see Comment and (Response 87.

Some comments claim that the laboratories that currently conduct shell egg testing tend not to be accredited to ISO/IEC 17025. These comments express concern that such laboratories may not become LAAF-accredited, which may result in a bottleneck effect (due to insufficient laboratory capacity). First, as discussed earlier in this response, FDA does not intend to require owners and consignees to use a LAAF-accredited laboratory for the testing described in § 1.1107 until the program has attained sufficient laboratory capacity for the relevant testing, even if that means that a LAAF-accredited laboratory is required for some categories or subcategories of testing described in § 1.1107 sooner than for other categories or subcategories. Accordingly, the implementation of this program should not result in a bottleneck for shell egg testing.

The research supporting the FRIA for this final rule (Ref. 4), and the information we gleaned from our consultations with the National Poultry Improvement Plan, is consistent with comments' claim that the majority of laboratories that currently conduct the shell egg testing described in § 1.1107(a)(1)(ii) are not accredited to ISO/IEC 17025. Although we believe some of those laboratories will pursue ISO/IEC 17025 and LAAF-accreditation as a result of this final rule, we have no way of knowing with certainty.

We estimate that once this final rule is fully implemented, FDA will receive about 3,771 analytical reports of shell egg testing per year (Ref. 4). Due to the testing regime required under the FDA

egg safety rule, each analytical report will consist of 50 tests (each shell egg sample of 1,000 eggs is separated into 50 pools of 20 eggs each). (See § 118.6.) Accordingly, we expect that more than 188,000 FDA-required shell egg tests currently conducted each year to comply with § 118.6 will eventually be conducted by LAAF-accredited laboratories. If the laboratory market responds rationally, a sufficient number of laboratories will react to the business opportunity those shell egg tests create and choose to become LAAF-accredited. If a sufficient number of laboratories that currently conduct shell egg tests choose not to become LAAF-accredited, then other laboratories will emerge to seize this opportunity. The costs of becoming LAAF-accredited for laboratories new to shell egg testing will be lowest for those laboratories that are already accredited to ISO/IEC 17025; it would therefore be reasonable to expect such laboratories to pursue LAAF-accreditation to conduct shell egg testing. The FRIA in section II.F.3.f. accounts for the costs for some shell egg producers to switch laboratories if the one they are currently using is not LAAF-accredited (Ref. 4).

Shell egg testing is only required if the poultry house has tested positive for *Salmonella* Enteritidis, and the producer chooses not to divert the eggs to treatment. The central purpose of this final rule is to help ensure that the results of certain food testing that takes place amidst just this sort of heightened food safety concern, are reliable and accurate. No comments suggest that shell egg testing should be excluded from the coverage of this final rule, or subject to less stringent standards. We expect to avoid the logistical problem identified by these comments. And as noted above, we are committed to providing 6 months' notice via a **Federal Register** document before shell egg producers are required to use a LAAF-accredited laboratory to conduct the testing described in § 1.1107(a)(1)(ii).

C. Comments Regarding General Provisions

TABLE 2—CHANGES TO GENERAL PROVISIONS

Final rule	Proposed rule	Note
§ 1.1101 What documents are incorporated by reference in this subpart?	N/A	New section for centralized incorporation by reference (IBR).
§ 1.1102 What definitions apply to this subpart?	§ 1.1102 What definitions apply to this subpart?	See preamble table below for specific changes to § 1.1102.
§ 1.1103 Who is subject to this subpart?	§ 1.1103 Who is subject to this subpart?	See preamble discussion below for specific changes to § 1.1103.

1. What documents are incorporated by reference in this subpart (§ 1.1101)?

In the proposed rule, we proposed to incorporate by reference two international voluntary consensus standards: ISO/IEC 17011, Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second edition, November 2017 (Ref. 2), for accreditation bodies, and ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, Third edition, November 2017 (Ref. 3), for laboratories.

This final rule implements section 422 of the FD&C Act against the backdrop of the broader Federal policies on consensus standards and conformity assessment under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113). The NTTAA, together with the Office of Management and Budget (OMB) Circular A–119, revised January 27, 2016 (81 FR 4673), directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. OMB Circular A–119 states that the use of voluntary standards, whenever practicable and appropriate, is intended to eliminate the cost to government of developing its own standards; decrease the cost of goods procured and the burden of complying with Agency regulation; provide incentives and opportunities to establish standards that serve national needs, and encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and further the policy of reliance upon the private sector to supply the government with cost-effective goods and services (Ref. 8).

As directed by OMB in Circular A–119, the National Institute of Standards and Technology (NIST), in the **Federal Register** of September 29, 2020 (85 FR 60904), issued updated policy guidance on Federal conformity assessment activities. The Federal conformity assessment guidance is codified at 15 CFR part 287 and applies to all Federal Agencies that set policy for, manage, operate, or use conformity assessment activities or results (85 FR 60904 at 60905). The guidance advises Agencies on using conformity assessment to meet government needs in a manner that is efficient and cost-effective for both the Agency and its stakeholders (15 CFR 287.1(a)). In keeping with these national policies, FDA has determined that it is appropriate and will be beneficial to both the Agency and the public if we rely on voluntary consensus standards to provide the baseline requirements for both accreditation bodies and laboratories wishing to participate in the LAAF program.

In the proposed rule, the incorporation by reference information was repeated throughout the codified text (*e.g.,* § 1.1113(b) (ISO/IEC 17011:2017); § 1.1138(a)(2) (ISO/IEC 17025:2017)). On our own initiative, for readability we have revised the final rule to include a centralized incorporation by reference section at § 1.1101. Note that throughout the codified, after the year of each standard, we included the letter ''E'' to clarify that we are incorporating the standard in English (*e.g.,* ''ISO/IEC 170211:2017(E)).'' However for readability, we did not repeat the ''E'' after each mention of the standards throughout the preamble.

We received a few comments regarding the proposal to incorporate by reference the two consensus standards. These comments are addressed below.

(Comment 16) Several comments support our reliance on existing international voluntary consensus standards: ISO/IEC 17011:2017 for accreditation bodies and ISO/IEC 17025:2017 for laboratories.

(Response 16) Voluntary consensus standards such as ISO/IEC 17011:2017 and ISO/IEC 17025:2017 are developed by organizations with the involvement of interested parties representing various roles, concerns, and perspectives, via a robust process that seeks to achieve consensus (Ref. 9). As noted in the immediately preceding

section, Federal law and policy direct us to use voluntary consensus standards rather than creating our own unique standards whenever practical and consistent with our legal obligations. Further, section 422(a)(6) of the FD&C Act specifically directs the FDA to ''consult existing standards'' in the course of developing model standards for this rulemaking.

Comments do not suggest that we consider any other standard for accreditation bodies wishing to participate in this program. And although some comments recommend that we permit the participation of laboratories that meet certain industry-specific standards (see Comment 87 and Comment 88), no comment suggests a standard other than ISO/IEC 17025:2017 as a baseline requirement. We appreciate support for our position that ISO/IEC 17011:2017 and ISO/IEC 17025:2017 are the most appropriate globally recognized and widely used standards for the LAAF final rule.

2. What definitions apply to this subpart (§ 1.1102)?

TABLE 3—REVISIONS TO THE PROPOSED DEFINITIONS IN § 1.1102

Term	Revision
Accreditation	Term revised to ''laboratory accreditation for analyses of foods (LAAF) accreditation'' to clarify that decisions regarding accreditation under this subpart are limited to the LAAF program.
Accredited laboratory	Term revised to ''LAAF-accredited laboratory.''
Analyst	No change.
Corrective action	New term that we define as an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.
Food	No change.
Food testing, testing of food	No change.
Food testing order	Term revised to ''directed food laboratory order'' to more accurately describe the order. Revised the definition to strike reference to § 1.1107(a)(2); the definition now states the order is issued only under § 1.1108.
Owner or consignee	Definition revised to refer to the circumstances in § 1.1107(a) instead of repeating the circumstances in § 1.1107(a) in the definition.
Recognition	Definition revised to refer to LAAF-accreditation of laboratories.
Recognized accreditation body	Definition revised to refer to the accreditation body's authority with respect to LAAF-accredited laboratories.
Representative sample	Definition revised to clarify that accuracy is to a ''statistically acceptable degree'' in response to comments and a grammatical revision made on our own initiative.
Sampler	Definition revised to reference the individual who collects a sample.
Sampling firm	New term that we define as an entity that provides sampling services.
Scope of accreditation	Term revised to ''scope of LAAF-accreditation'' and definition revised to delete the second sentence of the definition to remove the phrases, ''in-whole'' and ''in-part'' from the definition and throughout the rule.

We proposed to apply the definitions in section 201 of the FD&C Act unless otherwise specified. Additionally, we proposed to codify several terms used in the LAAF regulations. We received several comments on this section. As discussed in the following paragraphs, we have revised many of the terms and proposed definitions in response to comments received, as well as on our own initiative. Where we disagree with comments or decline a suggested revision, we offer an explanation in response. Some definitions were finalized as proposed.

The definitions for terms used in the laboratory accreditation for analyses of foods regulations are codified in § 1.1102.

Accreditation, Accredited Laboratory

We proposed to define *accreditation* and *accredited laboratory* to relate to determinations regarding a laboratory under this subpart. On our own initiative, we moved the phrase, ''under this subpart'' in the definition of the term, ''LAAF-accredited laboratory'' to clarify that food testing is conducted under this subpart as opposed to using methods of analysis under this subpart, as proposed.

(Comment 17) A number of comments express concern with the proposed definitions of ''accreditation'' and ''accredited laboratory,'' suggesting that they may result in confusion with similar terms already being used by industry. Some comments recommend aligning the definitions of ''accreditation'' and ''accredited laboratory'' under this regulation with their meaning in the conformity assessment industry to avoid potential confusion. Others propose that we differentiate the terms under this regulation from those used elsewhere and suggest the more specific terms, ''Section 422 accreditation'' and ''Section 422 accredited laboratory'' as potential options.

(Response 17) We acknowledge the potential for confusion regarding the terms, ''accreditation'' and ''accredited laboratory'' under this subpart with the use and understanding of these terms by industry. Accordingly, we have revised the terms to be specific to the LAAF program. Therefore, the terms have been revised to ''LAAF-accreditation'' and ''LAAF-accredited laboratory'' respectively in § 1.1102 and throughout the rule to clarify the impacts and limitations of accreditation decisions under this subpart. See also Comment and Response 10.

Analyst

We received no comments on the proposed definition of ''analyst'' and therefore have finalized the definition as proposed.

Corrective Action

We have added a definition for corrective action to clarify that in this subpart, it means, ''an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.'' For additional discussion, see Comment and Response 31.

Food

In the proposed rule, we defined ''food'' as having the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)). The proposed definition would align with the definition of ''food'' in the ''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (21 CFR 1.600 *et seq.*) (Accredited Third-Party Certification Program) and the ''Foreign Supplier Verification Programs for Food Importers'' (21 CFR 1.500 *et seq.*) (FSVP) regulations.

(Comment 18) Some comments express support for the proposed definition of ''food,'' which the comments characterize as being the same as the definition in section 201(f) of the FD&C Act.

(Response 18) We appreciate the support for our proposed definition of ''food'' and we are retaining it without change. We note that for the purposes of this subpart, we are not giving the term, ''food,'' the same meaning as in section 201(f) of the FD&C Act. Under section 201(f), ''food'' is not defined to exclude pesticides, whereas the definition in this subpart expressly indicates that food does not include pesticides. As we stated in the proposed rule, we have not identified a need for ''food'' to include pesticides for purposes of this final rule, and no comment suggests otherwise.

Food Testing, Testing of Food

We proposed to define ''food testing'' and ''testing of food'' to mean the analysis of food product samples or environmental samples.

(Comment 19) Numerous comments indicate support for the inclusion of environmental testing within the definition for ''food testing'' and ''testing of food'' in the proposed rule. These comments assert that both food product and environmental testing are important to protecting public health. Conversely, multiple comments oppose the proposal to include environmental testing within the definition of ''food testing'' and ''testing of food.'' Some of these comments suggest that because FSMA section 202 did not explicitly mention environmental testing, the statute only permits the testing of food product samples, and not environmental samples, within the scope of this regulation. Other comments suggest that the definition of ''food testing'' and ''testing of food'' should be consistent in scope with the statutory definition of ''food'' in section 201(f) of the FD&C Act and limited to the analysis of food product samples only. Some comments further specify that although they oppose the inclusion of environmental testing within the definition for ''food testing'' and ''testing of food,'' they recognize the utility of environmental monitoring in ensuring food safety. Similarly, some comments state that the food industry has conducted environmental testing for a long time and argue that industry does not need this final rule to cover environmental testing to continue conducting such testing.

(Response 19) After carefully considering the comments and the statute, we define ''food testing'' and ''testing of food'' to mean, ''the analysis of food product samples or environmental samples.''

As discussed in the proposed rule, the terms, ''food testing'' and ''testing of food,'' used in section 422 of the FD&C Act, are not defined in the statute (84 FR 59452 at 59460). We find these terms ambiguous and rely on context for their interpretation. Section 202(a) of FSMA is located in Title II of FSMA, which is titled ''improving capacity to detect and respond to food safety problems.'' Further, in describing some of the testing to be covered by this subpart, section 422(b)(1)(A) of the FD&C Act twice includes testing that addresses, ''an identified or suspected food safety problem.'' This context indicates the critical importance of ''food testing'' and ''testing of food'' being interpreted to include the analysis of environmental samples, so that this final rule will cover an important method of detecting and responding to identified and suspected food safety problems. We acknowledge and appreciate those comments asserting that including environmental testing is important to addressing food safety concerns and protecting public health. We also note that even some comments that oppose defining ''food testing'' and ''testing of food'' to include environmental testing state that such testing plays a valuable role in identifying potential pathways for contamination and helping to ensure food safety.

We agree with aspects of comments that acknowledge the importance of testing food production environments (*e.g.,* the environment where food is grown, harvested, packed, held, processed, or manufactured). The term, ''environment'' includes food contact surfaces such as utensils and table surfaces. Pathogens in the environment can be (and unfortunately, sometimes are) transmitted to food. Therefore, environmental testing is sometimes used as a followup test to verify that cleaning and sanitizing designed to eliminate an identified pathogen, was sufficient to eradicate that pathogen. Environmental testing may also be employed to determine the source of an identified pathogen (*e.g.,* in circumstances where a food product tested positive for a pathogen but it is not yet known how the food became adulterated). It is important that FDA be able to utilize this subpart to help ensure valid testing in the context of those sorts of heightened food safety concerns.

Some comments indicate that Congress used the term, ''environmental testing'' in other parts of the statute and could have done so here. Although we do not disagree with that statement, we note that Congress also used the term, ''product testing,'' in other parts of the statute, and could have done so here. We do not believe the absence of these phrases implies a lack of statutory authority to include both product and environmental testing within the scope of this final rule. Furthermore, the inclusion of both types of testing within the scope of the final rule serves a central purpose of section 422 of the FD&C Act, which is to improve FDA's access to reliable and accurate results of public health significance, thus improving our capability to protect U.S. consumers from unsafe food.

Some comments contend that the statutory definition of ''food'' limits our definitions of ''food testing'' and ''testing of food,'' to product samples. As we acknowledged in the preamble to the proposed rule, that is one, but not the only, reasonable interpretation of the statute. For the reasons discussed, we are adopting a different and more public health-protective interpretation and therefore finalize the definition of ''food testing'' and ''testing of food'' without change.

Finally, we appreciate that many in the food industry have long monitored their production environment through environmental testing. We applaud and encourage the continued practices of firms that conduct robust environmental monitoring programs. As discussed further in Response 35, this final rule does not cover routine environmental testing.

Food Testing Order

We proposed to define ''food testing order'' as an order issued by FDA under §§ 1.1107(a)(2) and 1.1108 requiring food testing to be conducted under this subpart by or on behalf of an owner or consignee. Although we did not receive specific comments regarding the proposed definition, we received many comments about the food testing order provisions in proposed §§ 1.1107 and 1.1108. We discuss those comments in section V.D. below; however, we are also making a change to the related terminology. We have revised the term, ''food testing order'' to ''directed food laboratory order'' throughout the rule to more accurately reflect the order and its impact. To reduce confusion, we generally use the term, ''directed food laboratory order,'' throughout this document, even when referring to discussions in the proposed rule.

On our own initiative, we revised the definition to strike the reference to § 1.1107(a)(2) and now state the order is issued solely under § 1.1108, as this provision directly describes FDA's issuance of such orders.

Owner or Consignee

We proposed to define ''owner or consignee'' as a person with an ownership interest in the food or environment samples in the circumstances described in proposed § 1.1107. On our own initiative, we have revised the definition to refer more generally to the circumstances described in § 1.1107 instead of repeating the circumstances in the definition.

Recognition

We proposed to define ''recognition'' to mean a determination by FDA that an accreditation body meets the applicable requirements of the LAAF program and is authorized to accredit laboratories under this subpart. As a result of revising the terms, ''accreditation'' and ''accredited laboratory'' to be specific to the LAAF program, we have revised the definition of ''recognition'' to reflect that a recognized accreditation body will LAAF-accredit laboratories to conduct food testing under this subpart.

(Comment 20) Some comments state that having a definition for ''recognition'' specific to this regulation may result in confusion, as the term is already used by the conformity assessment industry in other contexts outside of this regulation.

(Response 20) In contrast to the many comments that argue that our proposed use of the terms ''accreditation,'' ''accredited laboratory,'' and ''assessment,'' created confusion, only a small number of comments claim that our proposed use of the term, ''recognition,'' would create the potential for confusion. Further, these comments provide no specific examples of how the term, ''recognition,'' would be confusing, and do not offer alternative terms or definitions.

In addition, the FDA Foods Program uses the term, ''recognition,'' in the same way as proposed in our Accredited Third-Party Certification Program (see 21 CFR 1.600), and has not heard from those program participants that the term has proved problematic. For more information on the Accredited Third-Party Certification Program, see *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.*

Therefore, we are retaining the definition of the term, ''recognition'' in the final rule.

Recognized Accreditation Body

We proposed to define ''recognized accreditation body'' as an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit laboratories under this subpart. We have revised the definition to state that the recognized accreditation body is authorized to LAAF-accredit laboratories under this subpart. This change aligns with our overall revisions to terminology throughout the rule.

Representative Sample

We proposed to define ''representative sample'' to mean ''a sample that accurately, to a scientifically acceptable degree, represents the characteristics and qualities of the food product or environment the sample was collected from.''

(Comment 21) Several comments contend that the proposed definition of ''representative sample'' is vague and impractical. Some comments suggest we clarify that determining whether a sample is ''representative'' involves an assessment of various factors. Others suggest that FDA clarify the Agency's expectations regarding ''representative sample'' by specifying sampling protocols within import alerts or including specific procedures and sampling plans for different foods and analyses within the final rule. Some comments suggest the addition of a definition for ''representative sampling,'' based on the concern that if sampling is not performed appropriately, results may be invalidated.

Some comments specify that the phrase, ''to a scientifically acceptable degree'' is difficult to understand and vague; these comments suggest that we replace the phrase, ''to a scientifically acceptable degree,'' with the phrase, ''based on a scientific risk-based rationale.'' These comments also suggest we add a second sentence to the definition to explain that the suggested phrase, ''includes consideration of the environment, food matrix, and analyte of interest, among other factors.''

(Response 21) We agree that whether a food testing sample is representative depends on a variety of factors. Relevant factors include what is being sampled, the population from which the sample is taken, the dispersion pattern of potential adulterants, and adherence to any time and temperature controls, to name just a few. We also appreciate the desire for clarity expressed in the comments suggesting that we specify sampling protocols for the samples that will be tested under this final rule. However, the purpose of defining ''representative sample'' in this subpart is not to prescribe how to achieve a representative sample either generally or specifically for the testing conducted under this program. Instead, it is to accurately communicate the concept of a representative sample. We considered altering the definition, but because every food product and environmental testing circumstance is slightly different, and as already noted, there are many relevant factors that also vary, our attempts to add specificity to the definition resulted in unnecessarily complex language or the introduction of some inaccuracy. Accordingly, although we understand that some comments describe the proposed definition as vague and impractical, we are retaining it with limited changes because we conclude that it broadly satisfies the purpose for which it was created. We also consider the definition to be similar to and consistent with definitions that are accepted nationally and internationally. (See, *e.g.,* Codex Alimentarius Commission, General Guidelines on Sampling document CAC/GL–50–2004, § 2.2.3: ''A representative sample is a sample in which the characteristics of the lot from which it is drawn are maintained. It is in particular the case of a simple random sample where each of the items or increments of the lot has been given the same probability of entering the sample'' (Ref. 10).

Some comments suggest that the proposed phrase, ''to a scientifically acceptable degree,'' is difficult to understand and vague, and suggest instead the phrase, ''based on a scientific risk-based rationale.'' We agree that the proposed phrase could be improved. However, we do not believe the proffered alternative phrase is the best choice, because it would not always be applicable and also, is less common in the laboratory industry and therefore not widely understood. Instead, we have replaced ''to a scientifically acceptable degree,'' with, ''to a statistically acceptable degree,'' which we believe communicates with more precision than the proposed phrase the need for samples to be selected based on a statistical sampling design. A sample that represents the whole to a statistically significant degree will yield information about the average composition of the whole, and therefore enable valid, accurate test results.

We decline the suggestion to add a second sentence to the definition to explain the phrase at issue but have already agreed with the concept it expressed, which is that determining whether a sample is representative involves considering a host of varying factors. We also decline the suggestion to add a definition of ''representative sampling,'' to this subpart. Although we certainly agree that sampling techniques are critical to obtaining a representative

sample, this final rule does not set standards for those techniques and therefore our discussion of them is not so extensive as to justify the need to define the term.

On our own initiative, we also made grammatical changes to this definition.

See our discussion of § 1.1149 below for additional information on sampling requirements and resources.

Sampler

We proposed to define ''sampler'' as an individual or individuals who perform sampling.

(Comment 22) A few comments disagree with the proposed definition of ''sampler,'' and state that a sampler may also be an entity (for example, in the case of laboratories that are commercially liable for the performance of the persons collecting the samples). These comments suggest that FDA include definitions for both ''sampler'' (an entity) and ''sample collector'' (individual(s)) within the final rule to clarify this distinction.

(Response 22) We agree that it would be clearer to use two distinct terms throughout the rule regarding activities related to sampling. First, we have clarified the definition of the term, ''sampler'' to mean an individual who collects samples. Second, we have added a new term, ''sampling firm,'' which we define as an entity that provides sampling services. Accordingly, we have revised the final rule to use the term, ''sampling firm'' where appropriate.

Scope of Accreditation

We proposed to define this term to refer to the methods of analysis for which the laboratory is accredited. The proposed definition went on to state that ''[r]eferences in this subpart to accreditation 'in-whole' refers [sic] to all methods in the accredited laboratory's scope of accreditation and references to accreditation 'in-part' refers [sic] to only certain methods in the accredited laboratory's scope of accreditation.'' 84 FR 59452 at 59502. We received no comments on this proposed definition; however, we have revised the proposed term and definition to be consistent with our terminology changes throughout the final rule. The term has been revised to ''scope of LAAF-accreditation'' and the definition of the term has been revised to refer to ''. . . the methods of analysis for which the laboratory is LAAF-accredited.''

We have omitted the proposed second sentence in the definition which removes the terms, ''in-whole'' and ''in-part.'' Instead, in the final rule we generally employ the construct that changes in LAAF-accreditation relate to specific methods, or apply to all methods, within a laboratory's scope of LAAF-accreditation. Additionally, in the final rule, to better align with the ISO/IEC conformity assessment paradigm, we consistently use the word, ''withdraw'' to refer to the action a recognized accreditation body takes to remove all methods within the laboratory's scope of LAAF-accreditation, and we use the phrase, ''reduce the scope of LAAF-accreditation'' to refer to recognized accreditation body actions which remove only certain methods from the laboratory's scope of LAAF-accreditation.

Additional Definitions

On our own initiative, we have included a definition for the term ''street address'' which appears throughout the final rule. We define the term to mean the full physical address, including the country. We go on to clarify that, for purposes of this rule, a post office box number alone is insufficient; however, a post office box number may be provided in addition to the street address.

We received comments requesting that we include and define additional terms in the final rule. We address these comments below.

(Comment 23) Multiple comments suggest adding a definition for ''identified or suspected food safety problem,'' stating that doing so would help to clarify when it would be necessary to use a LAAF-accredited laboratory for testing.

(Response 23) For the reasons stated in the preamble to the proposed rule, we decline the recommendation to include a specific definition for ''identified or suspected food safety problem'' (see 84 FR 59452 to 59462). Instead, we proposed codifying the specific circumstances in which use of a LAAF-accredited laboratory would be required under this subpart. As discussed below in section V.D, we have revised some of the circumstances in response to public comments and have added additional discussion in the preamble.

(Comment 24) Some comments suggest adding definitions for ''quality assurance'' and ''raw data,'' stating that similar terms are used by other programs, entities, and regulations—such as FDA's Good Laboratory Practice for Nonclinical Laboratory Studies at 21 CFR part 58—that may serve as a basis for developing a definition under this subpart.

(Response 24) We decline to add definitions for these terms to the final rule.

Quality assurance is a critical pursuit that must undergird both recognized accreditation body and LAAF-accredited laboratory processes. Indeed, we consider the integral nature of quality assurance in ISO/IEC 17011:2017 and ISO/IEC 17025:2017 to be among the standards' greatest strengths (Ref. 2, Ref. 3). In this final rule we are establishing requirements consistent with our perspective that quality assurance must be nurtured (*e.g.,* incorporation of the corrective action process for both recognized accreditation bodies and LAAF-accredited laboratories, submission by recognized accreditation bodies of their internal audit reports, proficiency test requirements for each method within the laboratories' scope of LAAF-accreditation at least every 12 months). Nevertheless, we decline the suggestion to define ''quality assurance'' in this subpart because we conclude a definition is neither necessary nor would it meaningfully add to the final rule. We prefer instead to include in our standards provisions that will require the quality assurance processes and actions we deem necessary for this program.

We note that the term, ''quality assurance'' appeared in § 1.1148 of the proposed rule (''What quality assurance requirements must accredited laboratories meet?''). In the final rule, we have omitted the specific section regarding quality assurance requirements and incorporated those requirements into § 1.1138, which addresses the eligibility requirements for LAAF-accredited laboratories.

The term, ''raw data'' is not used so extensively in the final rule as to warrant a definition. In fact, it only appears once in the codified text, in § 1.1152(d)(8), where we require as part of a full analytical report, ''[a]ll original compilations of raw data secured in the course of the analysis.'' We explain the term in two ways. First, section 1.1152(d)(8) includes some examples of raw data, and second, in our discussion of that provision at Response 119, below, we have expounded on our thinking regarding this requirement. We consider these forms of explanation to be sufficient in the context of this subpart.

(Comment 25) Some comments state that the term, ''specific major food testing discipline'' is used throughout the proposed rule and suggest that a definition for the term be added to the regulation for additional clarity.

(Response 25) We included the term, ''specific major food testing discipline'' in proposed § 1.1152(d) regarding permission to submit abridged

analytical reports. To clarify the term, we have included detail in the final rule at § 1.1153(a) regarding the three major food testing disciplines under this rule for purposes of submitting abridged analytical reports. We identified these in the preamble to the proposed rule regarding § 1.1152(d) (see 84 FR 59484 (Nov. 4, 2019)) using slightly different terms: ''microbiology, chemistry, and physical (filth).'' In the final rule at 21 CFR 1.1153(a), we have codified the specific major food testing disciplines that will be used to categorize analytical reports for purposes of determining permission to submit abridged analytical reports as ''biological, chemical, and physical.''

3. Who is subject to this subpart (§ 1.1103)?

Proposed § 1.1103 listed the entities subject to the subpart: recognized accreditation bodies, entities seeking to become recognized accreditation bodies, LAAF-accredited laboratories, entities seeking to become LAAF-accredited laboratories, and owners and consignees who are required to use LAAF-accredited laboratories for the food testing under this program.

We have made minor changes throughout this section to reflect revised program terminology. Specifically, we have modified the term, ''accreditation'' to ''LAAF-accreditation'' in this section and throughout the rule. Additionally, we have made minor editorial changes on our own initiative to improve clarity. Comments regarding this section are discussed below.

(Comment 26) Some comments request clarification of which owners and consignees will be covered by this final rule, stating that there may be multiple owners and consignees in the context of imported food.

(Response 26) FDA-regulated products imported into the United States must comply with the same FDA laws and regulations that apply to domestic products. Entries are submitted to U.S. Customs and Border Protection which then refers entries of FDA-regulated products to FDA for review. Imported items may not be distributed into commerce until FDA has determined admissibility.

If FDA detains a food product at the border under section 801(a) of the FD&C Act because the food is or appears to be adulterated or misbranded, but FDA has not yet refused admission, the owner or consignee of the food may introduce testimonial evidence that the food is admissible. Owners and consignees often engage laboratories to test the food and submit to FDA the results of the testing, as testimony to support admission. If FDA determines that the food testing results are valid and that they demonstrate the detained product does not violate the FD&C Act, FDA will release the food from detention and allow it to proceed into the United States. The testing of detained product at the direction of such owners and consignees is covered by this final rule (see § 1.1107(a)(4)).

The DWPE procedure allows FDA to detain an imported product without physically examining it at the time of entry. FDA employs the DWPE procedure when there is a history of product that violates or appears to violate the FD&C Act, or when other information indicates that future entries may be violative. Import alerts inform FDA staff and the public that we have enough evidence to allow for DWPE of particular products. Testing to support removal from an import alert is also covered by this final rule (see § 1.1107(a)(5)). For more information on FDA's import program generally see *https://www.fda.gov/industry/import-program-food-and-drug-administration-fda;* for more information on DWPE, see *https://www.fda.gov/media/71776/download.*

It is true that for a particular food shipment or entry being offered for import into the United States, multiple parties may be considered owners and/or consignees of the entry or of particular products within that entry (*i.e.,* line items or lines). However, there is generally only one importer of record for each entry,[2] and it is the importer of record that is ultimately responsible for ensuring that the product(s) complies with the FD&C Act and implementing regulations at the time of entry. (See § 1.83(a), where the term, ''owner or consignee'' is defined for the purposes of articles offered for import.) The importer of record may negotiate or contract with another party such that the other party agrees to engage the laboratory to test the product. Such arrangements are purely between the parties to the shipment; at the end of the day the importer of record remains the party ultimately responsible for the compliance of that entry and therefore is ultimately responsible for amassing any testimonial evidence (*e.g.,* test results and associated analytical documentation) in support of admission of the food.

D. Comments Regarding General Requirements

TABLE 4—REVISIONS TO GENERAL REQUIREMENTS

Final rule	Proposed rule	Notes
§ 1.1107 When must food testing be conducted under this subpart?	§ 1.1107 Under what circumstances must food testing be conducted under this subpart by an accredited laboratory?	Revised section title to simplify language and incorporate revised terminology.
§ 1.1108 When and how will FDA issue a directed food laboratory order?	§ 1.1108 When and how will FDA issue a food testing order?	Revised section title to reflect revised terminology.
§ 1.1109 How will FDA make information about recognized accreditation bodies and LAAF-accredited laboratories available to the public?	§ 1.1109 How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public?	Revised section title to reflect revised terminology.
§ 1.1110 What are the general requirements for submitting information to FDA under this subpart?	N/A	New section which consolidates requirements from throughout the proposed rule.

[2] There may not be an importer of record for some informal entries. (Informal entries, as defined by U.S. Customs and Border Protection regulations, are usually valued at less than $2,500 (value subject to change) (19 CFR 143.21), and usually do not require a bond. Some products are restricted from informal entry (for example, high risk products), regardless of value.) For such shipments that are not accompanied by an importer of record when making entry, the owner or consignee of the line(s) will serve as the responsible party when presenting evidence to FDA in support of admission of the food.

1. When must food testing be conducted under this subpart (§ 1.1107)?

Proposed § 1.1107(a) stated that food testing must be conducted under this subpart whenever food testing is conducted by or on behalf of an owner or consignee in any of the following five circumstances: (1) In response to explicit testing requirements that address an identified or suspected food safety problem in existing FDA regulations covering sprouts (21 CFR 112.146(a), (c) and (d)), shell eggs (§§ 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), 118.6(e)), and bottled drinking water (§ 129.35(a)(3)(i) (21 CFR 129.35(a)(3)(i))) (regarding the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli* (*E. coli*)); (2) as required by FDA in a directed food laboratory order (issued under § 1.1108 of this rule); (3) to address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the FD&C Act (21 U.S.C. 350*l*) prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the FD&C Act (21 U.S.C. 350d) submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the FD&C Act (21 U.S.C. 334(h)(4)(A)); (4) in support of admission of an article of food under section 801(a) of the FD&C Act; and (5) to support removal from an import alert through successful consecutive testing.

Section 1.1107(b) of the proposed rule stated that when food testing is conducted under paragraph (a), analysis of samples must be conducted by a laboratory that is LAAF-accredited for the appropriate method(s). Proposed paragraph (c) stated the requirement for food testing on articles of food offered for import into the United States to be conducted after the articles have arrived in the United States unless FDA has provided prior written authorization to the owner or consignee that a sample(s) of the article(s) taken prior to arrival in the United States is or would be representative of the article(s) offered for import.

We revised the proposed rule section title, ''Under what circumstances must food testing be conducted under this subpart by an accredited laboratory?'' to ''When must food testing be conducted under this subpart?'' in the final rule. We have made changes throughout this section to incorporate revised terminology. We also have made non-substantive revisions to paragraph (a)(2) (to add the word, ''issued''), to paragraph (a)(3) to add an inadvertently omitted word (''of''), and to paragraph (c) to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 27) We received several comments regarding the proposed policy to allow all testing under this subpart to be conducted ''by or on behalf of an owner or consignee.'' Some comments contend that laboratories operated by owners or consignees (''in-house'' laboratories) should be ineligible to conduct some or all tests described in § 1.1107. Other comments voice agreement with the proposal.

(Response 27) After considering the comments in light of the statute, we are retaining the proposed policy such that in-house laboratories may become LAAF-accredited to conduct any or all the testing described in § 1.1107 as long as those laboratories meet all the laboratory requirements of this subpart. Please see the discussion of this issue in Response 101 where we address the general eligibility of these laboratories, as well as the impartiality and conflict of interest requirements contained in § 1.1147.

(Comment 28) We received a few comments asking us to clarify the foods to which the testing requirements in the final rule will apply. Some of these comments ask whether any commodities would be exempt from the final rule and state that seafood, juice, and low-acid canned foods are exempt from certain requirements of the ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food'' (preventive controls for human food) regulation (part 117 (21 CFR part 117)). Other comments inquire whether the final rule would apply to any commodities other than sprouts, shell eggs, and bottled drinking water.

(Response 28) Proposed § 1.1107(a) described the specific circumstances under which food testing would need to be conducted under this subpart by a LAAF-accredited laboratory. Sprouts, shell eggs, and bottled drinking water are the only commodities for which specific testing requirements contained in existing regulations are currently covered by the final rule (see § 1.1107(a)(1)(i) through (iii)). The remaining circumstances in § 1.1107(a) could require food testing under this subpart for any food or environment within FDA's jurisdiction. We note that hazards addressed by hazard analysis and critical control point (HACCP) regulations for seafood (21 CFR part 123) and juice (21 CFR part 120), and those addressed by regulations for low-acid canned food (21 CFR part 113), are exempt from certain requirements of the preventive controls for human food regulation because those commodities and hazards are covered by commodity-specific HACCP or other regulations that predate the preventive controls for human food regulation. Seafood, juice, and low-acid canned foods are not exempt from this final rule. If seafood, juice, low-acid canned foods, or any article of food or environment within FDA's jurisdiction are covered by any of the circumstances described in § 1.1107(a)(2) through (5), then food testing must be conducted under this subpart by a LAAF-accredited laboratory. For a discussion of program implementation, see Response 14.

(Comment 29) Some comments agree with our proposal regarding the scope of testing that would be covered by the final rule. Some comments express alignment with the general notion of FDA requiring the use of LAAF-accredited laboratories in circumstances where heightened food safety concerns exist. Other comments support the proposed requirement that testing prescribed by certain explicit testing requirements in FDA regulations to address an identified or suspected food safety problem should be covered by this final rule. Specifically, some comments support the inclusion of the bottled drinking water testing required in § 129.35(a)(3)(i) and agree that other bottled drinking water testing required by FDA regulations does not constitute testing in connection with an ''identified or suspected food safety problem'' and therefore was properly excluded from coverage in the proposed rule.

(Response 29) Section 422 of the FD&C Act prescribes several circumstances in which testing must be conducted by a LAAF-accredited laboratory. First, section 422(b)(1)(A)(i) of the FD&C Act requires testing under this subpart to be conducted, ''in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem.'' As discussed in the proposed rule, we proposed to interpret section 422(b)(1)(A)(i) to apply to provisions of the FD&C Act or its implementing regulations that explicitly require food testing. 84 FR 59452 at 59462. We identified nine explicit testing requirements in our regulations that we tentatively concluded address an identified or suspected food safety problem because each of those testing requirements was a followup test after a

routine test indicated the presence of a pathogen or indicator organism (*i.e.,* an organism that indicates conditions in which an environmental pathogen may be present). For example, § 118.4(a)(2)(i) of our shell egg safety regulation requires an environmental test for *Salmonella* Enteritidis when the pullets are 14 to 16 weeks of age. If the environmental test is positive, § 118.4(a)(2)(iii) requires shell egg testing to commence within 2 weeks of the start of egg laying (unless the eggs are diverted to treatment, see § 118.6(a)(2)). We tentatively concluded that the followup shell egg testing would be covered by the rule, but the initial environmental testing would not. Section 422(b)(1)(A)(i) of the FD&C Act is implemented in § 1.1107(a)(1) of this final rule. For a discussion of FDA's interpretation of ''identified and suspected food safety problem,'' see Response 35.

Section 422(b)(1)(A)(ii) of the FD&C Act requires testing to be conducted under this subpart, ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' Section 422(b)(1)(A)(ii) of the FD&C Act is implemented in § 1.1108 of this final rule, which addresses the directed food laboratory order. (For discussion of the directed food laboratory order, see Comment 41 through Comment 56 and Responses, below.) Section 422(b)(1)(A)(ii) of the FD&C Act also authorizes § 1.1107(a)(3) of this final rule, which requires that food testing be conducted under this program when it is conducted to address an identified or suspected food safety problem and is presented to FDA in three administrative procedural settings: As part of evidence for a hearing under section 423(c) of the FD&C Act prior to the issuance of a mandatory recall order, as part of a corrective action plan under section 415(b)(3)(A) of the FD&C Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the FD&C Act.

Section 422(b)(1)(B)(i) of the FD&C Act requires testing to be conducted under this subpart, ''in support of admission of an article of food under section 801(a).'' Section 422(b)(1)(B)(i) of the FD&C Act is implemented in § 1.1107(a)(4) of this final rule. Section 422(b)(1)(B)(ii) of the FD&C Act requires testing to be conducted under this subpart when such testing is to support removal from an import alert through successful consecutive testing, and is implemented in § 1.1107(a)(5) of this final rule.

We appreciate those aspects of comments that express support for the proposed testing provisions.

(Comment 30) Some comments note that there have been foodborne illnesses associated with shell eggs produced at farms with less than 3,000 laying hens. These comments also note that food safety recalls associated with shell eggs, including from cage-free and free-range egg farms that have less than 3,000 laying hens, affect all egg farms. In the view of these comments, FDA's egg safety rule should therefore not exclude shell egg producers with less than 3,000 laying hens, and all egg farms regardless of size should be subject to this rule for the testing described in § 1.1107(a)(1)(ii).

(Response 30) This final rule requires use of a LAAF-accredited laboratory for certain followup tests that already are required by other food safety regulations (§ 1.1107(a)(1)). Because shell egg farms that have less than 3,000 laying hens are exempt from the egg safety rule, such farms are not subject to this final rule for the egg safety rule testing that falls within the scope of this subpart.

(Comment 31) Some comments opine that our use of the term, ''corrective action testing'' with respect to followup testing in response to an identified or suspected food safety problem appears to mean something different than it does in the world of conformity assessment. These comments assert that for conformity assessment purposes, ''corrective action'' means that a laboratory takes an ''action to eliminate the cause of a nonconformity and to prevent recurrence;'' these comments cite ISO/IEC 9001.

(Response 31) In the proposed rule, we used the term, ''corrective action'' to refer to actions taken by a conformity assessment entity in response to a deficiency (see, *e.g.,* 84 FR 59452 at 59491 (''the probation notice would either inform the laboratory that the laboratory has a specified time period to take corrective actions specified by FDA[,] or request that the laboratory submit a corrective action plan to FDA for FDA's approval that identifies the corrective actions it will take to address deficiencies identified''). In the proposed rule, we also used the term, ''corrective action'' to describe followup activities undertaken by a food manufacturer or processor after product or environmental testing indicates the presence of a pathogen or indicator organism (84 FR 59452 at 59455).

We understand why comments express the view that it may have been confusing for the term, ''corrective action'' to mean two different things in the proposed rule. In addition, in the proposed rule, we could have been more precise in our use of the term, ''explicit corrective action testing'' to describe testing covered by section 422(b)(1)(A)(i) of the FD&C Act. Section 422(b)(1)(A)(i) directs this program to cover testing ''in response to a specific testing requirement under [the FD&C Act] or implementing regulations, when applied to address an identified or suspected food safety problem.'' Not all the testing described by this statutory language may be properly categorized as corrective action testing, (*e.g.,* the sprouts environmental tests at 21 CFR 112.146(c) are considered verification tests within the sprouts regulatory framework; see § 1.1107(a)(1)(i)).[3] To improve clarity and precision, we use the phrase, ''explicit followup testing'' in the final rule to mean the testing that we have determined will be subject to this subpart under our section 422(b)(1)(A)(i) authority.

For the foregoing reasons, including to minimize risk of confusion and to improve the final rule, we generally reserve use of the term, ''corrective action,'' to the conformity-assessment context, in this document. Exceptions include discussion related to the preventive controls regulations; see Comment and Response 37. For clarity we have added the following definition of ''corrective action'' to § 1.1102: ''*Corrective action* means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.'' Relatedly, in §§ 1.1121, 1.1131, and 1.1161 of the final rule, we have added references to the specific sections of the relevant ISO/IEC standard to clarify the process a recognized accreditation body or LAAF-accredited laboratory must take to address deficiencies through corrective action.

(Comment 32) In the proposed rule, we described the circumstances under which testing of imported food would be subject to the requirements of this final rule. In brief, we proposed that an owner or consignee whose entry has been detained because the food is or appears to be adulterated or misbranded must use a LAAF-accredited laboratory to conduct the food testing used as testimonial evidence supporting admission to the United States. The

[3] For more information on sprouts environmental testing, see the ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations'' draft guidance, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-compliance-and-recommendations-implementation-standards-growing-harvesting.*

other import testing that we proposed to cover in this final rule is testing to support the removal of food from import alert through successful consecutive testing. Import alerts inform FDA's field staff and the public that the Agency has enough evidence to allow for DWPE of products that appear to be in violation of FDA's laws and regulations.

Some comments express appreciation that the proposed rule included information on when imported foods would need to be tested. Some comments support our proposal to require the use of a LAAF-accredited laboratory for testing conducted to support removal from import alert. These comments endorse the portion of the proposed rule preamble that discussed the importance of reliable testing of imports and indicate that in the past, food commodities subject to import alert have caused multiple foodborne illness outbreaks. These comments state that although it will take many tools and approaches to ensure the safety of imported foods, reliable testing is a critical component of a successful strategy.

(Response 32) With appreciation for these supportive comments, we confirm that the import-related circumstances under which food testing is required by this subpart in the proposed rule remain unchanged in the final rule: Testing in support of admission of an article of food under section 801(a) of the FD&C Act (§ 1.1107(a)(4)) and testing to support removal from an import alert through successful consecutive testing (§ 1.1107(a)(5)).

(Comment 33) Some comments express confusion about when this final rule would apply and asked when the requirements of the final rule would apply to regulatory feed testing laboratories.

(Response 33) A regulatory feed testing laboratory may choose to seek LAAF-accreditation to conduct testing under this subpart. If animal food were the subject of testing required to be conducted under this program (*i.e.,* the subject of food testing under § 1.1107(a)(2) through (5)), then an owner or consignee would need to use a LAAF-accredited laboratory to conduct the test. For a discussion of program implementation, see Response 14.

(Comment 34) Some comments express the erroneous understanding that the laboratory accreditation final rule would apply only when food testing is conducted in a food manufacturing or processing facility. These comments express the concern that adulteration may occur after the food leaves the production facility, in which case testing conducted during production is outdated and inaccurate, and potentially masks a food safety problem.

(Response 34) We first clarify that the testing covered by this rule is not limited to testing in a food manufacturing or processing facility. Certain testing at farms is also covered; for example, § 1.1107(a)(1)(ii) describes shell egg testing, and those eggs originate on a poultry farm. In addition, this rule covers a significant number of tests of imported food (§ 1.1107(a)(4) and (5)). Because FDA agrees that adulteration may occur while food is in transit, the final rule generally requires imported food products subject to this final rule to be sampled and tested after the food has arrived in the United States. (See § 1.1107(c) and Response 40 for more on this topic.) Thus, testing of imported food subject to this final rule generally will occur at or near the U.S. border.

FDA also has other tools to address adulteration that occurs outside of production establishments, including another FSMA regulation, the ''Sanitary Transportation of Human and Animal Food'' regulation (part 1, subpart O), which requires shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food, to use sanitary transportation practices to ensure that the food is not transported under conditions that may render the food adulterated.

(Comment 35) In the preamble to the proposed rule, we discussed considerations in our interpretation of the phrase, ''identified or suspected food safety problem,'' which appears in section 422(b)(1)(A)(i) and (ii) of the FD&C Act and is therefore important in determining which testing will be covered by this subpart. Among other things, we explored other uses of similar phrases elsewhere in FSMA. We tentatively concluded that an ''identified food safety problem'' could be present when a specific article of food violates a provision of the FD&C Act that relates to food safety. We tentatively concluded that a ''suspected food safety problem'' typically would have a basis in fact about a particular article of food (*e.g.,* a lot or batch) or food production environment (*e.g.,* a specific facility). We reasoned that the requisite suspicion would not be satisfied by the common or usual characteristics of food (*e.g.,* whether a food is considered ''high risk'') or the manner in which the food is typically produced. We tentatively concluded that the routine product testing and environmental monitoring requirements required by the preventive controls for human food regulation (see § 117.165(a)(2) and (3), respectively), are not conducted to address a suspected (or identified) food safety problem, because this testing is conducted to verify the implementation and effectiveness of preventive controls (''verification testing'') and not because a food safety problem is suspected or identified. 84 FR 59452 at 59462. This same tentative conclusion would apply to the routine product testing and environmental monitoring requirements required by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals (preventive controls for animal food) regulation (§ 507.49(a)(2) and (3) (21 CFR 507.49(a)(2)) and (3), respectively).

In the proposed rule we explained that, in the preventive controls for human food regulation, FDA indicated that an ''unanticipated food safety problem'' could occur where a preventive control is not properly implemented, including where a pathogen or indicator organism is detected during routine product or environmental testing (verification testing). In the proposed rule we tentatively concluded that, depending on the circumstances, a routine test that indicated the presence of an indicator organism would not necessarily constitute a suspected food safety problem. 84 FR 59452 at 59462.

Some comments dispute our interpretation of ''identified or suspected food safety problem.'' From their perspective, there is no need for the problem to be particularized to an article of food or a facility. These comments state that the statute does not direct that ''an identified or suspected food safety problem,'' could only be present in relation to a specific article of food or facility. The comments argue that the appearance of the phrase, ''food safety problems'' in two FSMA titles that cover multifaceted approaches to food safety (Title I: ''Improving Capacity to Prevent Food Safety Problems'' and Title II: ''Improving Capacity to Detect and Respond to Food Safety Problems'') supports the position that Congress did not intend for the same terms to be read narrowly in the context of section 422 of the FD&C Act. These comments indicate that the economic analysis accompanying the proposed rule estimated that far fewer tests would be subject to the LAAF program under section 422(b)(1)(A) than under section 422(b)(1)(B) of the FD&C Act.

(Response 35) The phrase, ''identified or suspected food safety problem,'' appears twice in section 422(b)(1)(A) of

the FD&C Act and therefore helps demarcate which testing will be covered by this subpart. The statute does not define either ''identified or suspected food safety problem,'' or ''food safety problem,'' nor do those phrases appear elsewhere in the body of FSMA. As referenced above, the phrase, ''food safety problem'' appears in the FSMA titles: Title I, ''Improving Capacity to Prevent Food Safety Problems,'' and Title II, ''Improving Capacity to Detect and Respond to Food Safety Problems.'' Comments urge us to infer from the breadth of the various provisions within each of those two titles, that when Congress used the same phrase in section 422(b)(1)(A) of the FD&C Act, it intended the phrase to be broadly interpreted. However, we cannot impute such an intention to Congress without some indication of that intent in section 422 of the FD&C Act or the legislative history. Indeed, one could reasonably infer the opposite—that from the breadth of the provisions within FSMA Titles I and II, Congress must have intended for the phrase, ''food safety problems'' to have different meanings in different contexts. In sum, ''food safety problem'' is not defined in the statute, and thus it falls to FDA to elaborate on its meaning.

In the proposed rule, we looked at other FSMA standards and other FSMA regulations, before making the tentative conclusions described above in Comment 35. We finalize those conclusions without change.

In this vein, we observe that the purpose of routine product and environmental testing under the preventive controls regulations is to verify that preventive controls are consistently implemented and are effective (§§ 117.165(a) and 507.49(a)). Accordingly, such testing does not address an identified or suspected food safety problem, and is not covered by this subpart.

(Comment 36) In the proposed rule, we tentatively concluded that although section 422(b)(1)(B)(i) of the FD&C Act requires testing, ''in support of admission of an article of food under section 801(a)'' to be conducted under this subpart, it was reasonable not to apply section 422(b)(1)(B)(i) to food testing related to FSVP. We explained that under section 801(a)(3) of the FD&C Act, FDA may refuse admission of an article of food if the food is, or appears to be, adulterated or misbranded. When FDA determines that an article of food is, or appears to be, adulterated or misbranded, we must notify the owner or consignee of our determination, and state the reason(s) for such determination (§ 1.94(a)). FDA must also specify a period of time during which the owner or consignee may introduce testimony relevant to the admissibility of the article of food. Id. Owners or consignees often engage laboratories to test the food and then introduce the test results (along with associated data and analysis) as evidence that the food is admissible. If FDA determines that the sampling methods and testing results are valid and indicate that the article of food does not appear to violate the FD&C Act, FDA will determine that the article of food is admissible, release it from detention, and permit its entrance into the United States. Thus, the focus of section 422(b)(1)(B)(i) of the FD&C Act is the characteristics of an article of food that is pending at the border. Under § 1.1107(a)(4) of this final rule, the testing obtained by the owner or consignee and submitted as testimony to support release of the article of food from detention, must be conducted under this subpart.

FSMA amended the FD&C Act to add section 805, ''Foreign Supplier Verification Program,'' to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying that imported food meets applicable U.S. safety requirements. The FSVP regulation, codified in §§ 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes requirements related to supplier verification. Depending on the circumstances, sampling and testing of a food may be an appropriate supplier verification activity. See § 1.506(d)(1)(ii)(B). If an FSVP importer fails to comply with the FSVP regulations for a particular food, that food may be refused admission under section 801(a)(3) of the FD&C Act.[4] However, such refusal is not because the article of food pending at the border is, or appears to be, adulterated or misbranded. Instead, the refusal is a consequence of the importer's failure to comply with its FSVP obligations. Testing the article of food detained at the border in this instance would have no impact on its admissibility under section 801(a)(3) of the FD&C Act, because the detention is due to the characteristics of the importer. In the proposed rule we tentatively concluded that, because the focus of the FSVP provision in section 801(a)(3) of the FD&C Act is entirely different than the focus of the circumstances addressed by section 422(b)(1)(B)(i) of the FD&C Act, it is reasonable not to apply the latter subpart to the testing of food conducted under FSVP.

Several comments agree with our reasoning regarding testing under FSVP and our proposal that such testing not require use of a LAAF-accredited laboratory. However, other comments disagree, expressing the perspective that as the proposed rule would cover testing to support removal from import alert, it seems more consistent with the FSMA framework to also require testing related to FSVP to be conducted under this subpart. We understand these comments to mean that, because FSVP addresses the safety of food imports, and testing related to import alerts also addresses the safety of food imports, FDA is being inconsistent in covering import alert testing under this subpart, but not testing related to FSVP. These comments further suggest that we not require test results related to FSVP to be sent directly to FDA. The comments do not explain why FSVP tests, which they argue should be subject to this subpart, should nevertheless be excepted from the requirement that all test results under this subpart be submitted directly to FDA.

(Response 36) We disagree that our determinations regarding testing related to FSVP are inconsistent with covering testing to support removal from import alert under this subpart. As an initial matter, the section of the statute authorizing the LAAF program explicitly directs that testing to support removal from import alert be subject to this program, and does not mention FSVP. Further, for the reasons discussed in the proposed rule and briefly described in the comment summary above, we conclude that it is reasonable not to apply section 422(b)(1)(B)(i) of the FD&C Act to food testing related to FSVP. These comments do not explain why FSVP test results would warrant an exception from the § 1.1152(b) requirement to submit all tests results under this program directly to FDA, and as the final rule will not cover testing related to FSVP, the suggestion is inapplicable.

(Comment 37) Some comments agree with our tentative conclusion in the proposed rule that the routine product and environmental testing that occurs pursuant to a preventive controls food safety plan should not require the use of a LAAF-accredited laboratory. Some of these comments encourage FDA to make explicit in the final rule that routine product testing under the preventive control regulations is performed to verify that applied controls have been

[4] For more information on FSVP, see *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.*

effective, and not to address an identified or suspected food safety problem, and therefore is not covered by the laboratory accreditation final rule. Some comments also request that FDA clarify that environmental testing conducted in response to routine environmental monitoring results indicating the presence of a pathogen or indicator organism would not typically be considered testing conducted to address an identified or suspected food safety problem, and would therefore typically fall outside the scope of the laboratory accreditation final rule. According to these comments, facilities should have an opportunity to perform an analysis of the root cause for the environmental positive, take corrective actions and conduct additional testing as needed, before FDA determines that an identified or suspected food safety problem exists and possibly warrants testing by a LAAF-accredited laboratory.

On the other hand, some comments urge FDA to include within the purview of this final rule all food testing required by our regulations, and at a minimum the verification testing and followup testing conducted under the preventive controls and FSVP regulations.[5] Some of these comments contend that FDA has misinterpreted the statute, and claim that section 422(b)(1)(A) of the FD&C Act grants broad discretion to FDA to require use of a participating laboratory in such circumstances.[6] Some comments highlight the language in section 422(b)(1)(A)(ii) of the FD&C Act, which states in relevant part, ''as the Secretary deems appropriate, to address an identified or suspected food safety problem,'' and argue that such language grants FDA ''expansive'' authority for the final rule to cover circumstances where either FDA or facilities themselves have identified a food safety hazard and are using testing as part of the approach to address the hazard. Such comments express the view that if FDA does not require more domestic food testing to be conducted under this program, FDA is failing to address food safety problems as Congress intended. Comments encourage the Agency to adopt a broader statutory interpretation of section 422(b)(1)(A) of the FD&C Act even if we do not expand the testing subject to the final rule, so that we may preserve the authority to add more testing to § 1.1107 in the future.

In support of their contentions, some comments offer an example of a Georgia food processing facility that was conducting environmental testing as required by the preventive controls for human food regulation but whose products (boiled eggs) nevertheless caused an outbreak, which, according to the comments, calls into question the accuracy of the test results and the quality of the facility's testing program.

These comments posit that perhaps FDA did not propose to include testing related to the preventive controls or FSVP regulations within the scope of this subpart because testing under those regulations is not always required; depending on the circumstances the facility or importer may find other actions sufficient. These comments find such reasoning unpersuasive because in their view, whenever testing is required as a verification or followup activity under the preventive controls or FSVP regulations, the testing is being conducted ''in response'' to a regulatory requirement and so is covered by section 422(b)(1)(A) of the FD&C Act.

These comments alternatively posit that perhaps FDA did not propose to cover preventive controls and FSVP testing because this approach might be burdensome for industry. According to these comments, if that is the case, then such concerns could be addressed by providing additional time for implementation; further, any such concerns would be offset by the positive health and economic benefits that they suggest testing would create by preventing outbreaks.

(Response 37) Some comments contend that section 422(b)(1)(A) of the FD&C Act grants FDA broad discretion to require testing to be conducted under this subpart. We address the two subparagraphs of section 422(b)(1)(A) in turn.

Section 422(b)(1)(A)(i) of the FD&C Act

Section 422(b)(1)(A)(i) of the FD&C Act provides that testing must be covered by this program when the testing is conducted, ''in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem.'' We discussed our interpretation of ''identified and suspected food safety problem'' in Response 35, above, and concluded that routine product and environmental testing that occurs pursuant to a preventive controls food safety plan (§§ 117.165(a) and 507.49(a)) is not covered by this subpart. We turn now to our interpretation of the phrase, ''in response to a specific testing requirement under this Act or implementing regulations.''

In the proposed rule, we tentatively interpreted, ''specific testing requirement under this Act or implementing regulations'' to mean that this subpart would cover food testing explicitly required by a statutory or regulatory provision. 84 FR 59452 at 59462. We identified nine testing requirements in FDA regulations that were both explicit and address an identified or suspected food safety problem: Five testing requirements in the egg safety rule (§§ 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), and 118.6(e)), three in the standards for the growing, harvesting, packing, and holding of sprouts (§ 112.146(a), (c), and (d)), and one in our regulations on the processing and bottling of bottled drinking water (§ 129.35(a)(3)(i)).

Comments do not directly dispute our proposed interpretation of the term, ''specific,'' but some contend that all food testing requirements in our regulations should be covered by this subpart. However, the statute only authorizes testing to be covered by this subpart if it is both an explicit testing requirement and a testing requirement that addresses an identified or suspected food safety problem. Not all food testing requirements in FDA regulations satisfy those two prongs of section 422(b)(1)(A)(i) of the FD&C Act. Indeed, if Congress had intended for all food testing required by FDA regulations to be covered by this program, they could have said so.

Some comments argue that testing under the preventive controls and FSVP regulations falls within the purview of section 422(b)(1)(A)(i) of the FD&C Act. More specifically, these comments identify the testing done to verify the effectiveness of controls, or as part of corrective actions taken when issues are identified, as testing that should be covered by this subpart.

First, these comments discuss testing in relation to FSVP jointly with testing under the preventive controls regulations. However, we have already concluded that testing related to FSVP is not covered by this subpart (see Response 36); for the remainder of this response we consider comments just in relation to the preventive controls regulations.

Some comments acknowledge that the preventive controls regulations do not always require testing. Briefly, the preventive controls regulations apply to most registered food facilities. A wide variety of registered food facilities process, manufacture, pack, or hold all

[5] Some comments refer to ''corrective action testing;'' we have changed the phrase to ''explicit followup testing.'' See Response 31.

[6] Some comments imply that the testing required under section 422(b)(1)(A) of the FD&C Act is limited to domestic food production circumstances. However there is nothing in the statute that limits section 422(b)(1)(A) to testing of food produced domestically, and accordingly § 1.1107(a)(1)–(3) of this final rule also refrains from imposing that limitation.

kinds of foods, so these regulations are structured to address a plethora of circumstances. Under the preventive controls regulations, facilities are responsible for analyzing food safety hazards to determine if there are hazards requiring a control and then developing and implementing a plan for the control of those hazards. The regulations are written to provide significant flexibility to facilities, and that flexibility is reflected in the provisions that address testing.

For example, facilities must verify that their controls are being consistently implemented and are effective at minimizing or preventing the identified hazards. The regulations identify testing as one verification activity, but the facility is responsible for determining which verification activities are appropriate in their particular circumstances. By way of another example, facilities must establish and implement corrective action procedures that must be taken if a preventive control was not properly implemented. See §§ 117.150(a) and 507.42(a). A routine verification test indicating the presence of a pathogen or indicator organism in a ready-to-eat product would signal that a preventive control was not properly implemented. See § 117.150(a)(1). In certain circumstances, followup testing would be one appropriate corrective action a facility could take in response to such a signal. However, the regulations do not prescribe exactly when followup testing is required, instead placing the responsibility for making that determination on the facility.

Comments argue that because any verification or followup testing that occurs under the preventive controls regulations is ''in response'' to the regulations, such tests fall within the purview of section 422(b)(1)(A)(i) of the FD&C Act. These comments may prefer that the word, ''specific'' not appear in section 422(b)(1)(A)(i) of the FD&C Act, but it does, and it must be given meaning. Regulatory provisions that confer significant discretion on regulated entities for determining when food testing is necessary, are not explicit testing requirements and therefore are not covered by this subpart. We finalize our proposed interpretation of ''specific'' testing requirements without change and conclude that neither routine verification testing nor followup testing under the preventive controls regulations is covered by this subpart using our section 422(b)(1)(A)(i) authority.

Some comments opposing our interpretation of section 422(b)(1)(A)(i) of the FD&C Act discuss whether we chose not to include verification and followup testing under the preventive controls regulations because it would place a greater burden on those facilities. Comments state that if that is the case, our concerns could be addressed by providing more time for such entities to comply with this final rule. Comments also state that there would be public health benefits from requiring the use of a LAAF-accredited laboratory for such testing. However, as discussed above, we have determined that the regulatory provisions describing verification and followup testing in the preventive controls regulations are not explicit testing requirements, and therefore we do not interpret them to satisfy the statutory requirements of section 422(b)(1)(A)(i).

For the foregoing reasons, we conclude that we have properly identified the nine FD&C Act testing requirements that are currently covered by this subpart under our section 422(b)(1)(A)(i) authority. It is possible that in the future, FDA may require additional specific followup testing in FD&C Act regulations, and that testing would be covered by this subpart. However for now, we finalize § 1.1107(a)(1) without change.

Section 422(b)(1)(A)(ii) of the FD&C Act

Section 422(b)(1)(A)(ii) authorizes FDA to require testing to be conducted under this subpart, ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' In the final rule we rely on this statutory provision to require that testing conducted pursuant to a directed food laboratory order be conducted under this subpart; see § 1.1108. Very briefly, as we interpret this statutory provision, directed food laboratory orders will generally be limited to the rare situations when we have reason to question the accuracy or reliability of past or present test results, and an identified or suspected food safety problem exists. (The directed food laboratory order is discussed in Comment 41 through Comment 56 and Responses, below.) We also rely on our section 422(b)(1)(A)(ii) authority to require in the final rule that testing related to certain administrative proceedings be conducted under this subpart; see § 1.1107(a)(3). (For discussion of the use of section 422(b)(1)(A)(ii) authority to cover certain administrative proceedings testing under this subpart, see the proposed rule (84 FR 59452 at 59463–64)). We agree with those aspects of comments noting that the language of section 422(b)(1)(A) of the FD&C Act is broad enough that, in the future, we could cover additional testing under this subpart by relying on that authority. This could occur if we deem it appropriate to expand this program to cover additional testing, and the additional testing addresses an identified or suspected food safety problem. Further, we intend to make such a change only through notice-and-comment rulemaking.

Some comments request that FDA clarify that environmental testing conducted in response to routine environmental monitoring results indicating the presence of a pathogen or indicator organism would not typically be considered testing conducted to address an identified or suspected food safety problem, and would therefore typically fall outside the scope of the laboratory accreditation final rule. We have determined that the routine verification and followup testing provisions in the preventive controls regulations do not state explicit testing requirements and are therefore not appropriate to include in § 1.1107(a)(1); therefore, they will typically fall outside the scope of this final rule. We have also determined that routine verification testing that occurs pursuant to a preventive controls food safety plan (§§ 117.165(a) and 507.49(a)) does not address an identified or suspected food safety problem (Response 35). However, followup testing in response to routine verification test results indicating the presence of a pathogen or indicator organism in either a food product or the food production environment may qualify as testing that addresses an identified or suspected food safety problem, depending on the circumstances. We affirm the statement we made in the proposed rule that, depending on the circumstances, a positive indicator organism test would not necessarily constitute a suspected food safety problem; for example, a single positive *Listeria* spp. on a food contact surface in a facility would not necessarily constitute a suspected food safety problem. However, when a routine verification test of a food product indicates the presence of a pathogen, in many circumstances we would conclude that there is at least a suspicion of a food safety problem. For example, the presence of *Salmonella* in nuts indicates a suspicion of a food safety problem, but the presence of *Bacillus cereus* in tree nuts is not likely to indicate a food safety problem, since the organism cannot grow to the high numbers needed to cause illness due to the low water activity of tree nuts. Additionally, in many circumstances a

routine environmental monitoring test result indicating the presence of a pathogen in a facility producing a ready-to-eat product could be classified at least as a suspected food safety problem.

Followup testing that addresses an identified or suspected food safety problem under the preventive controls regulations—or in the context of the FD&C Act, or any FDA food safety regulation—may fall within the purview of section 422(b)(1)(A)(ii) of the FD&C Act. Under this final rule, this means that such testing may be the subject of a directed food laboratory order under § 1.1107(a)(2), and may be the subject of the testing in certain administrative proceedings described in § 1.1107(a)(3). We do not anticipate frequent testing under § 1.1107(a)(2) or (3); as a result, under this final rule, followup testing that addresses an identified or suspected food safety problem, but that is not expressed in an explicit testing requirement, will typically fall outside the scope of this subpart. Again, were we to seek to expand the testing subject to this final rule, we would go through the rulemaking process. (For discussion of the circumstances in which we anticipate issuing a directed food laboratory order, see Response 47.)

We do not agree that the 2019 foodborne illness outbreak linked to hard-boiled eggs and cited in comments is evidence that this final rule should generally cover routine verification and followup testing under the preventive controls regulations. In the above-referenced situation, the facility was processing shell eggs into hard-boiled egg products; the hard-boiled eggs were linked to an outbreak of *Listeria monocytogenes* infections. The facility was processing a ready-to-eat product that was exposed to the facility environment prior to packaging; in those circumstances, the preventive controls for human food regulation generally requires that the facility establish sanitation controls verified in part by an environmental monitoring program that involves regularly testing the facility environment. See § 117.165(a)(3). We thus maintain the view that the existing preventive controls for human food regulation adequately covers this situation. When FDA collected environmental samples as part of its investigation, the facility did as well. There would be no point in requiring tests such as those taken by the facility to be subject to this subpart when FDA was onsite to conduct its own investigational tests. Indeed, the tests of environmental samples the facility collected alongside FDA inspectors would not be categorized as verification or followup tests, and thus would not fall within the purview of this final rule, even if the rule did cover these test categories.[7]

As support for their argument that FDA is applying section 422(b)(1)(A) of the FD&C Act too narrowly, some comments state that the economic analysis accompanying the proposed rule indicated that many more tests would be conducted under this subpart stemming from section 422(b)(1)(B) than section 422(b)(1)(A). The economic analysis accompanying a rule simply reflects the rule it analyzes; this point appears to be another facet of the argument that we have misinterpreted the statute. We disagree for the reasons already stated.

We also disagree that in issuing this final rule FDA is falling short of addressing important food safety problems. For the reasons discussed throughout this response, we believe we have interpreted the statute appropriately, and we look forward to achieving significant public health benefits as a result of this rule (Ref. 4).

(Comment 38) Some comments generally urge a broader scope for the laboratory accreditation final rule. Some of these comments discuss the critical role food laboratories play in helping to keep the food supply safe, including the corresponding need for accurate and reliable results, and therefore seek Federal oversight of all food testing laboratories. Some of these comments advocate for a requirement that all food testing laboratories be accredited, which we understand to mean either that these comments express the belief that all food testing laboratories should be required to be accredited to ISO/IEC 17025:2017, or should be subject to LAAF-accreditation under this subpart. Other comments suggest that all laboratories that test food for human consumption should be required to satisfy the baseline requirement of this final rule and be accredited to ISO/IEC 17025:2017. These latter comments suggest that the additional requirements of this final rule could then be reserved just for the testing identified in § 1.1107(a).

(Response 38) We appreciate the critical role that all food testing laboratories play in helping to keep the food supply safe, and we acknowledge the importance of accurate and reliable test results. However, section 422 of the FD&C Act does not contemplate FDA regulation of all food testing laboratories, or of all laboratories that test food for human consumption. We therefore do not require that all food testing, or human food testing, laboratories be accredited to ISO/IEC 17025:2017 or comply with the laboratory requirements in this subpart.

(Comment 39) Some comments request additional information about the role the LAAF-accredited laboratories will play in relation to food manufacturing facilities that are subject to required product or environmental testing under the final rule. These comments assert that the proposed rule was ''not clear regarding the level of authority an accredited lab has in order to perform on-site collection activities at food manufacturing facilities.'' These comments recommend that FDA clarify in the final rule the roles and responsibilities of the participating laboratory and facility, such as which information and records the facility would be required to make available to the laboratory.

(Response 39) We believe these comments misunderstood the proposed rule. When food testing is required to be conducted under this subpart, an owner or consignee must use a LAAF-accredited laboratory. However, the owner or consignee will select a LAAF-accredited laboratory from the online registry (see § 1.1109), and engage the laboratory, and that laboratory will have no more authority over the owner or consignee than specified in the business arrangement between the parties. The final rule requires that the sample be collected by a person qualified by training or experience to do so, and requires certain sampling documents (§ 1.1149), but the owner or consignee may select any sampler or sampling firm it likes, as long as the entity or person is qualified and will provide the documentation required under the final rule. Sometimes owners or consignees collect their own samples, sometimes they engage third-party sampling firms, and sometimes they pay the laboratory that will analyze the sample to collect the sample. Under this subpart, that choice remains with the owner or consignee. Therefore, FDA declines to further articulate any roles or responsibilities of these parties beyond the requirements of the final rule.

(Comment 40) In the proposed rule, for imported food, we provided that testing under this rule generally could only be conducted on samples taken after the articles of food have arrived in the United States. We proposed one exception to that policy, where FDA determines that a sample taken prior to arrival is representative of the article of food offered for import. We said that we would make such a determination on a

[7] Comments also state that the facility in question engaged a laboratory to validate a process control, but comments do not suggest that this final rule should cover such testing.

case-by-case basis. We received several comments on this aspect of our proposal.

First, some comments appear to understand that we proposed that *sampling* prior to arrival may be allowed in certain circumstances, but they seem unsure whether *testing* prior to arrival may also be allowed. These comments ask whether foreign laboratories could participate in this program and encourage FDA to clarify the extent to which the requirements of this final rule would apply to such foreign laboratories.

Some comments support allowing sampling and testing prior to arrival in certain circumstances, such as sampling for removal from import alert. Other comments maintain that we should allow no exceptions to the policy that sampling of imports occur after arrival in the United States. These comments opine that allowing sampling prior to entry would amount to ''self-policing'' by the owner or consignee. They also argue that allowing sampling prior to entry would ignore the risk that changes may occur during transit that would impact the test results. They view the proposed exception as creating a public health concern.

Additionally, some comments in favor of the proposed policy suggest that when FDA determines that a sample taken prior to entry is or would be representative of the article of food offered for import, FDA should make its determination publicly and widely available (*i.e.,* ''publish'' it).

(Response 40) To clarify, foreign laboratories may seek LAAF-accreditation to conduct food testing under this subpart. All laboratories that choose to participate, whether foreign or domestic, must meet the same accreditation standards and comply with all provisions of the final rule (see section 422(a)(5) of the FD&C Act). There is no requirement that testing of imports subject to this rule must be conducted by a laboratory in the United States; testing may be conducted by any LAAF-accredited laboratory, regardless of location. However, we are finalizing the proposed policy that under this subpart, sampling generally must occur after arrival in the United States, unless FDA has granted an exception. This requirement protects public health by helping to ensure that the test results we are relying on to make admissibility decisions accurately reflect the conditions of the article of food when offered for import into the United States.

At the same time, we disagree with the comments contending that all import sampling should occur after arrival without exception. We are finalizing the proposed exception for those situations in which we determine that food sampled prior to export is representative of the article offered for import (§ 1.1107(c)). The FDA determination to grant the exception must be received by the owner or consignee, in writing, prior to testing of samples taken prior to arrival in the United States (id.). We generally would base such a determination on specific circumstances of each shipment (*e.g.,* characteristics of the product and analyte, specifics of packaging and transportation) and grant any exceptions on a case-by-case basis. We decline the suggestion to publish our determinations of scenarios where a sample taken prior to arrival is or would be representative of the article of food offered for import because we expect our determinations to be situation-specific. We may consider issuing guidance in the future on the factors we evaluate in making such determinations, which we believe would be more useful to our constituents than case-by-case publication.

It is possible that we could make such a determination for an article of food subject to DWPE (on an import alert). Again, any such determination generally would be made on a case-by-case basis, based on clear evidence that the product sampled is representative of the product offered for import (see § 1.1107(c); 84 FR 59452 at 59465). In the proposed rule, we solicited feedback on whether circumstances warrant application of the exception broadly, for instance, to a particular commodity or analyte generally. We received no comments with suggestions for broader applications of the exception.

As discussed in Response 101, the rule does not prohibit owners or consignees from collecting a sample or conducting their own test, as long as all the requirements of the rule are satisfied.

2. When and how will FDA issue a directed food laboratory order (§ 1.1108)?

Proposed § 1.1108 described the circumstances under which we would issue a food testing order. Paragraph (a) described when we would require an owner or consignee to have food testing conducted under this subpart (''. . . to address an identified or suspected food safety problem related to the article of food.'') Proposed § 1.1108(b) and (c) also specified what we would include in the order (*e.g.,* the food product or environment to be tested, any particular methods, and other elements required by part 16 (21 CFR part 16) related to a regulatory hearing). As previously discussed, we have changed the terminology in this section from ''food testing order'' to ''directed food laboratory order,'' and to avoid confusion we use the new term throughout this document, even when referring to discussions in the proposed rule.

On our own initiative, we made a few revisions to this section. We revised the proposed rule section title, ''When and how will FDA issue a food testing order?'' to ''When and how will FDA issue a directed food laboratory order?'' in the final rule and made changes in the section to incorporate revised terminology. We removed the unnecessary phrase, ''related to the article of food'' in § 1.1108(a). We also removed the phrase, ''of an article of food'' from § 1.1108(a) since the definition of owner or consignee in § 1.1102 specifies interest related to the food product or environment subject to food testing. We also made minor editorial changes to this section.

Many comments support the rulemaking and the Agency's efforts to implement section 422 of the FD&C Act; however, they do not support the directed food laboratory order provision. Some comments raise ''substantial'' concerns with the Agency's proposal, specifically legal, policy, and practical aspects of the proposed rule with respect to directed food laboratory orders. We address these comments below.

(Comment 41) A number of comments argue that the Agency lacks explicit and implied statutory authority in FSMA and the FD&C Act to issue directed food laboratory orders. The comments conclude that the Agency is limited by the authority delegated by Congress in FSMA and under the FD&C Act, and that because neither the plain terms nor the core purpose of the relevant sections of the statute contemplate directed food laboratory orders, there is no explicit authority to issue a directed food laboratory order.

The comments further argue that the Agency has misinterpreted section 422(b)(1)(A)(ii) of the FD&C Act as providing implied authority to issue directed food laboratory orders. Comments explain that section 422(b)(1)(A)(ii) is limited by section 422(b)(1)(A)(i) because the clauses are linked by the word, ''and'' and therefore must be read conjunctively. To support this interpretation, several comments cite the plain language of the statute and case law in support of the associated canon of statutory interpretation. Comments assert a presumption that Congress intended ''and'' to be read

conjunctively. Some comments indicate that even though sections 422(b)(1)(A)(i) and 422(b)(1)(A)(ii) of the FD&C Act repeat the phrase, ''to address an identified or suspected food safety problem,'' this repetition does not support reading the ''and'' disjunctively to signify ''or.'' To support this position, the comments cite the case of *Loving* v. *IRS* (917 F. Supp.2d 67), in which the D.C. Circuit Court rejected the IRS argument that existence of overlapping or redundant statutory language should override the plain meaning of ''and.'' The comments thus conclude that the statute may only be read to require food testing under this subpart in two circumstances, as opposed to the five circumstances specified in § 1.1107 of the proposed rule.

Interpreting the statute in this way to require food testing in only two circumstances, some comments claim that the two circumstances when LAAF-accredited laboratories must be used are when food testing is conducted: (1) In response to a specific testing requirement under the FD&C Act or implementing regulations, when applied to address an identified or suspected food safety problem and as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem or (2) in support of admission of an article of food under section 801(a) of the FD&C Act and under an import alert that requires successful consecutive tests. Comments add that even if the plain meaning is proven otherwise to read the ''and'' disjunctively, it still does not provide the Agency with discretionary authority to issue directed food laboratory orders. Comments urge that this authority cannot be expanded even if the intent is to further the goals of Congress.

Comments explain that the plain language of the statute requires that section 422(b)(1)(A) of the FD&C Act apply only ''in response to'' and ''to address'' a food safety problem, not to seek one out. Were directed food laboratory orders implemented as proposed, comments argue that this approach would create an additional investigative tool not contemplated by the statute. Comments express that FDA already has the authority to conduct food testing and to choose a laboratory. Comments state further that there is no evidence that Congress intended to shift the Agency's responsibilities to owners and consignees.

Some comments state that any authority provided under section 422 of the FD&C Act to require food testing under this subpart, absent an explicit requirement in statute or regulation to conduct testing, must only apply in narrow circumstances where the basis for the food safety problem has been established. These comments state they would support testing by accredited laboratories as part of evidence for a hearing prior to the issuance of a mandatory recall order, an order suspending a food facility's registration, or an administrative detention order. Likewise, other comments add support for the Agency to issue a directed food laboratory order as part of the corrective action plan after a facility's registration has been suspended.

Some comments echo the call for FDA to keep the scope of the rule narrow and support applying the rule to specific testing requirements in FDA's regulations, *e.g.,* certain post-remediation testing after *E. coli* has been identified in the source water for bottled drinking water.

A few comments characterize Congress's grant of authority to the FDA to address an ''identified or suspected food safety problem'' in FSMA as broad and state that these terms were not defined; however, the comments do not support the use of the statute to add what they view as a new enforcement tool, namely, the directed food laboratory order. These comments seek additional background regarding how this tool fits with other FDA authorities as they did not anticipate the Agency implementing the statute through the use of directed food laboratory orders as set forth in the proposed rule.

(Response 41) We disagree with the assertions in the comments that the Agency lacks the statutory authority to issue directed food laboratory orders. Section 422(b)(1)(A)(ii) provides authority for testing under this subpart ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' The ''and'' joining the two clauses in sections 422(b)(1)(A) and (B) is appropriately read as joining lists containing two separate and distinct circumstances. Reading the ''and'' conjunctively as some comments urge would create an absurd result since both clauses of 422(b)(1)(A) repeat the phrase, ''to address an identified or suspected food safety problem.''

We also disagree with the notion that directed food laboratory orders would inappropriately shift the burden of testing to owners or consignees. The responsibility to produce safe food rests with the food producers. Food testing by LAAF-accredited laboratories under this subpart will provide assurance of the accuracy of the results conducted in response to identified or suspected food safety problems of significance to public health and will better enable both the Agency and the owner or consignee to act in the best interest of public health.

As we discuss below in Response 47, we believe the circumstances in which we anticipate using a directed food laboratory order and the examples provided demonstrate that a directed food laboratory order will be used ''to address'' an identified or suspected food safety problem.

We also disagree with aspects of comments asserting that the basis for the food safety problem must be ''established'' in order for food testing to be subject to this subpart. The statutory standard for when the Agency may issue a directed food laboratory order is explicitly set forth in section 422(b)(1)(A)(ii) of the FD&C Act: Such an order may be issued ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.''

As proposed, we agree that this subpart will apply to testing in relation to certain administrative proceedings. Under § 1.1107(a)(3), certain testing as part of evidence for a hearing prior to the issuance of a mandatory recall order, as part of the corrective action plan after a food facility's registration has been suspended, as well as an appeal of an administrative detention order, is subject to this subpart.

(Comment 42) Several comments argue that the directed food laboratory order provision violates the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) (APA), because the proposal lacked a reasoned explanation for the provision and contained insufficient detail to facilitate meaningful public comment. These comments conclude that finalizing the directed food laboratory order provision as proposed would put this tool at risk of being invalidated if challenged as arbitrary and capricious under the APA. Some comments state that the Agency can finalize the laboratory accreditation rule and meet all statutory obligations without issuing directed food laboratory orders and therefore conclude directed food laboratory orders are not ''fit for purpose.''

Many comments state that directed food laboratory orders are not aligned with the purpose and principles of FSMA and the intent of section 422 of the FD&C Act. Comments state that Congress's purpose in section 422 of the FD&C Act is to address the practice of importers engaging in ''laboratory shopping'' (*i.e.,* a practice whereby an owner or consignee sends samples to several laboratories in hopes that one will return results indicating the sample complies with FDA requirements and if

so, the owner or consignee submits only that result to FDA) by requiring that food testing results be sent directly to the Agency; these comments argue that the directed food laboratory order provision of the proposed rule does not advance this objective.

Other comments frame the purpose of section 422 of the FD&C Act as ensuring reliable and accurate test results. These comments counter that instead of supporting this purpose, the proposed directed food laboratory order creates a new investigatory and enforcement tool for FDA, which is unnecessary given the Agency's existing enforcement tools; namely, that FDA may already sample the product and the environment and choose the laboratory to conduct the analysis. Comments state that Congress carefully considered which additional tools were necessary through FSMA and did not contemplate a duplicative enforcement tool. Comments state that there is no indication that Congress intended to shift this burden to industry through directed food laboratory orders in section 422 of the FD&C Act and that doing so would be unfair. Comments suggest that additional Agency funding is the more appropriate solution to address limited Agency resources. Several comments offer revisions to the directed food laboratory order provision that they consider necessary to link the proposed provision to the purpose of the statute. Additionally, some comments indicate that facilities must implement environmental and product testing according to food safety plans under other FSMA provisions and FDA may review this information during routine inspections; comments express the belief that this represents sufficient oversight into testing methodology, laboratory choice, procedures, and test results. In sum, comments argue that without a demonstrated concern with laboratory integrity and a public health need, directed food laboratory orders are inappropriate and outside the scope of section 422 of the FD&C Act.

Comments argue that the proposed rule preamble provided limited information regarding the Agency's need or justification for directed food laboratory orders, such as historical events or situations when such orders would have been useful. Regarding the justification, many comments state that the preamble fails to explain the problem directed food laboratory orders are intended to address, as there is no documented issue regarding the reliability of test results that would warrant testing by LAAF-accredited laboratories. Some comments state that without a clear explanation for the Agency's need for what they perceive as a potentially expansive enforcement tool, comments cannot support the directed food laboratory order provision. Additionally, some comments state that the Agency has not considered how the proposed directed food laboratory order provision would harm industry, including by increasing costs to food companies associated with the use of LAAF-accredited laboratories and disrupting production to hold product while waiting for test results.

Some comments state that in the proposed rule we did not address operational details of the directed food laboratory order such as who in FDA would issue such orders, how the orders would be delivered; how long the directed food laboratory order would be in place; and when and how a directed food laboratory order would be lifted. We understand some comments to argue that it was legally necessary for FDA to describe these operational details in the proposed rule. Finally, according to some comments, the proposed rule should have reflected that we considered alternative approaches to the directed food laboratory order.

(Response 42) The proposed rule contained a reasoned explanation and sufficient detail on this topic to facilitate meaningful comment and therefore fully satisfied APA requirements. In the proposed rule we articulated the legal authority for the directed food laboratory order, a description of the tool, and the substantive issues involved. We stated that we were interpreting section 422(b)(1)(A)(ii) of the FD&C Act to give FDA authority to propose the directed food laboratory order. We described the proposed content of the directed food laboratory order (*e.g.,* it will specify the timeframe for the testing, and any method that must be used). We communicated that the proposed directed food laboratory order addresses an identified or suspected food safety problem, and we discussed the meaning of that phrase at some length. We made clear that the proposed tool could be used to compel either product or environmental testing and explained our basis for including environmental testing within the proposed definition of ''food testing.'' We also explained that under the proposed rule owners or consignees subject to a directed food laboratory order may request a regulatory hearing.

Comments also argue that the proposed rule was insufficient because the Agency failed to explain a need for the directed food laboratory order, for example by describing past enforcement cases in which the Agency would have found it helpful to employ such a tool. It is true that we did not describe a past case, but it was clear from the proposed rule that the tool is directed at unreliable test results in circumstances where we have reason to suspect, or have identified, a particular food safety problem for which a particular owner or consignee is responsible. Further, although we did not discuss our consideration of alternative approaches in the proposed rule, based on our knowledge and experience implementing FSMA, we have determined that the directed food laboratory order is an appropriate application of section 422(b)(1)(A)(ii) of the FD&C Act. See also, Response 41 and the analysis of regulatory alternatives to this rule in the FRIA (Ref. 4).

With regard to comments expressing concern that we did not justify an expansive new tool in the proposed rule, we believe this reflects a misperception: The directed food laboratory order is a precise new tool that will help us protect public health in a relatively narrow set of circumstances. Section 422(b)(1)(A)(ii) of the FD&C Act gives FDA authority to require testing to be conducted under this subpart as we deem appropriate, to address an identified or suspected food safety problem. As we interpret this statutory provision, directed food laboratory orders will generally be limited to the rare situations when we have reason to question the accuracy or reliability of past or present test results, and an identified or suspected food safety problem exists. (See Response 47 for discussion of the standard; see Response 35 for discussion of ''identified or suspected food safety problem.'')

Some comments appear to express doubt that there are ever any problems with the reliability of food testing conducted by or for owners or consignees, and claim that because the proposed rule did not document that such problems exist, and threaten public health, there is insufficient justification for the directed food laboratory order. We suspect that this reflects the misperception in some comments regarding the directed food laboratory order as an expansive new tool, which in turn may have created a belief that the proposed rule should contain a lengthy description of widespread problems with the validity of an array of test results. As clarified above, however, the directed food laboratory order is not a tool that we expect to apply broadly or frequently. Rather, it will be applied in particularized circumstances. If there were never any particularized problems

with the reliability of food testing conducted by or for owners and consignees, Congress would not have enacted section 422 of the FD&C Act. However, in this provision of the FD&C Act, Congress has specifically reserved for the Agency the authority to require testing to be conducted under this subpart in circumstances beyond just those defined by Congress. And, given some of the egregious situations and behaviors FDA has encountered in enforcing the food safety provisions of the FD&C Act, many of which have been widely publicized, we do not believe anyone could reasonably doubt the existence of particular circumstances in which owners or consignees failed to use a quality, reliable laboratory and where public health harm resulted. (See Response 47 for examples of situations in which a directed food laboratory order may be appropriate.)

Similarly, some comments claim that registered food facilities conduct routine testing consistent with their obligations under the preventive controls regulations, and there is no evidence that, ''as a general matter,'' those test results are unreliable. Again, the directed food laboratory order is not intended to be applied generally; it will be applied in response to a particular set of circumstances. Unfortunately, some registered food facilities do not perform routine testing in a manner that is consistent with their preventive controls obligations. We also note that the directed food laboratory order may be applied to entities that are not subject to the preventive controls regulations.

One piece of evidence indicating the sufficiency of the proposed rule with respect to the directed food laboratory order is the quality of the public comments on the topic. We appreciate commenters' robust feedback and assure them we have carefully considered their input. Several comments contained questions, suggestions, and requests regarding the details of the application of the directed food laboratory order; to the extent possible, we respond to those comments in the subsequent responses in this section of the preamble. However, the fact that such details, including operational details, did not appear in the proposed rule does not call into question the legal sufficiency of the proposal. In sum, the proposal adequately apprised the public of the proposal under consideration in a manner that allowed for meaningful comment on the directed food laboratory order.

We reject the contention that, because it would be possible to implement other portions of section 422 of the FD&C Act without the directed food laboratory order, the tool must not be ''fit for purpose.'' The degree to which the directed food laboratory order affects the success of the overall LAAF program framework does not define its fitness for purpose. The relevant question is whether the statute authorizes FDA to implement the directed food laboratory order, which it does, as discussed in Response 41.

In contrast to the contention of some comments, the directed food laboratory order squarely aligns with both the purpose of FSMA and the intent of section 422 of the FD&C Act. We particularly agree with those aspects of comments stating that a central purpose of section 422 of the FD&C Act is to help ensure accurate and reliable test results in certain circumstances identified in the statute. Directed food laboratory orders will serve that purpose by increasing confidence in testing results in particular circumstances when we have reason to question the accuracy or reliability of past or present test results and an identified or suspected food safety problem exists. To the extent that preventing ''laboratory shopping'' was a purpose of section 422(b)(2) of the FD&C Act, which requires all test results to be submitted directly to FDA, such purpose must be consistent with the rest of section 422, including the provision granting discretion to the Agency to include in this final rule testing, ''as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' Section 422(b)(1)(A)(ii) of the FD&C Act.

The central purpose of FSMA was to shift the focus of food safety efforts to preventing contamination of the food supply, rather than primarily responding to problems after they occur. Directed food laboratory orders serve this purpose by addressing the need for reliable food testing when there are particular circumstances where past or current testing is suspect and FDA has determined there is an identified or suspected food safety problem. Testing in such circumstances would be aimed at gathering trustworthy scientific information to help FDA and others avoid or mitigate a food safety event.

Some comments categorize the proposed directed food laboratory order as a new investigatory and enforcement tool, and maintain that FDA already has the authority to collect samples and send those samples to the laboratory of the Agency's choosing. They also state that, through the preventive controls regulations, FDA already has the authority to review records of test results when inspecting a registered food facility, which provides sufficient oversight of such testing. Again, the directed food laboratory order is a tool that may be applied to owners and consignees that are not registered food facilities subject to the preventive controls regulations. Further, section 422(b)(1)(A) of the FD&C Act makes plain that Congress intended to require entities to be subject to this subpart even though FDA already regulates testing for that industry. Accordingly, it is irrelevant that FDA may already have the authority to collect samples at an enterprise or review the enterprise's testing records; the directed food laboratory order is an appropriate new tool authorized by section 422(b)(1)(A)(ii) of the FD&C Act.

It is also irrelevant whether Congress specifically contemplated the existence of the directed food laboratory order because Congress delegated authority to the FDA to require testing to be conducted under this subpart, as we deem appropriate, when an identified or suspected food safety problem exists and the codified use of directed food laboratory orders is fully consistent with the text and purpose of the statute. We disagree that the directed food laboratory order is a mechanism to shift the burden of enforcement and investigation onto private industry or stretch FDA's budget; it is a precise tool that will be rarely used and is not anticipated to impose significant burden on regulated entities. We discuss comments on the estimated costs of the directed food laboratory order in the FRIA (Ref. 4). (For more information on all the estimated costs and benefits of the final rule, see the FRIA (Ref. 4).)

(Comment 43) Several comments raise concerns that directed food laboratory orders will have negative policy implications that the Agency has not considered. These comments state the belief that directed food laboratory orders could disincentivize facilities from implementing ''seek and destroy'' pathogen environmental monitoring. These comments assert that in response to FSMA, the industry already has implemented robust environmental monitoring programs. These comments further argue that the food safety and public health benefits of these programs could be jeopardized by directed food laboratory orders and the possibility that a facility's own routine testing could result in issuance of a directed food laboratory order. These comments state that uncertainty regarding the timing, duration, and cost associated with directed food laboratory orders will cause facilities to avoid routine testing for fear of triggering such an order. A few comments state that some firms may modify their environmental testing programs to avoid finding

positive results, negating what the comments characterize as the ''positive steps'' FDA has taken ''to encourage aggressive environmental sampling in the 2017 publication of the (''Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry'' draft guidance (Ref. 11)), through the acknowledgment that a finding for *Listeria* species on a food contact surface does not render product adulterated.'' [8]

Some comments express concern that basing a directed food laboratory order on environmental results increases the risk that the test results could be taken out of context; several of these comments mention that there would be a lack of information connecting the test result to a product. A few comments request that FDA reiterate that routine testing of product and environment related to a facility's food safety plan is not required to be performed by LAAF-accredited laboratories under this subpart and that followup sampling and testing in response to routine environmental monitoring positive results for pathogen/indicator organisms should not be covered by this subpart.

Some comments express concern that the LAAF program will cause testing by laboratories not participating in the program to be devalued or viewed as suspect. Some comments warn that widespread use of directed food laboratory orders could cause testing performed by laboratories not LAAF-accredited under FDA's program to be scrutinized. These comments assert that many in-house and external laboratories are not ISO-accredited; however, the laboratories still ensure integrity and accuracy of test results and data. These comments stress the important role in-house and other laboratories play in providing timely test results on which food safety decisions are made. These comments suggest that these laboratories may choose not to participate in the LAAF program. Further, some comments are concerned that FDA and investigators may question analytical results from non-LAAF-accredited laboratories. Overall, comments assert there is no evidence to suspect that non-ISO-accredited laboratories produce inaccurate or suspect results.

Some comments urge FDA to consider the potential significant costs associated with directed food laboratory orders as well as the potential business disruption that may occur if product subject to testing is placed on hold pending results. A few comments explain that holding product under a directed food laboratory order could challenge the company's hold capacity and disrupt both production and the supply chain, as well as have additional costs for industry. Several comments state that the preliminary economic impact analysis did not include any costs for directed food laboratory orders and should be revised accordingly.

(Response 43) We disagree that the directed food laboratory order provision, as clarified, will have negative policy implications. The authority under section 422 of the FD&C Act is intended to increase confidence in receiving accurate and reliable test results. As stated in Response 35, the purpose of routine environmental testing under the preventive controls regulations (§§ 117.165(a) and 507.49(a)) is to verify that preventive controls are consistently implemented and are effective. Therefore, such testing does not address an identified or suspected food safety problem and is not covered by this subpart. The additional clarity we are providing in this final rule regarding the directed food laboratory order in terms of the standard of issuance, authority to issue such orders, and procedural details, should provide sufficient boundaries to enable firms to continue or expand robust environmental monitoring programs developed in the wake of FSMA and in support of an overall culture of food safety, without fearing that such programs will invite issuance of a directed food laboratory order. We expect that it will be uncommon for us to issue a directed food laboratory order. Further, we expect that facilities that have implemented robust environmental monitoring programs and that are taking appropriate corrective actions in response to positive findings (''seek and destroy'') generally are not likely to be subject to such an order.

However, as discussed in Response 37, followup testing in response to routine environmental test results that indicate the presence of a pathogen or indicator organism in the food production environment may qualify as testing that addresses an identified or suspected food safety problem, and therefore could warrant issuance of a directed food laboratory order, depending on the circumstances. We disagree with the contention that use of a directed food laboratory order for environmental testing could cause results to be taken out of context. As explained in Response 47, the use of a directed food laboratory order is appropriate only in a narrowly defined set of circumstances. Accordingly, in our view, the context (including relevant product(s)) for any environmental tests required by a directed food laboratory order) will be sufficiently clear.

Absent a specific reason to question the reliability and accuracy of results from a particular firm or laboratory, we do not believe that testing from an in-house, third-party private, or other laboratory that is not LAAF-accredited would be questioned solely based on the decision of that laboratory not to participate in this program, and certainly not as a result of the directed food laboratory order tool. We discuss examples of circumstances in which we would employ a directed food laboratory order in Response 47. As reiterated throughout our discussion of the directed food laboratory order in this preamble, and as reflected in the FRIA, we do not expect widespread use of such orders (Ref. 4). We address costs related to a directed food laboratory order in the FRIA, see (Ref. 4).

(Comment 44) Several comments state that the proposed rule does not specify who has the authority to issue a directed food laboratory order, nor does it indicate whether such authority could be delegated. These comments recommend that the authority to issue a directed food laboratory order remain a non-delegable function of the FDA Commissioner. A subset of these comments mentions that this recommendation aligns with section 415(b)(7) of the FD&C Act (regarding the authority to issue an order to suspend a registration or vacate an order of suspension [of a food facility]) and mandatory recall authority. Some comments assert that the authority to issue a directed food laboratory order would not be appropriate for FDA investigators or State inspectors. A few comments ask whether State regulators inspecting farms under the produce safety rule would have authority to issue a directed food laboratory order.

(Response 44) In proposed § 1.1108, we stated that a directed food laboratory order may be issued by FDA. Although we agree that the authority to issue a directed food laboratory order would

[8] The ''Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry'' draft guidance describes followup actions a facility should take in response to a finding of *Listeria* spp. on a food contact surface. Although it is true that the draft guidance indicates that we expect to find *Listeria* in certain food facilities, we also expect that such facilities will implement environmental monitoring plans to find *Listeria* when present and take followup actions to ensure that *Listeria* does not contaminate food. Our investigators will inspect a facility's environmental monitoring results and the followup activities the facility performs in the event of an environmental positive, to ensure that product does not become adulterated. If we have concerns about the facility's application of current good manufacturing practices and preventive controls with respect to *L. monocytogenes,* we may perform our own sampling of the facility's environment and may also take food samples.

not be delegated to FDA investigators or State inspectors, we decline to make the issuance of a directed food laboratory order a non-delegable function of the FDA Commissioner. Section 415(b)(7) of the FD&C Act and section 423(h) of the FD&C Act contain explicit provisions limiting certain authority to the Commissioner. Section 422 of the FD&C Act (21 U.S.C. 350k) does not include a similar limitation. Absent an explicit statutory limitation regarding delegation, we find no reason to impose one for the issuance of a directed food laboratory order. Consistent with longstanding Agency practice and the APA, we intend to limit the delegation of authority to issue a directed food laboratory order under this subpart to FDA officials with the appropriate level of responsibility. See 5 U.S.C. 553(a)(2).

(Comment 45) Several comments state that the proposed directed food laboratory order procedures raise due process concerns for the potential recipient of such an order. In support of this position, the comments describe their perception of the uncertain standards and the Agency's unfettered discretion to issue a directed food laboratory order. Some comments urge FDA to have a transparent process and clear standards with a documented sound scientific basis for issuance of a directed food laboratory order. Some comments request more specific examples of when the Agency would issue a directed food laboratory order. These comments argue that without specifying who in the Agency may issue a directed food laboratory order, it appears that FDA investigators could issue them. The comments state that the perceived lack of a process prior to issuance and the perceived lack of a guaranteed process once a directed food laboratory order has been received contribute to the overall insufficient due process associated with the proposed provision.

(Response 45) We address several aspects of these concerns elsewhere in this preamble, in Response 44 and Response 47. Specifically, we clarify the standard of issuance for a directed food laboratory order, who has the authority to issue such an order, and certain procedural aspects associated with issuance of such an order. With these details and the applicable procedures of part 16 in place, we believe there is sufficient due process associated with the directed food laboratory order provision.

(Comment 46) Several comments state that food testing pursuant to a directed food laboratory order should be limited to product testing and should not include environmental testing. These comments state that FSMA section 202, Laboratory Accreditation for Analyses of Foods, refers only to ''food testing'' and ''testing of food,'' without defining these terms. The comments indicate that while environmental testing is not specifically mentioned in section 202, Congress explicitly refers to environmental testing elsewhere in FSMA (section 103, which creates section 418(f)(4) of the FD&C Act). Further, some comments suggest that including environmental testing would create the potential for test results to be taken out of context; several of these comments state that there would be a lack of information connecting the test result to a product. A few comments explain that routine testing, including environmental testing, is covered by FDA guidance and considers multiple variables; these comments state that it is not clear whether and how all variables will be considered in determining when a directed food laboratory order is issued. Some comments conclude that there is no legal basis for requiring environmental testing under a directed food laboratory order and that directed food laboratory orders must only be used for food product testing.

(Response 46) We decline to limit directed food laboratory orders to product testing. As already discussed in Response 19, FDA defines ''food testing'' and ''testing of food'' to include environmental testing for purposes of this subpart. As stated in Response 19 and discussed further in Response 35, routine environmental testing (§§ 117.165(a)(3) and 507.49(a)(3)) is not covered by this subpart. As we noted in Response 43, we do not believe the directed food laboratory order will cause environmental test results to be taken out of context. For these reasons, in light of our legal authorities under section 422 of the FD&C Act, and for the policy reasons already discussed in relation to both environmental testing and the directed food laboratory order, under this final rule and as appropriate, FDA may issue a directed food laboratory order subjecting either product testing or environmental testing to the requirements of this subpart.

(Comment 47) Some comments state that the proposed rule did not provide enough information regarding the standard for issuance of a directed food laboratory order. These comments express concern that the proposed standard, an identified or suspected food safety problem, could be present regardless of whether the article of food violates the FD&C Act. Comments state that the examples provided in the preamble to the proposed rule suggest that mere suspicion of a food safety problem, such as the presence of *Listeria monocytogenes* on a food contact surface, could lead to issuance of a directed food laboratory order when there is no violative article involved. Comments argue that issuance of a directed food laboratory order when there is no violative product would exceed FDA's authority. Otherwise, comments suggest the results of a food facility's routine testing could inappropriately trigger a directed food laboratory order. Comments propose instead that an identified or suspected food safety problem should only give rise to a directed food laboratory order when there is a public health need or when the food has a reasonable probability of serious adverse health consequences or death to humans or animals (SAHCODHA).

A few comments express concerns that although FDA notes the suspicion will ''typically be particularized'' as it relates to specific articles of food or a specific portion of the food production environment, it is not clear that this will always be the case. Several comments suggest that the suspicion standard could lead to bias or subjective determinations by an investigator where no problem exists. Some comments propose instead that directed food laboratory orders should include a direct reference to a violation. Other comments state that issuance of a directed food laboratory order should require a reasonable belief that the food is violative, similar to the standard set forth in FSMA section 101 (relating to inspections of records).

These comments recommend that if the directed food laboratory order provision remains in the final rule, it should be limited to circumstances when both of the following factors are met: (1) An identified or suspected food safety problem representing a SAHCODHA hazard is established and (2) a substantiated concern exists regarding the adequacy of the laboratory used by the owner or consignee such that testing by an accredited laboratory under this program is necessary to determine the food safety problem has been resolved. Comments state that a concern about laboratory adequacy is necessary as Congress intended section 202 of FSMA to address ''laboratory shopping'' and other situations which raise questions about the validity of laboratory results. The comments state that the directed food laboratory order should not be used by FDA as an investigative tool.

Some comments recommend that issuance of the directed food laboratory order be limited to cases where the pathogen risk is immediate and FDA's

existing enforcement tools are not adequate to address the situation.

A few comments ask FDA to specifically exempt from a directed food laboratory order pathogen/indicator organism positive results from routine environmental testing since the manufacturer should have the opportunity to resolve any associated concerns through corrective actions.

A few comments request that the Agency provide additional information, guidance, and examples for when a food safety problem is ''suspected'' in animal food, as well as more specific examples of when a directed food laboratory order would be issued under the rule.

(Response 47) Per section 422(b)(1)(A)(ii) of the FD&C Act, the standard for issuance of a directed food laboratory order is ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' We disagree that SAHCODHA should be the standard, as Congress explicitly specified a different standard here. For the same reason, we decline to use the standard set forth in FSMA section 101 (reasonable belief that the food is violative). The statutory clause in the section related to the LAAF program, ''identified or suspected food safety problem'' specifically allows for issuance of a directed food laboratory order when there is no violative product.

Regarding the standard of issuance, we believe the phrase, ''as the Secretary deems appropriate,'' in the context of the FSMA laboratory accreditation program, generally would limit our issuance of a directed food laboratory order to situations where we have evidence or experience with a firm or laboratory which calls test results into question, *i.e.,* situations in which we have reason to question the accuracy or reliability of past or present test results. In such circumstances, there would be a clear benefit to receiving analytical results directly from a LAAF-accredited laboratory. Ensuring accurate and reliable test results is the precise issue Congress intended to address in section 202 of FSMA. In the final rule, we have revised the language in § 1.1108(a) to better align with the statutory text by adding the qualifying language, ''as FDA deems appropriate.''

In terms of the comment expressing apprehension that FDA will use the directed food laboratory order as a tool to gather testing information in the absence of heightened food safety concerns, we reiterate that the order is only appropriate to address an identified or suspected food safety problem. Similarly, regarding the contention in some comments that a directed food laboratory order should only be issued if there are concerns with laboratory adequacy, as just noted, we interpret, ''as the Secretary deems appropriate'' to mean that the tool would generally only be appropriate if we have reason to question past or present test results.

Further, we intend to use a directed food laboratory order within the context of other Agency authorities and tools, FSMA-related and otherwise; accordingly, positive results from routine testing would not normally trigger a directed food laboratory order absent other circumstances (*e.g.,* suspect test results) necessitating a directed food laboratory order. Therefore, we decline to include specific exemptions for pathogen/indicator organism positive results from routine environmental testing or to limit issuance of a directed food laboratory order to cases when the pathogen risk is immediate and the Agency's other enforcement tools are not adequate to address the situation.

We offer the following examples of the types of situations in which we believe a directed food laboratory order would be useful and appropriate ''as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem.'' Some of these descriptions are modeled on our experience with past compliance cases.

- Following a for-cause inspection of a human food firm with a documented history of falsified laboratory reports, after the Agency's receipt of information from an employee informant indicating that the firm continued to provide false or misleading certificates of analysis to conceal the production of adulterated human food;
- Following a recall by an animal food firm because the firm's laboratory historically used an inappropriate method and reported results that differed from FDA laboratory results; and
- If FDA laboratories have on multiple occasions obtained positive pathogen results on food products in past years that conflict with the company's contract laboratory's results. Given a pattern of past ineffective monitoring by the company, coupled with the public health risk, on the next positive finding by FDA that leads to a voluntary recall for pathogen adulteration in this company's food products, FDA might issue a directed food laboratory order.

In light of the additional parameters for issuance of a directed food laboratory order discussed above and limitations on who can issue a directed food laboratory order (discussed in Response 44), we believe issuance of directed food laboratory order would be insulated from bias.

(Comment 48) A few comments state that pathogens in not ready to eat (NRTE) food, and specifically in raw agricultural commodities such as grains, which do not undergo a kill step in the mill, should not be considered an identified or suspected food safety problem subject to a directed food laboratory order. These comments state further that the preamble to the proposed rule offered few examples of circumstances that could generate a suspected food safety problem and mentioned ''potential contamination events'' as an example although we did not define this phrase. These comments request that the Agency define that phrase and explicitly state that the presence of pathogens in NRTE foods is not considered an identified or suspected food safety problem. The comments express the concern that directed food laboratory orders could be used as a basis for requiring the milling industry generally to sample food manufacturing environments or products through use of LAAF-accredited laboratories. The comments suggest that any testing in these circumstances would not be appropriate, regardless of whether the use of a LAAF-accredited laboratory is required.

(Response 48) The proposed rule explored the meaning of the statutory phrases, ''identified food safety problem,'' and ''suspected food safety problem.'' (84 FR 59452 at 59455, 59462). In Response 35, above, we finalize our tentative conclusions about the meaning of those phrases.

A number and variety of factors impact food safety risk (*e.g.,* the pathogen, the history of foodborne illness outbreaks associated with the pathogen in the food, whether the food undergoes further processing with a kill step at a registered food facility). In some circumstances a pathogen in an NRTE food may be considered an identified or suspected food safety problem. For example, foodborne illness outbreaks have been associated with *Salmonella* in raw tuna (*https://www.cdc.gov/salmonella/newport-04-19/index.html*) and Shiga-toxin producing *E. coli* in raw bison burgers (*https://www.cdc.gov/ecoli/2019/bison-07-19/index.html*). The strains of pathogens associated with the outbreaks are capable of causing severe illnesses (both outbreaks resulted in hospitalizations), and these raw foods were consumed without a treatment to significantly minimize the hazard and

prevent illnesses. Consistent with the broader food safety regulatory framework, which includes the preventive controls for human food regulation and the preventive controls for animal food regulation, FDA will consider all applicable regulations and relevant circumstances in determining whether an identified or suspected food safety problem exists. As explained in Response 47, a directed food laboratory order is appropriate in situations in which an identified or suspected food safety problem exists along with specific evidence or experience with a firm or laboratory which calls past or present test results into question. Accordingly, we expect to employ the directed food laboratory order rarely. In many cases involving a pathogen in an NRTE food, other food safety regulations or tools outside the scope of the LAAF program may adequately address the risk.

We decline the request to define ''potential contamination event.'' We have defined the terms that describe the standard of issuance for a directed food laboratory order (see Response 35). Consistent with these definitions, a directed food laboratory order may be appropriate in circumstances related to potential contamination events; *e.g.,* where a pathogen in the food production environment is transmitted to the food, thereby causing the food to be adulterated, and where we have specific evidence or experience with a firm or laboratory which calls past or present test results into question.

(Comment 49) A few comments suggest that neither chemical nor physical hazards would be appropriate for a directed food laboratory order. According to such comments, the directed food laboratory order should be limited to circumstances where there is a reasonable likelihood of serious adverse health consequences or death to humans or animals due to the potential for pathogens to be present in the food product.

(Response 49) We decline to exempt chemical or physical hazards from a potential directed food laboratory order. As previously stated, a directed food laboratory order will generally be limited to the rare situation when we have reason to question the accuracy or reliability of past or present test results and where an identified or suspected food safety problem exists. In addition to biological hazards, both chemical and physical hazards are capable of causing food safety problems. Therefore it is possible that any of the three types of hazard could, in certain circumstances, form the basis for issuance of a directed food laboratory order.

We also note that chemical and physical hazards are specifically covered by other FSMA regulations such as the preventive controls regulations (§§ 117.130 and 507.33). We believe it is appropriate to align coverage of a potential directed food laboratory order with the potential hazards covered by those regulations.

(Comment 50) Several comments raise questions about operational details related to the issuance of directed food laboratory orders. These comments ask about the intended recipient of the directed food laboratory order (corporate parent, facility, or both), means of transmission (electronic, in-person, mail), and whether the issuance would change based on multiple owner or consignee scenarios. Comments state that these details are critical given the proposed 24-hour appeal deadline for directed food laboratory order recipients.

(Response 50) FDA intends to provide the most legally responsible person at the firm that day with written notice of a directed food laboratory order, generally via email. We will make every attempt to call to inform the firm of the order prior to its arrival.

In the imports context, there are sometimes multiple owners or consignees. In such a case, we would generally deliver the written notice to the importer of record. (See Response 26 for additional discussion of multiple owner or consignee scenarios.)

As discussed in Response 138, we have extended the appeal deadline from 24 hours to within 3 business days of receipt of a directed food laboratory order.

(Comment 51) Several comments suggest that the lack of detail surrounding the duration and termination of directed food laboratory orders raises due process issues. These comments recommend that a directed food laboratory order should be ''closed'' once the identified or suspected food safety problem has been resolved. These comments also request that FDA include a hearing process to permit owners or consignees to submit evidence in support of the resolution to terminate a directed food laboratory order or to have the directed food laboratory order vacated. Additionally, some comments request that directed food laboratory orders include a timeframe for the order and frequency for testing. Further, a few comments suggest that FDA use a hearing process if the Agency seeks to modify a directed food laboratory order once issued. Some comments request that FDA provide additional information on what is considered a reasonable timeline to conduct testing required by a directed food laboratory order.

(Response 51) In general, a directed food laboratory order would last until we have adequate assurances that the underlying known or suspected food safety problem has been resolved. However, we agree that the order will be ''closed'' once the identified or suspected food safety problem has been resolved. We anticipate that this approach will incentivize firms to resolve issues quickly. However, details regarding the duration and termination of a directed food laboratory order will be contingent on the specific facts and circumstances of the order, which will vary greatly. For example, whether the order covers product or environmental testing, whether it is designed to address a very discrete issue or a system-wide issue, the applicable regulations, and the role of other resources and tools applied to the circumstances, are just a few of the factors that may impact the length of time a directed food laboratory order would be appropriate. Some orders may initially define the timeframe and testing frequency, but again, we will determine these matters on a case-by-case basis.

At present we do not believe it necessary to create a hearing process around the conclusion of a directed food laboratory order; however, we expect to be in dialogue with the entity subject to the order and intend to take their feedback into consideration.

(Comment 52) Some comments state that the proposed rule did not include details regarding whether or how directed food laboratory orders would be made public. These comments request that FDA clarify that directed food laboratory orders will not be made public. The comments argue that only the owner or consignee must take action under a directed food laboratory order, so there is no need to make a directed food laboratory order public.

(Response 52) We may include directed food laboratory orders on an Agency website such as the data dashboard (see *https://www.fda.gov/about-fda/transparency/fda-data-dashboard*), so that other entities in the supply chain can be aware of their existence as they research and evaluate suppliers. We similarly publicize injunctions, seizures, and warning letters on the data dashboard and believe that inclusion of directed food laboratory orders would contribute to the overarching goals of FDA's food safety communication strategy.

We also note that a directed food laboratory order generally would be subject to the Freedom of Information

Act (FOIA). Any disclosures would be made in accordance with our regulations in part 20 (21 CFR part 20) (*i.e.,* redacting any confidential commercial information as necessary).

(Comment 53) A few comments request additional information regarding whether directed food laboratory orders only apply domestically. These comments argue that directed food laboratory orders must apply to both domestic and foreign facilities producing food for consumption in the United States to comply with international commitments. The comments state that, as proposed, directed food laboratory orders will be issued more frequently to domestic entities, resulting in unfair treatment, since the FDA conducts more domestic inspections, therefore giving rise to more opportunities to issue such orders domestically. These comments state that there may be significantly fewer LAAF-accredited laboratories outside of the United States, which could make it more difficult for foreign manufacturers to comply with the requirements of a directed food laboratory order. These comments argue there is an inherent unfairness to the lack of parity and ask FDA to consider this when determining the need for directed food laboratory orders.

(Response 53) We agree that a directed food laboratory order could be used in both foreign and domestic settings; however, we disagree that conducting more domestic inspections necessarily will mean there are more opportunities to issue a directed food laboratory order domestically. As discussed in Response 44, FDA investigators will not be able to issue directed food laboratory orders. This limitation and the additional clarifications provided regarding the standard of issuance (see Response 47) will limit use of a directed food laboratory order to those limited circumstances discussed and address the potential for unfairness.

LAAF-accredited laboratory capacity for testing under this subpart is addressed in Response 15 and will include consideration of both foreign and domestic laboratories.

(Comment 54) Some comments request additional information regarding whether FDA will specify the method to the owner or consignee of the food subject to a directed food laboratory order so that the owner or consignee can provide such information to the LAAF-accredited laboratory.

(Response 54) We will specify the method to the owner or consignee and, in some circumstances, may provide flexibility to use equivalent methods, so that there may be access to a greater number of LAAF-accredited laboratories that may conduct the food testing. See § 1.1151(b)(2).

(Comment 55) Some comments maintain that directed food laboratory orders should be issued only where a validated test method exists and where there is sufficient LAAF-accredited laboratory capacity for that method and the specific food matrix.

These comments are concerned that if a directed food laboratory order were issued for a method requiring validation, it could effectively prohibit the facility from operating until a method is validated. Comments estimate validation of a single method could take 6 months or more and cost between $35,000 and $300,000, depending on the complexity of the method. Comments contend that the proposed rule was not clear regarding who bears the cost of validating a method; these comments argue industry should not have to bear such costs as a result of the issuance of a directed food laboratory order. Comments state further that costs to validate a method were not included in the preliminary economic impact analysis. A few comments assert that if directed food laboratory orders are limited to SAHCODHA hazards posed by pathogens, there would be fewer method validation concerns.

Some comments state that proposed § 1.1151(e) would allow an accredited laboratory to request FDA's permission to use a method outside its scope of accreditation but FDA would only approve the request if there is a ''food emergency.'' These comments express concern that FDA could define a ''food emergency'' to exclude circumstances specific to a particular food or facility. If narrowly construed in this manner, the comments argue the lack of a validated method or LAAF-accredited laboratory availability necessary under a directed food laboratory order could effectively block a facility from operating. Further, these comments assert that this provision would not mitigate the concerns raised regarding the impact of a directed food laboratory order for a method requiring validation.

(Response 55) We intend to issue a directed food laboratory order when there exist both a validated method and sufficient laboratories LAAF-accredited to that method. Under § 1.1108(b), FDA will specify the test method in a directed food laboratory order.

As discussed above in Response 47, the general standard for issuance of a directed food laboratory order is that FDA has reason to question the accuracy or reliability of past or present test results and an identified or suspected food safety problem exists. Necessarily, then, if a directed food laboratory order has been issued, the food testing at issue is not novel because it has been happening for at least long enough that FDA has reason to question the results. In such circumstances, we believe a validated method will exist. Section 422(b)(3) of the FD&C Act expressly gives FDA the authority to waive requirements of the LAAF program if: (1) A new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies and (2) the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(Comment 56) Many comments assert, based on legal, policy, and practical concerns with the proposed rule, that directed food laboratory orders should be removed from the final rule. Some of these comments suggest that since FSMA section 202 does not contemplate directed food laboratory orders, inclusion of the directed food laboratory order provisions in the final rule is not required as part of the rulemaking. Comments suggest that removing the directed food laboratory order provision will help FDA meet its deadline to issue a final rule.

Several comments argue that if FDA can establish both statutory authority and a justified public health need for directed food laboratory orders, either an independent rulemaking or a supplemental notice of proposed rulemaking would be necessary to allow for additional input, to clarify the proposal in terms of scope, procedures, and policy concerns, and to avoid litigation. Some comments suggest FDA has good cause to request modification of the consent decree deadline to extend the deadline due to the issues raised in the comments and the COVID–19 pandemic's impact on the Agency. Some of these comments raise the concern that additional time is needed to allow the Agency to give due consideration to the issues raised and to engage industry on the food safety concerns addressed by directed food laboratory orders.

However, some comments recommend revisions to directed food laboratory orders to limit their scope and otherwise address procedural aspects that they believe would make directed food laboratory orders feasible if not removed from the final rule. These comments insist that a supplemental notice of proposed rulemaking is necessary to fully vet any revised proposal. A few comments ask that

directed food laboratory orders be used judiciously with specific guidance for use, should FDA confirm it has authority to issue directed food laboratory orders.

Some comments suggest that FDA should publish additional guidance on directed food laboratory orders prior to issuing a directed food laboratory order.

(Response 56) We decline the recommendation to remove the directed food laboratory order from the final rule. As discussed above throughout the comments and responses related to directed food laboratory orders, we have addressed the necessary legal, policy, and practical concerns raised. Additionally, we received meaningful comments which we have carefully considered in developing the directed food laboratory order provision of the final rule. Therefore, we do not agree a supplemental rulemaking is necessary. We will consider issuing additional guidance on directed food laboratory orders.

4. How will FDA make information about recognized accreditation bodies and LAAF-accredited laboratories available to the public (§ 1.1109)?

Proposed § 1.1109(a) provided that FDA would place on our website a publicly available registry listing recognized accreditation bodies and LAAF-accredited laboratories in the LAAF program. The proposed list would include certain information regarding each recognized accreditation body and LAAF-accredited laboratory such as the name, contact information, duration of an accreditation body's recognition, and the scope of accreditation for each laboratory. We also proposed including certain information about changes in recognition of an accreditation body, including probation, revocation, voluntary relinquishment, or expiration and the effective date for any change. Likewise, we proposed including certain information regarding changes in LAAF-accreditation of laboratories, such as withdrawal, revocation, probation, voluntary relinquishment and the effective date for any change. Proposed § 1.1109(b) reiterated the statutory requirement for FDA to coordinate with the Department of Homeland Security regarding the online registry.

On our own initiative, we have revised the section title to include ''LAAF-accredited laboratories,'' consistent with terminology changes throughout the rule. We also have clarified in the final rule that FDA will place on its website a publicly available registry listing information about recognized accreditation bodies and LAAF-accredited laboratories. As discussed at Response 10, we have revised the terminology used in the final rule to better clarify roles and actions taken by recognized accreditation bodies and FDA under this subpart. As discussed in section V.C. regarding of the definition of ''scope of LAAF-accreditation'' above, in the final rule we also changed the verbiage, ''withdraw in part,'' to ''reduce the scope of LAAF-accreditation.'' This section has been updated to reflect the revised terminology. For transparency, we added denial of renewal of recognition to the changes in recognition that will be included on the website (see § 1.1109(b) of the final rule); we stated we would post information about denial of renewal of recognition in § 1.1129(h) of the proposed rule, which appears in § 1.1115(h) of the final rule. Additionally, on our own initiative, we removed the language that appeared in § 1.1109(b) of the proposed rule. Section 422(a)(4) of the FD&C Act directs FDA to coordinate with the Department of Homeland Security on the time, manner, and form of the online registry of recognized accreditation bodies and LAAF-accredited laboratories; we have done so. It is unnecessary to reiterate this duty in the codified text and so we have removed that text from the final rule. We also revised the section to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 57) Several comments support our proposal to maintain on our website a registry of recognized accreditation bodies and participating laboratories. Some comments request that the registry include information regarding the methods to which specific laboratories are accredited. Some comments suggest that the registry include hyperlinks to the websites of the recognized accreditation bodies, as those are updated regularly with information on LAAF-accredited laboratories, including current scope information.

Some comments request that the registry include information beyond that related to recognized accreditation bodies and LAAF-accredited laboratories; they advocate for FDA to maintain a list of all ISO/IEC 17011:2017 accreditation bodies that are ILAC-Mutual Recognition Arrangement (MRA) signatories and accredit food laboratories, as well as all food laboratories that are accredited to ISO/IEC 17025:2017. These comments express the view that such a listing would be a helpful public service.

Some comments propose that the registry indicate which participating laboratories are permitted to submit abridged analytical reports; from their perspective, such information would be helpful to industry in choosing a laboratory.

Other comments ask how the public will know which laboratories are LAAF-accredited, and some comments consider the proposed rule to be unclear regarding how the public will know the methods for which each laboratory is LAAF-accredited and recommend this information be posted on the public website.

(Response 57) We appreciate the support for the public registry and note that its establishment is required by section 422(a)(1)(B) of the FD&C Act. To be clear, under the final rule, the online registry will list all LAAF-accredited laboratories and the scope of LAAF-accreditation for each, among other things. See § 1.1109.

We decline the recommendation to include on the public registry hyperlinks to the websites of recognized accreditation bodies and LAAF-accredited laboratories. Recognized accreditation bodies and LAAF-accredited laboratories must report changes that impact their recognition and LAAF-accreditation as specified in this final rule. This will ensure the public registry contains accurate and up-to-date information for use by owners and consignees.

We also decline the recommendation to expand the registry to include a list of all ISO/IEC 17011:2017 accreditation bodies that are ILAC–MRA signatories that accredit food laboratories and all ISO/IEC 17025:2017-accredited laboratories; expansion of the registry in this manner is not specified in section 422(a)(1)(B) of the FD&C Act, which describes the registry as including information regarding accreditation bodies recognized by the FDA and the laboratories which are LAAF-accredited by the recognized accreditation bodies.

Finally, we also decline the recommendation to indicate on the public registry which LAAF-accredited laboratories are permitted to submit abridged analytical reports. We do not consider testing conducted by laboratories permitted to submit abridged analytical reports to be of a higher quality than testing conducted by laboratories without such permission. Nor do we have any reason to conclude that owners and consignees would get test results faster from a laboratory with permission to submit abridged analytical reports. Note that under § 1.1153(d), FDA may request that a LAAF-accredited laboratory that is

permitted to submit abridged analytical reports submit additional documentation or a full analytical report within 72 hours of FDA's request. As stated in § 1.1150(d) of the proposed and final rule, a LAAF-accredited laboratory must document the testing information and test results to the extent necessary to account for all information that is required to be in a full analytical report.

(Comment 58) Regarding the public registry that lists recognized accreditation bodies and participating laboratories, some comments express concern about our proposal to include revocation or probation information in the registry. These comments take issue with our proposed use of both terms, and those issues are discussed at Response 10. Specifically, regarding the term, ''probation,'' the comments indicate that including references to this status on the public registry would inaccurately convey that such organizations are in poor standing, given what the term, ''probation'' normally means in the conformity assessment arena. Regarding the term, ''revocation,'' the comments express the belief that attaching such a label to laboratories in the public registry would cause confusion because it would imply that FDA can revoke the ISO/IEC 17025:2017 accreditation of a laboratory, which is not the case.

(Response 58) We have made revisions throughout the final rule to address terminology concerns (see Response 10). As discussed in Responses 13, 71, and 82, we revised the final rule so that a recognized accreditation body may suspend a LAAF-accredited laboratory under § 1.1121 whereas FDA may place a recognized accreditation body or a LAAF-accredited laboratory on probation under §§ 1.1131 and 1.1161, respectively. We also revised the final rule to allow corrective action under § 1.1161 prior to any public change in LAAF-accreditation status (see Response 133). With these clarifications, the status information contained on the public registry is more clearly limited to the LAAF-accreditation status of the laboratory as opposed to the laboratory's ISO/IEC 17025 accreditation status. Given the revisions throughout the final rule, we will retain, with clarifications, the provision which makes public a LAAF-accredited laboratory's probationary status to maintain transparency for the public and specifically for the owners and consignees with food testing subject to this subpart.

5. What are the general requirements for submitting information to FDA under this subpart (§ 1.1110)?

On our own initiative, we added § 1.1110 to consolidate information previously repeated throughout the proposed codified text regarding the requirement to submit applications, reports, notifications, and records required by this subpart to FDA electronically and in English, unless otherwise specified. The section states further that if records are maintained in a language other than English, the recognized accreditation body or LAAF-accredited laboratory must provide an English translation within a reasonable time. Paragraph (b) specifies that a program applicant must provide translation and interpretation services needed by FDA during the processing of the application, including during any onsite assessments of the applicant. See table 5 for a list of consolidated sections in § 1.1110.

TABLE 5—CONSOLIDATION OF PROPOSED RULE SECTIONS RELATED TO SUBMITTING INFORMATION TO FDA UNDER THIS SUBPART

Final rule	Proposed rule
§ 1.1110 What are the general requirements for submitting information to FDA under this subpart?	§ 1.1123(a) § 1.1124(b) § 1.1128(d) § 1.1129(f) § 1.1131(b)(2) § 1.1132(a) § 1.1152(a) § 1.1153(c) § 1.1162(c) § 1.1163(a) § 1.1171(b) § 1.1173(b) § 1.1174(b)

E. Comments Regarding FDA Recognition of Accreditation Bodies

TABLE 6—REORGANIZATION OF SECTIONS REGARDING FDA RECOGNITION OF ACCREDITATION BODIES

Final rule	Proposed rule	Notes
FDA Recognition of Accreditation Bodies	Recognition of Accreditation Bodies	Added ''FDA'' to clarify that FDA is making recognition determinations.
§ 1.1113 What are the eligibility requirements for a recognized accreditation body?	§ 1.1113 What requirements must an accreditation body meet to be recognized by FDA? § 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?	Consolidated these two proposed sections and revised the section title. Made conforming changes to reflect eligibility requirements as opposed to requirements for seeking recognition and remaining recognized.
§ 1.1114 How does an accreditation body apply to FDA for recognition or renewal of recognition?	§ 1.1128 How does an accreditation body apply to FDA for recognition or renewal of recognition?	Moved section to 1.1114 of the final rule.
§ 1.1115 How will FDA evaluate applications for recognition and renewal of recognition?	§ 1.1129 How will FDA review applications for recognition and applications for renewal of recognition?	Moved section to 1.1115 of the final rule. Changed ''review'' to ''evaluate'' in the section title. Removed second instance of ''applications for'' in the section title.
§ 1.1116 What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition?	§ 1.1132 What must a recognized accreditation body do if it wants to voluntarily relinquish its recognition or does not want to renew its recognition?	Moved section to 1.1116 of the final rule. Minor editorial changes to section title.
§ 1.1117 How may an accreditation body request reinstatement of recognition?	§ 1.1133 How does an accreditation body request reinstatement of recognition?	Moved section to 1.1117 of the final rule. Minor editorial changes to section title.

1. What are the eligibility requirements for a recognized accreditation body (§ 1.1113)?

Proposed § 1.1113, ''What requirements must an accreditation body meet to be recognized by FDA?'' included the requirements an accreditation body must meet to become recognized by FDA under this subpart, including the following: (a) Be a full member of ILAC and a signatory to the ILAC–MRA that has demonstrated competence to ISO/IEC 17011:2017; (b) demonstrate it meets the requirements of ISO/IEC 17011:2017; (c) demonstrate that it possesses sufficient scientific/technical expertise to be able to substantively assess certain work of the laboratories it accredits; and (d) demonstrate it is capable of complying with this rule's proposed requirements for recognized accreditation bodies. Similarly, proposed § 1.1118, ''What are the general requirements for recognized accreditation bodies to remain recognized?'' included the requirement that recognized accreditation bodies continue to meet the requirements of § 1.1113 in order to remain recognized by FDA.

In the final rule, FDA has consolidated proposed §§ 1.1113 and 1.1118. The new consolidated section is titled ''What are the eligibility requirements for a recognized accreditation body?'' and is located at § 1.1113 of the final rule. Accordingly, FDA has revised the section title to refer to eligibility requirements for recognized accreditation bodies and has made minor conforming changes throughout the section to accommodate the change. We also have reordered the list of eligibility requirements and split the requirement that appeared in paragraph (a) of the proposed sections into two distinct items, *i.e.,* separating the requirement of full membership of ILAC from status as a signatory to the ILAC–MRA that has demonstrated competence to ISO/IEC 17011:2017 with a scope of ''Testing: ISO/IEC 17025.'' FDA has added the clarification that a scope of ''Testing: ISO/IEC 17025'' is required; this requirement previously appeared only among the LAAF-accredited laboratory requirements against which a recognized accreditation body must assess a laboratory seeking LAAF-accreditation.

FDA also has removed the requirement in proposed § 1.1113(c)(1) through (3) regarding a recognized accreditation body's scientific and technical expertise to review certain validation and verification required by proposed § 1.1138(a)(1), to review laboratory determinations regarding the availability of proficiency testing program, and to assess the adequacy of a laboratory's proposal to use a comparison program in lieu of a proficiency. For additional discussion regarding this change, see Comment 62 and Response. Finally, FDA has revised the section to modify ''accreditation'' with the prefix ''LAAF-'' to incorporate revised terminology for the final rule discussed at Response 10. Comments regarding this section are discussed below.

(Comment 59) Some accreditation bodies, including ones located outside of the United States, express interest in participating in this program and request information about their role.

(Response 59) We appreciate global interest in the LAAF program. An accreditation body that meets the eligibility requirements in § 1.1113 may apply to FDA to become recognized, regardless of where the accreditation body is located. See Response 14 for our implementation discussion.

Recognized accreditation bodies will assess and oversee laboratories seeking LAAF-accreditation against the requirements in this final rule. The requirements for recognized accreditation bodies are in §§ 1.1113–1.1131 and the requirements for LAAF-accredited laboratories are in §§ 1.1138–1.1162.

(Comment 60) Many comments endorse the proposed requirement that a recognized accreditation body must be an ILAC–MRA signatory that has demonstrated competence to ISO/IEC 17011:2017. They support the use of both ISO/IEC 17011:2017 and ISO/IEC 17025:2017 as the foundational requirements for this rule. Some of the comments express the belief that reliance on the ILAC framework and ISO standards will ensure an efficient and effective food testing program by FDA.

Some comments mention that the rigorous ILAC–MRA process provides ongoing reassurance to regulators that ILAC–MRA signatories and their accredited laboratories are meeting relevant international standards and criteria for competence. Some comments provide examples of other Federal government Agencies and programs that rely on ILAC member accreditation bodies including the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA) National Lead Laboratory Accreditation Program, and Department of Defense Environmental Laboratory Accreditation Program. Other comments refer to the analysis we described in the proposed rule which indicated that all the accredited laboratories that submitted import-related food testing results in 2016 and 2017 were accredited by accreditation bodies that are full members of ILAC and signatories to the ILAC–MRA. According to these comments, it is unsurprising that owners and consignees choose to rely on laboratories accredited by ILAC–MRA signatories.

Similarly, some comments state that accreditation bodies already satisfy the foundational requirements for participating in the LAAF program. Further, these comments state that accreditation bodies are willing to establish internal procedures and processes to ensure that they and the laboratories they LAAF-accredit meet all additional program requirements beyond ISO/IEC 17011:2017, ILAC–MRA signatory status, and ISO/IEC 17025:2017. Finally, some comments encourage FDA to collaborate with NIST as we establish this accreditation program. Some comments applaud FDA's proposed adoption of voluntary consensus standards and state that such action is in furtherance of the NTTAA.

(Response 60) We appreciate the support expressed for the selected standards and requirements for recognized accreditation bodies in the LAAF program. We also appreciate the information provided regarding the accreditation landscape, as well as the support expressed in these comments for the LAAF program generally. We have consulted with NIST throughout this rulemaking process and appreciate their technical assistance and support.

(Comment 61) In the proposed rule, when we discussed our proposal to require accreditation bodies to be ILAC–MRA signatories, we mentioned the laboratory accreditation program established by the CPSC (84 FR 59452 at 59467). We restated with approval the CPSC's rationale for establishing the same requirement.

A few comments suggest that we also consider emulating the CPSC's laboratory accreditation program. Some comments particularly appreciate that, according to these comments, CPSC relies solely on ILAC–MRA signatory status to determine whether an accreditation body may accredit laboratories under CPSC's program; CPSC imposes no additional standards or requirements for accreditation bodies. According to these comments, CPSC also exercises very minimal oversight of accreditation bodies.

We note that the CPSC does not directly regulate accreditation bodies, but instead requires that laboratories participating in its program be accredited to ISO/IEC 17025 by an

accreditation body that is an ILAC–MRA signatory (see § 1112.13(a)(2)(i)). Comments contend that a similar approach by FDA would provide accreditation bodies with more flexibility and reduce FDA's costs related to accreditation body oversight. These comments suggest that even with a reduced oversight role, FDA still could participate in accreditation body assessments and ILAC peer evaluations, as do other Federal Agencies with accreditation programs. Other comments appear to misunderstand our discussion related to the CPSC in the proposed rule and perceive it as a potential framework FDA intends to use as a model for our relationship with accreditation bodies under this subpart.

(Response 61) Under Federal law, children's products must be tested by a third party, CPSC-accepted laboratory to ensure compliance with relevant safety requirements. The CPSC established requirements for third party conformity assessment bodies wishing to conduct these tests and maintains on its website a list of those conformity assessment bodies that have been accepted by the CPSC for that purpose. (For more information on the CPSC program, see *https://www.cpsc.gov/Regulations-Laws-Standards/Rulemaking/Final-and-Proposed-Rules/Third-Party-Conformity-Assessment-Bodies/*.)

Emulating the framework of the CPSC program is not feasible for the LAAF program. Whereas the CPSC does not have a formal relationship with accreditation bodies, section 422 of the FD&C Act requires that FDA establish standards for, and recognize, accreditation bodies. The statute also directs FDA to periodically review the recognition of accreditation bodies and to provide a public registry of recognized accreditation bodies. Therefore, we believe the statutory requirements for the LAAF program preclude using the CPSC framework as a model for our program.

(Comment 62) In proposed § 1.1113(c), we provided that accreditation bodies seeking recognition demonstrate sufficient scientific and technical expertise to be able to review validation and verification studies, assess a laboratory's determination that no proficiency test is available for a given method, and assess the adequacy of a laboratory's proposed alternative to a proficiency test, where none is available. In the preamble we stated that we did not consider such reviews and determinations to be traditional functions of accreditation bodies and that accreditation bodies may need to hire or contract with additional persons possessing this scientific/technical expertise.

Many comments support the notion that accreditation bodies must have the expertise to conduct substantive reviews of validation and verification studies, as well as alternatives to proficiency testing when a proficiency test is not available. However, several comments express the view that FDA need not include such a requirement in this rule because an equivalent requirement already exists, albeit in general terms, in ISO/IEC 17011:2017, and in order to be an ILAC–MRA signatory. Further, several of these comments disagree with FDA's statement that conducting a substantive review of validation and verification studies and assessing proposed alternatives to proficiency testing constitute non-traditional functions for accreditation bodies. Instead, these comments clarify that accreditation bodies routinely conduct those activities as part of the ISO/IEC 17025:2017 assessment and routinely hire qualified staff and assessors to carry out this work. They also state that satisfying the ILAC requirement is enforced and ensured by way of ILAC's robust peer evaluation process. Other comments offer conditional support for the proposed requirement that accreditation bodies demonstrate that they possess scientific/technical expertise, as long as our requirements do not impair the ability of accreditation bodies to fulfill their mission.

Some comments stress the robust nature of the peer evaluation system that provides evaluation and surveillance of ILAC–MRA signatories. Some comments express the belief that an ILAC–MRA signatory accreditation body necessarily would possess the scientific/technical expertise that FDA described in proposed § 1.1113(c).

(Response 62) Upon consideration of these comments, we agree that the requirement in proposed § 1.1113(c) regarding scientific and technical expertise is unnecessary; it does not appear in the final rule. Also, as described above, we proposed to require that accreditation bodies seeking recognition demonstrate sufficient scientific and technical expertise in part to support their review of certain validation and verification studies that would be required in connection with the testing conducted under this subpart. Under the final rule FDA will review all verification and validation studies that are required in connection with the testing conducted under this subpart. See Comment and Response 122.

(Comment 63) In the proposed rule, in connection with our discussion of recognized accreditation bodies assessing certain validation and verification studies required under this subpart as well as alternatives to proficiency tests, we stated that we may consider a variety of activities such as issuing guidance and regular roundtable meetings with recognized accreditation bodies, to communicate our expectations for such assessments. (See 84 FR 59452 at 59467). Several comments encourage FDA to provide such guidance. Some comments request a defined list of the items FDA considers necessary for a complete validation report. These comments state that an accreditation body's recognition may be revoked if the accreditation body allows a laboratory to use a method and the method was not appropriate due to errors or omissions in the validation study. Several comments suggest that clearly communicated expectations from FDA would better ensure consistency among laboratories and accreditation bodies and increase the likelihood that the studies and alternatives would be satisfactory to the Agency.

(Response 63) We acknowledge that these comments encourage FDA to issue guidance communicating our expectations for the validation and verification studies required under this subpart. Although we may do so, there is information already available on our website regarding FDA expectations for validation studies: Foods Program Methods Validation Processes and Guidelines are available at *https://www.fda.gov/food/laboratory-methods-food/foods-program-methods-validation-processes-and-guidelines.*

2. How does an accreditation body apply to FDA for recognition or renewal of recognition (§ 1.1114)?

Section 1.1128 of the proposed rule concerned how an accreditation body would apply to FDA for recognition or renewal of recognition. Paragraphs (a) and (b) of proposed § 1.1128 included the requirement for an accreditation body to submit its application for recognition or renewal of recognition to FDA. Paragraph (c) of the proposed section discussed the specific documentation requirements for an accreditation body applicant, including documentation of conformance with ISO/IEC 17011:2017, separate documentation of ILAC–MRA signatory status demonstrating competence to ISO/IEC 17011:2017, and documentation of compliance with proposed § 1.1113(c) and (d) (concerning the requirement to possess sufficient scientific and technical expertise: (1) To review certain

validation and verification studies, (2) to assess a laboratory's determination regarding proficiency test availability, and (3) to assess a laboratory's proposed comparison program; and the requirement to meet all additional requirements of the subpart) or proposed § 1.1118(c) and (d) (which covered the same provisions as proposed § 1.1113(c) and (d) for recognized accreditation bodies seeking renewal of recognition). Paragraph (d) of proposed § 1.1128 included the requirement to submit the application electronically and in English and to provide any required translation services needed by FDA during the processing of the application or an onsite assessment of the accreditation body. Finally, paragraph (e) of proposed § 1.1128 covered requirements for signing the application for recognition or renewal of recognition.

As part of our overall reorganization of the final rule, we have moved the contents of proposed § 1.1128 to § 1.1114 of the final rule. We received no comments directly related to this section of the rule; however, we have made several editorial and conforming changes to improve clarity and readability and to streamline the section. We combined proposed paragraphs (a) and (b) into a single paragraph (a) of the final rule to cover both initial and renewal applications. Paragraph (c) of the proposed rule regarding documentation has been updated to reflect correct cross-references since proposed §§ 1.1113 and 1.1118 were combined; the documentation paragraph of the final rule is now paragraph (b). We relocated the contents of proposed paragraph (d) (regarding submitting documents to FDA electronically and in English) to § 1.1110 of the final rule. Finally, proposed paragraph (e) is now paragraph (c) of the final rule.

3. How will FDA evaluate applications for recognition and renewal of recognition (§ 1.1115)?

Section 1.1129 of the proposed rule, ''How will FDA review applications for recognition and applications for renewal of recognition?'' concerned FDA evaluation of applications for recognition and renewal of recognition. Paragraph (a) of proposed § 1.1129 stated that FDA would notify an accreditation body applicant if the application is incomplete and would review completed applications in the order in which the completed application is received; however, FDA reserved discretion to prioritize review to meet program needs. Paragraph (b) of proposed § 1.1129 stated that FDA would evaluate applications and may include an onsite visit to determine whether the accreditation body applicant meets the requirements for recognition. We also noted that we may extend the term of recognition for an accreditation body if FDA's review of the application for renewal of recognition was not complete prior to the term's expiration. In paragraphs (c) and (d), we stated that we would notify an accreditation body if the application is approved and that we may grant recognition for a period up to 5 years from the date of recognition, unless our review of the application extends past the expiration of the term of recognition (as covered in proposed paragraph (b)). Proposed § 1.1129 also provided that we would notify an accreditation body applicant if we deny the application for recognition or renewal of recognition, including the basis for the denial and procedures for requesting reconsideration (see proposed § 1.1129(e)). If we deny an application for renewal of recognition, paragraph (f) stated that the accreditation body applicant would have to identify a records custodian to maintain records pursuant to proposed § 1.1124, and provide the custodian's contact information including email and street address. As discussed above regarding changes to § 1.1102, throughout this subpart when we say, ''street address,'' we mean full physical address including country; a mailing address that is not a physical address (*e.g.,* post office number) is insufficient, though supplying both types of address is acceptable (see new definition of street address in § 1.1102 of the final rule). Paragraphs (g) and (h) of proposed § 1.1129 stated that when the application for renewal of recognition is denied FDA would provide notice to laboratories accredited by the accreditation body and public notice on the website described in proposed § 1.1109.

As part of our overall reorganization of the final rule, we have moved the contents of proposed § 1.1129 to § 1.1115 of the final rule and revised the section title to ''How will FDA evaluate applications for recognition and renewal of recognition?'' We relocated the requirement in proposed § 1.1129(f) regarding submitting notifications electronically and in English to § 1.1110 of the final rule. We have made several revisions to the contents of this section to incorporate revised terminology and to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 64) Some comments suggest that FDA establish an initial accreditation body application deadline, and an approval date for all the accreditation bodies that apply for recognition by that deadline. They state that this approach would avoid any competitive advantage that might otherwise accrue to the accreditation body that first gains FDA recognition. The comments also suggest that FDA set up additional rounds of accreditation body application deadlines and recognition decisions.

(Response 64) As discussed in Response 14, we intend to implement the LAAF program in a stepwise fashion. The first step will be announcing that accreditation bodies may apply for recognition. We understand and acknowledge the concern that a competitive advantage may accrue to the first accreditation body recognized. We will consider this matter and communicate further on the details of the accreditation body application process when we announce that applications may be submitted.

4. What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition (§ 1.1116)?

Section 1.1132 of the proposed rule, ''What must a recognized accreditation body do if it wants to voluntarily relinquish its recognition or does not want to renew its recognition?'' concerned the procedures for voluntary relinquishment of recognition and non-renewal of recognition of a recognized accreditation body, including the requirement to provide to FDA a notice of intent 60 days prior to relinquishing recognition as well as a records point of contact for records required by proposed § 1.1124 (see proposed § 1.1132(a)). Paragraph (b) required the accreditation body to provide notice of intent to relinquish recognition to the laboratories the accreditation body LAAF-accredits, and paragraph (c) noted that FDA would provide notice of the same on the website described in proposed § 1.1109.

As part of our overall reorganization of the final rule, we have moved the contents of proposed § 1.1132 to § 1.1116 of the final rule. We received no comments directly related to this section of the rule; however, we made certain changes on our own initiative. First, we revised the section title to read, ''What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition?'' In paragraph (a) we clarified that when a recognized accreditation body notifies FDA of its intention to leave the program it must specify the date on which the relinquishment or expiration will occur.

We also deleted ''electronically, in English'' in paragraph (a) since this is covered by the new § 1.1110 in the final rule. We also made several conforming changes to update cross-references throughout the section to reflect the reorganized structure of the final rule and to update terminology, such as the change to ''LAAF-accreditation.'' We revised paragraphs (a) and (b) of the final rule to specify ''calendar'' days. Finally, we have made revisions to improve clarity and readability of the final rule.

5. How may an accreditation body request reinstatement of recognition (§ 1.1117)?

Section 1.1133 of the proposed rule, ''How does an accreditation body request reinstatement of recognition?'' concerned an accreditation body's request for reinstatement of recognition. Under proposed § 1.1133(a), an accreditation body that had its recognition revoked could seek reinstatement of recognition by submitting a new application along with evidence that the grounds for revocation have been resolved. As described in proposed § 1.1133(b), an accreditation body that allowed its recognition to expire or voluntarily relinquished recognition could submit a new application without additional requirements.

As part of our overall reorganization of the final rule, we have moved the contents of proposed § 1.1133 to § 1.1117 of the final rule and revised the title to read, ''How may an accreditation body request reinstatement of recognition?'' We received no comments directly related to this section of the rule; however, we revised the section to update cross-references to reflect the reorganized structure of the final rule and have made revisions to improve the clarity and readability of the final rule.

F. Comments Regarding Requirements for Recognized Accreditation Bodies

TABLE 7—CHANGES TO THE SECTIONS REGARDING REQUIREMENTS FOR RECOGNIZED ACCREDITATION BODIES

Final rule	Proposed rule	Notes
N/A (contents combined with § 1.1113)	§ 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?	
§ 1.1119 What are the conflict of interest requirements for a recognized accreditation body?	§ 1.1119 What requirements apply to how a recognized accreditation body must protect against conflicts of interests?	Editorial changes to section title.
§ 1.1120 How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories?	§ 1.1120 How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?	Revised section title to change ''evaluate'' to ''assess'' and to modify ''accreditation'' with the prefix ''LAAF-''.
§ 1.1121 When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, or reduce the scope of or withdraw the LAAF-accreditation of a laboratory?	§ 1.1121 What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant accreditation? § 1.1122(h) Appeals procedures.	Relocated section and revised section title to reflect opportunity for corrective action, to revise this use of ''probation'' to ''suspension,'' to modify ''accreditation'' with the prefix ''LAAF-,'' to refer to scope reduction, and to re-order the terms.
§ 1.1122 What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation?	§ 1.1122 When must a recognized accreditation body withdraw or reduce the scope of the accreditation of a laboratory, and when may a recognized accreditation body put an accredited laboratory on probation?	Relocated section and revised section title to include appeals for suspension, scope reduction, withdrawal, or denial of LAAF-accreditation.
§ 1.1123 What reports, notifications, and documentation must a recognized accreditation body submit to FDA?	§ 1.1123 What reports and notifications must a recognized accreditation body submit to FDA?	Revised title to include ''documentation'' to more accurately reflect the contents of the section.
§ 1.1124 What are the records requirements for a recognized accreditation body?	§ 1.1124 What records requirements must a recognized accreditation body meet?	Editorial changes to section title.
§ 1.1125 What are the internal audit requirements for a recognized accreditation body?	§ 1.1125 What internal audit requirements must a recognized accreditation body meet?	Editorial changes to section title.

1. What are the conflict of interest requirements for a recognized accreditation body (§ 1.1119)?

Proposed § 1.1119 concerned conflict of interest requirements for recognized accreditation bodies. In addition to meeting the impartiality and conflict of interest requirements in ISO/IEC 17011:2017, proposed § 1.1119(a)(1) stated the following requirements: An accreditation body, including its officers, employees, and other agents involved in accreditation activities, could not own, have a financial interest in, manage, or otherwise control a laboratory, including affiliates, parents, or subsidiary, that it LAAF-accredits. Paragraph (a)(2) prohibited the acceptance of money, gifts, gratuities, and other items of value by an accreditation body's officers, employees, and other agents from a laboratory it LAAF-accredits. Proposed § 1.1119(b) excluded the following from prohibited items of value: (1) Money representing payment for accreditation fees and services, (2) reimbursement of direct costs associated with an onsite assessment, and (3) lunch of a de minimis value in certain circumstances. Proposed § 1.1119(c) stated that the financial interest of a spouse or child under 18 years of age of any recognized accreditation body officer, employee, or other agent involved in accreditation activities would be considered the financial interest of such officer, employee, or other agent for purposes of the rule.

In addition to the changes discussed below, we have revised cross-references and terminology throughout the final rule to reflect the reorganization and revised terms in the final rule. We revised the title of the section to read, ''What are the conflict of interest requirements for a recognized accreditation body?'' We have relocated the contents of proposed paragraph (c) to paragraph (b) of the final rule to better accommodate the addition of two

new paragraphs described below. We also changed the phrase ''lunch of de minimis value'' (see proposed § 1.1119(b)(2)) to ''meal of de minimis value'' in § 1.1119(e)(2) of the final rule to provide flexibility. We also have revised this section to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 65) Many comments agree with the proposed accreditation body conflict of interest provisions in § 1.1119. Some comments express particular support that our proposed policy would allow individuals involved in accreditation decisions to accept both; (1) payment for accreditation services, including reimbursement for direct costs, and (2) lunch of de minimis value during an onsite assessment. However, some comments state that our proposed requirements would be duplicative of requirements in ISO/IEC 17011:2017.

(Response 65) We appreciate comments in support of the conflict of interest provisions. We disagree that the requirements of § 1.1119 are duplicative of ISO/IEC 17011:2017. The ISO/IEC 17011:2017 requirements for conflict of interest are stated in general terms and included in the sections on impartiality. ISO/IEC 17011:2017 section 4.4.4 specifically addresses financial conflict of interest as follows: ''All accreditation body personnel and committees who could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality. The accreditation body shall require all personnel and committee members to disclose any potential conflict of interest whenever it may arise'' (Ref. 2). In contrast, § 1.1119 offers more detailed and specific information than specified by ISO/IEC 17011:2017 with respect to what is permitted.

(Comment 66) Among the proposed conflict of interest provisions for accreditation bodies, one would prohibit the officers, employees, or other agents of an accreditation body from owning or having a financial interest in any laboratory (including an affiliate, parent, or subsidiary) LAAF-accredited by the accreditation body. Some comments specifically applaud this proposed policy. Other comments express concern that this proposed provision contains a much broader interpretation of ''conflict'' than is either the industry standard or practical in application. They state that, as proposed, this provision may apply to accreditation body board members, decision panel members, and technical committee members, among others, and could prohibit such individuals from investing in a mutual fund that includes a company with a financial interest in a laboratory accredited by the accreditation body, even if that laboratory is not LAAF-accredited and conducts no food testing. These comments suggest that FDA limit its conflict of interest provisions in two ways. First, they suggest that we limit our financial conflict of interest restrictions for accreditation bodies to the more limited cases of owning or having a financial interest in food testing laboratories LAAF-accredited by the accreditation body under this program, or that are in direct competition with listed laboratories, rather than all laboratories the accreditation body has accredited. Second, they seem to imply that the conflict of interest restrictions should apply only to individuals involved in assessments and LAAF-accreditation decisions. Certain comments from accreditation bodies explain that their practice is to ask the laboratories being assessed to declare that no conflict exists between the laboratory and the individual assessor(s) or accreditor(s). Finally, these comments mention that their conflict of interest policies have been deemed sufficient by other regulators as well as peer evaluators.

(Response 66) We appreciate support for the conflict of interest provisions proposed in § 1.1119. As a threshold matter, we note that the proposed rule defined ''accreditation'' in § 1.1102, in relevant part, as being limited to accreditation under this subpart. Therefore, proposed section 1.1119(a)(1) was intended only to prevent an accreditation body's ownership, financial interest in, management of, or control of any laboratory it LAAF-accredits under this subpart. As discussed at Response 10, we understand the potential for confusion and have updated the terminology to better clarify the scope of the rule and these conflict of interest provisions. With revisions to reflect these terminology changes, § 1.1119(a)(1) of the final rule specifies that the prohibited interests relate solely to laboratories that are LAAF-accredited by the recognized accreditation body. We decline the suggestion to apply the conflict of interest requirements for accreditation bodies as a prohibition against having a financial interest in laboratories in direct competition with LAAF-accredited laboratories because such a provision would be extremely challenging to monitor and enforce.

In response to concerns raised in these comments, we have added new paragraph (c) to this section in the final rule to permit a recognized accreditation body, including officers, employees, or other agents involved in LAAF-accreditation activities to have interest in a publicly traded or publicly available fund (such as a mutual fund), or a widely held pension or similar fund if the accreditation body exercises no control over the financial interests in the funds. We believe this type of interest to be low-risk and not to pose a meaningful conflict of interest for a recognized accreditation body.

However, we decline to only apply these and other conflict of interest restrictions to those individuals involved in LAAF-accreditation or LAAF assessment decisions. If any officer, employee, or other agent of the accreditation body owns or has a financial interest in, manages or otherwise controls a laboratory that the accreditation body LAAF-accredits, a conflict of interest exists. Protecting against conflicts of interest is critical to the integrity of this program.

(Comment 67) With regard to the proposed conflict of interest provisions for accreditation bodies, some comments indicate that whereas our proposed rule focused solely on financial conflicts of interest, ISO/IEC 17011:2017 also addresses other types of conflicts of interest such as consultation. We understand these comments to be asking whether individuals who provide consulting services to a LAAF-accredited laboratory apart from, or in preparation for, an assessment by an accreditation body (*e.g.,* the consultant who assists the laboratory with determining how to design their quality management system, or the consultant who provides services to the laboratory such as performing the laboratory's required internal audit) will be prohibited from serving as the consulting assessor that assesses the laboratory on behalf of the recognized accreditation body.

(Response 67) Proposed § 1.1119(a) stated that the conflict of interest requirements in that section were in addition to the conflict of interest requirements in proposed § 1.1118(b), which incorporated by reference, in its entirety, ISO/IEC 17011:2017. Likewise, in the final rule, § 1.1119(a) states that the conflict of interest requirements in that section are in addition to the conflict of interest requirements in § 1.1113(a), which incorporates by reference, in its entirety, ISO/IEC 17011:2017. Thus, all the requirements in ISO/IEC 17011:2017, including those regarding other conflicts of interest, are required by the final rule. Sections 4.4.11 through 4.4.13 of ISO/IEC 17011:2017 address consultancy among

the activities an accreditation body is restricted from performing. In addition to consultancy, this section of ISO/IEC 17011:2017 also addresses testing; calibration; inspection; certification of management systems, persons, products, processes and services; provision of proficiency testing; production of reference materials; and validations and verifications (Ref. 2).

(Comment 68) Some comments on the proposed section regarding conflict of interest requirements for accreditation bodies request that FDA clarify the term, ''other agents.'' These comments ask whether our proposal to include ''other agents'' among the actors prohibited from having a financial interest in any laboratory the accreditation body accredits, is intended to prohibit the accreditation body from contracting with technical assessors who may also work for a laboratory that the accreditation body LAAF-accredits. These comments state that the use of contract assessors who work in accredited laboratories is common in the industry. If we intended to prohibit that practice, these comments recommend that we instead allow it to continue. They further recommend that the applicant laboratory be made aware that the contract assessor is from another accredited laboratory and be given an opportunity to object to that assessor.

(Response 68) In light of these concerns, we have revised the final rule to include new § 1.1119(d) which permits a recognized accreditation body to use a contract assessor with a specified financial interest in a laboratory the recognized accreditation body assesses for LAAF-accreditation, if all the following circumstances apply: First, the contract assessor's primary occupation is owning or having a financial interest in, managing, or otherwise controlling a LAAF-accredited laboratory. Second, the assessor contracts with the recognized accreditation body to provide assessment services on an intermittent or part-time basis. Third, the contract assessor does not assess the LAAF-accredited laboratory that the assessor owns or has a financial interest in, manages, or otherwise controls. Finally, the contract assessor and the recognized accreditation body inform any laboratory that the contract assessor may assess or reassess for LAAF-accreditation, that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory. The laboratory seeking LAAF-accreditation assessment or reassessment must acknowledge that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory and be provided the option to be assessed by a different representative of the recognized accreditation body.

The addition of this paragraph to the final rule is intended to facilitate the existing industry practice of accreditation bodies using contract assessors from LAAF-accredited laboratories. We believe that any potential conflict of interest arising from this narrow exception is mitigated by the disclosure of the financial interest of the contract assessor to the laboratory subject to assessment for purposes of LAAF-accreditation, as well as an acknowledgement by the laboratory and the option to request a different assessor.

To accommodate changes to the final rule regarding the excepted interests described in § 1.1119(c) and (d) (see Responses 66 and 67) we have revised § 1.1119(a)(1) to expressly reference the new exceptions.

2. How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories (§ 1.1120)?

Section 1.1120 of the proposed rule, ''How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?'' concerned recognized accreditation body assessment of LAAF-accredited laboratories. This proposed section stated that recognized accreditation bodies would need to conduct an initial assessment of a laboratory seeking LAAF-accreditation onsite, unless the recognized accreditation body had conducted an onsite assessment of the laboratory in the last 2 years in accordance with ISO/IEC 17025:2017. The proposed section stated in paragraph (c) that a recognized accreditation body that had conducted an onsite assessment of a laboratory in the last 2 years in accordance with ISO/IEC 17025:2017 could conduct the initial assessment of such laboratory seeking LAAF-accreditation remotely and need only address the requirements beyond ISO/IEC 17025:2017. Once LAAF-accredited, proposed paragraph (d) required that a recognized accreditation body oversee the performance of a laboratory it LAAF-accredits in accordance with the requirements of this subpart. Proposed paragraph (e) required the assessment of the sample of the scope of LAAF-accreditation to be conducted onsite and at least every 2 years, unless, as proposed paragraph (f) stated, the initial assessment was conducted remotely under the exception in proposed paragraph (c), in which case the first assessment of the sample of the scope of LAAF-accreditation must be conducted within 2 years of the last onsite assessment in accordance with ISO/IEC 17025:2017. Proposed § 1.1120(g) also required that the reassessment of at the end of the LAAF-accredited laboratory's LAAF-accreditation cycle be conducted onsite. In all assessment scenarios in this proposed section, certain assessment activities could be conducted remotely if it would not aid the assessment to conduct them onsite. Finally, in paragraph (h), we proposed that any additional assessments beyond those referred to in the section could be conducted remotely.

We have updated cross-references and terminology throughout the section and, correspondingly, we revised the section title to read, ''How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories?'' On our own initiative, we revised § 1.1120(e) to improve clarity and readability. To better distinguish between initial assessment activities and activities conducted in subsequent assessments, we replaced several instances of ''assessment'' with ''reassessment.'' We also deleted references to assessing ''in accordance with'' ISO/IEC 17011:2017 because such references were redundant of the foundational ISO/IEC 17011:2017 requirement (§ 1.1113). Comments regarding this section are discussed below.

(Comment 69) Some comments praise FDA for the clarity of the requirements in § 1.1120. These comments state that the accreditation body would be responsible for deciding, within the parameters set by the rule, whether and when remote assessment would be sufficient.

A few comments indicate that the proposed rule did not distinctly address a laboratory's request to expand or extend its scope of LAAF-accreditation or propose requirements for how a recognized accreditation body would assess such a request. These comments suggest that a remote assessment should be allowed if the laboratory is simply adding analytes to a technique or method for which it is already LAAF-accredited. In contrast, these comments recommend that an onsite assessment be required if the request to extend the scope of LAAF-accreditation involves techniques or methods that are new to that laboratory.

(Response 69) We appreciate the support and agree that this section indicates minimum requirements but does not prevent a recognized

accreditation body from conducting additional site visits or remote visits if they so choose, provided they are not in conflict with our requirements.

Proposed § 1.1120 did not explicitly address assessments for extensions of LAAF accreditation. However, such assessments would be governed by the terms of § 1.1120, meaning that if such an assessment was not required to be onsite under paragraphs (a), (e), or (g), it would be covered by paragraph (h) and the recognized accreditation body would determine whether going onsite would aid the assessment. In most circumstances FDA would recommend that recognized accreditation bodies go onsite to assess a LAAF-laboratory for techniques, technology, and types of instrumentation that have not been previously observed during an onsite assessment. In our view, remote off-cycle assessments are generally sufficient in circumstances such as the addition of analyte(s) to a method previously evaluated during an onsite assessment, the addition of matrices to a method previously evaluated during an onsite assessment, and the addition of a method for a technique or technology that the laboratory has been determined to have competence to perform based on a previous onsite assessment.

3. When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, or reduce the scope of or withdraw the LAAF-accreditation of a laboratory (§ 1.1121)?

Proposed § 1.1122 concerned the probation, withdrawal, and reduction of scope of a laboratory's LAAF-accreditation. Paragraphs (a) and (c) of this proposed section described the grounds for withdrawal of LAAF-accreditation as when a laboratory substantially fails to comply with this subpart; it also provided that withdrawal may be limited to certain methods if the deficiencies only impact those methods within the scope of LAAF-accreditation. Paragraph (b) of this proposed section described grounds for probation as when a laboratory demonstrates deficiencies less serious than those warranting withdrawal that are reasonably likely to be fixed within a specified period of time. Proposed § 1.1122(d) stated the provision to submit required records as requested by the recognized accreditation body to assist in determining whether withdrawal or probation is warranted. This proposed section also included the procedures for withdrawal of LAAF-accreditation and for probation of a LAAF-accredited laboratory as well as the consequences of each: specifically, a laboratory would not be eligible to conduct testing under this subpart for any methods for which LAAF-accreditation had been withdrawn and a laboratory on probation could continue to conduct testing under this subpart. Paragraph (h) of this proposed section included the requirements for appeals procedures a recognized accreditation body would need to establish and implement for a laboratory to appeal any decision to withdraw LAAF-accreditation.

As a threshold matter, we moved the contents of proposed § 1.1122 to § 1.1121 in the final rule. Additionally, we have revised this section to remove proposed § 1.1122(h) regarding appeals procedures for reducing the scope of or withdrawal of LAAF-accreditation; this content has been incorporated into § 1.1122 of the final rule regarding appeals procedures for decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation. We have also revised the section to clarify that a recognized accreditation body can use suspension on a method-specific basis; we believe this change better aligns LAAF-accreditation with ISO/IEC 17025:2017 accreditation.

In response to comments, we have made substantial revisions to this section. In addition to updating terminology, we also have revised the section to include the opportunity to implement corrective action prior to suspension of a LAAF-accredited laboratory. See § 1.1121(a). A laboratory with its LAAF-accreditation suspended also has a corrective action opportunity before its LAAF-accreditation is withdrawn by the recognized accreditation body. We revised the section title to read, ''When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, or reduce the scope of or withdraw the LAAF-accreditation of a laboratory?'' to incorporate revised terminology and to better reflect the contents of the section in the final rule.

(Comment 70) Section 1.1122(a) of the proposed rule provided that a recognized accreditation body must withdraw a laboratory's LAAF-accreditation if the laboratory substantially fails to comply with this rule. We have addressed in Response 10 the confusion and concern some comments express regarding our proposed use of the word, ''accreditation'' to mean the laboratory had been approved to conduct testing under this subpart. Here we address the proposed requirement that an accreditation body act to remove a laboratory from this program if the laboratory substantially fails to comply with this rule.

Some comments state support for this proposed requirement, stating that it reflects common industry practice.

(Response 70) We appreciate support for the proposed requirements and note that the final rule is limited to impact on a laboratory's LAAF-accreditation, as opposed to having any impact on ISO/IEC 17025:2017 accreditation.

(Comment 71) Many comments highlight that the term, ''probation'' typically is not used in conformity assessment. Many comments also argue that marketplace confusion and commercial harm would likely result from use of the term, ''probation'' to describe an action that a recognized accreditation body could take against a laboratory—particularly in combination with our proposed specialized definition of the term, ''accreditation'' to mean that the laboratory satisfies the requirements of this subpart and the proposal that laboratories be labeled publicly with ''probation'' status via our online registry.

Some comments recommend that the rule allow for three actions that could be taken against a LAAF-accredited laboratory: probation, suspension, and withdrawal. Some comments recommend that FDA not establish another accreditation status outside of the ILAC–MRA and ISO/IEC 17011:2017, which provides for suspension, withdrawal, and reduction of the scope of accreditation. Some comments urge that, if FDA does use the term, ''probation'' in this subpart, we use the term solely to describe an action we might take, *e.g.,* in relation to the online registry, rather than an action taken by the accreditation body.

Some comments contend that a laboratory should not be placed on ''inactive'' status if it has been cited for noncompliance during an assessment. We understand this comment to mean that a laboratory should not be placed on probation or suspension from this program until after the laboratory has had an opportunity to take corrective action.

(Response 71) We understand that the term, ''probation'' typically is not used in this context and appreciate the recommendations for other terms. We have revised the terminology used here and throughout the rule to be more specific to LAAF-accreditation. In § 1.1121, we have revised the section to refer to ''suspension'' instead of ''probation,'' as we understand this to be a more appropriate term based on context. We also agree that the opportunity for corrective action should

be afforded prior to suspending a laboratory and we have revised the section to include such opportunity prior to a recognized accreditation body suspending a LAAF-accredited laboratory or withdrawing or reducing the laboratory's scope of LAAF-accreditation. We have retained the term, ''probation'' in the final rule to refer to an action taken by FDA with respect to a recognized accreditation body (see § 1.1131) or a LAAF-accredited laboratory (see § 1.1161).

We also acknowledge that laboratory suspension may occur at the request of the laboratory to accommodate temporary circumstances unrelated to deficiencies, such as to move locations, remodel, or while certain equipment is inoperable or otherwise unavailable. A suspension of ISO/IEC 17025 accreditation for any reason would necessarily impact LAAF-accreditation and therefore must be reported to FDA by the recognized accreditation body under § 1.1123. We intend to accurately maintain the information contained on the public registry described in § 1.1109.

Although we proposed in § 1.1122(g) that a LAAF-accredited laboratory would be permitted to continue to conduct food testing under this subpart while on probation, we have also revised the final rule to better align with the consequences of suspension in section 4.3.1 of ISO/IEC 17011:2017 (Ref. 2). Since a laboratory would not be able to hold itself out as accredited for a method subject to suspension, § 1.1121(f)(1) of the final rule states that a LAAF-accredited laboratory may not conduct food testing under this subpart using suspended methods.

(Comment 72) Some comments express concern about the proposed provisions regarding recognized accreditation bodies placing laboratories on probation or withdrawing LAAF-accreditation for the laboratory's failure to comply with the rule, when combined with what these comments describe as ''punitive and excessive'' documentation and reporting proposed requirements associated with analytical reports. We understand these comments to be expressing concern that if FDA applies exacting standards to all contents of the full analytical report, a laboratory may be deemed out of compliance with the rule for failing to satisfy those reporting requirements, at which point the recognized accreditation body may place the laboratory on probation or withdraw LAAF-accreditation.

(Response 72) We have revised the final rule to clarify that probation is an action that only FDA will take; under § 1.1121, a recognized accreditation body may suspend a LAAF-accredited laboratory. (See Response 10 for additional discussion of clarifying terminology changes in the final rule.)

It remains true in the final rule that a recognized accreditation body ''must reduce the scope of or withdraw the LAAF-accreditation of a laboratory it LAAF-accredits when the laboratory substantially fails to comply with this subpart'' (§ 1.1121(c)). However, the word, ''substantially'' is included in this regulatory provision for a reason, and that is to distinguish minor or isolated infractions from more serious failings. In the context of laboratory reporting requirements, ''substantially'' means that it would be unnecessary and inappropriate for an accreditation body to place a LAAF-accredited laboratory on probation, or to reduce the scope of or withdraw its LAAF-accreditation, for minor administrative errors in analytical reports. Nor would such errors ordinarily result in FDA placing the laboratory on probation or disqualifying the laboratory. Further, it is FDA's responsibility, and not the recognized accreditation body's, to review the performance of LAAF-accredited laboratories, including reviewing submitted analytical reports.

For more information on laboratory reporting requirements, see our discussion of § 1.1152, below. For more information on FDA review of analytical reports, see our discussion of § 1.1160 below.

4. What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation (§ 1.1122)?

Proposed § 1.1121 concerned the procedures for appeals of decisions to deny LAAF-accreditation. This proposed section specified requirements for appeals procedures in addition to those in ISO/IEC 17011:2017, including the requirement to make appeals procedures publicly available, and to use a competent person free from bias who has not participated in the accreditation decision and is not the subordinate of a person who participated in the accreditation decision.

As mentioned above, we have moved the contents of proposed § 1.1121 to § 1.1122 in the final rule. Considering the overlap between proposed §§ 1.1121 and 1.1122(h) (regarding appeals procedures for withdrawal of LAAF-accreditation), we have revised § 1.1122 of the final rule to cover appeals of denial, reduction of scope, and withdrawal of LAAF-accreditation. Additionally, we include appeals of suspension decisions in this section of the final rule; this requirement previously only appeared in § 1.1124 of the proposed rule. Accordingly, we have revised the section title to reflect the contents of the section in the final rule (''What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation?'') We also have revised the section in the final rule to update cross-references and to make minor editorial changes to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 73) Several comments support the proposed provision describing the appeal procedures that a recognized accreditation body must provide. Some comments state that ISO/IEC 17011:2017 does not specify which accreditation body actions may be appealed, and thus appreciate that the proposed rule would create appeal rights for accreditation decisions. Some comments also support our proposed requirement that an accreditation body's appeal procedures be written and publicly available. Some comments mention that at least some accreditation bodies already have internal appeals policies and procedures, some of which meet our proposed requirements, and some comments state that our proposed requirements describe the current appeals practices of ILAC–MRA accreditation bodies.

However, some comments disagree with the proposed policy that would render subordinates of the person who made the initial accreditation decision ineligible to decide the appeal. These comments suggest bias would be sufficiently avoided as long as the rule requires someone different than the initial decision-maker to decide an appeal.

(Response 73) We appreciate the comments in support of the proposed appeals procedures. Since publication of the proposed rule we have learned that ISO/IEC 17011:2017 specifies which actions an accredited laboratory may appeal within the definitions section of the standard. ISO/IEC 17011:2017 definitions, section 3.21 defines ''appeal'' as: ''request by a conformity assessment body (3.4) for reconsideration of any adverse accreditation decision (3.13) related to its desired accreditation (3.1) status''. Section 3.13 then defines ''accreditation decision'' as: ''decision on granting (3.14), maintaining (3.15), extending (3.16), reducing (3.17), suspending (3.18) and withdrawing (3.19) accreditation (3.1)'' (Ref. 2). We nevertheless specify the actions a

LAAF-accredited laboratory may appeal in § 1.1122 to maintain consistency and clarity within the subpart.

Furthermore, we also have come to appreciate that the requirement for a written and publicly available appeals procedure is required by ISO/IEC 17011:2017 as follows: section 7.13.1 requires ''The accreditation body shall have a documented process to receive, evaluate and make decisions on appeals''; 8.2.1(b)(5) states that ''[t]he accreditation body shall make publicly available . . . information on procedures for lodging and handling complaints and appeals.'' (Ref. 2). We are deleting from the final rule the requirement for a recognized accreditation body to make its appeals procedure publicly available because that requirement is already addressed by ISO/IEC 17011:2017.

Regarding the additional requirement in the proposed rule that would prohibit subordinates of the person who made the initial accreditation decision from hearing the appeal, we decline to remove this requirement because subordinates are generally not free to exercise authority that is fully independent of the supervisor, and are to some extent under the control and influence of the supervisor. Prohibiting subordinates from hearing the appeal will therefore better ensure a fair and unbiased review.

(Comment 74) A few comments request clarification as to whether an accredited laboratory can continue to conduct food testing under the LAAF program while appealing a recognized accreditation body's withdrawal of LAAF-accreditation. The comments opine that laboratories should not be permitted to conduct testing under this subpart during the appeal process.

(Response 74) We agree that laboratories should not be permitted to conduct testing under this subpart during the appeal process. Consistent with the intent of the proposed rule, the final rule provides that if a recognized accreditation body withdraws the LAAF-accreditation of a laboratory, the laboratory is immediately ineligible to conduct food testing under this rule. If the recognized accreditation body reduces the scope of LAAF-accreditation, the laboratory is immediately ineligible to conduct food testing under this rule with respect to the specific methods for which LAAF-accreditation was withdrawn. See § 1.1121(f)(2). The proposed rule would have allowed LAAF-accredited laboratories to continue to conduct tests under this subpart even if the recognized accreditation body had placed the laboratory on what we then called ''probation'' (and now call ''suspension''). To align with how suspension is handled under ISO/IEC 17011:2017 (see, *e.g.,* section 3.18 (Ref. 2)), the final rule provides that a LAAF-accredited laboratory may not conduct food testing under this subpart for any suspended methods. See § 1.1121(f)(1). Although the final rule requires the recognized accreditation body to provide an appeals process for decisions to suspend, reduce the scope of, or withdraw, LAAF-accreditation (§ 1.1122), pending such appeal, the laboratory is still suspended, has had its scope reduced, or has had its LAAF-accreditation withdrawn, and therefore cannot conduct applicable testing under this subpart.

5. What reports, notifications, and documentation must a recognized accreditation body submit to FDA (§ 1.1123)?

Proposed § 1.1123 concerned reports and notifications a recognized accreditation body must submit to FDA. Proposed paragraph (a) of this section included the general requirements for all reports and notifications under this subpart and specific recognized accreditation body and LAAF-accredited laboratory identifying information to be included as applicable. Proposed paragraph (b) of this section described the internal audit reporting requirements for a recognized accreditation body. Proposed § 1.1123(c) required immediate notification (within 48 hours) to FDA of the following: changes that affect the recognition status of the accreditation body and any LAAF-accreditation decisions such as granting, denying, or withdrawing LAAF-accreditation, putting a LAAF-accredited laboratory on probation, learning of a LAAF-accredited laboratory's intent to voluntarily relinquish LAAF-accreditation, and awareness of LAAF-accredited laboratory fraud. The proposed section included specific information to be included with each item requiring immediate notification.

On our own initiative, we revised the section title to read, ''What reports, notifications, and documentation must a recognized accreditation body submit to FDA?'' to more accurately reflect the contents of the section in the final rule. We have revised subsection (a) to remove the requirement to submit reports and notifications to FDA electronically and in English; this requirement is now in § 1.1110 of the final rule. We also revised paragraph (b) to specify ''calendar'' days. We have reorganized the section by the category of information to be submitted (*e.g.,* changes affecting recognition, changes in LAAF-accreditation) and have made revisions to improve clarity and readability, incorporate revised terminology, and update cross-references. Also, in § 1.1123(d) we have clarified that a certificate reflecting the scope of accreditation must be submitted by a recognized accreditation body within 48 hours of a change in LAAF-accreditation (*e.g.,* grant of LAAF accreditation, reduction in scope). We note that there will not be such a certificate when the recognized accreditation body denies LAAF-accreditation for all methods requested by the laboratory. In that scenario, the recognized accreditation body need only submit the information described in § 1.1123(d)(2): (i) The scope of LAAF-accreditation requested by the laboratory, (ii) the scope of LAAF-accreditation denied, and (iii) the grounds for denial.

On further review of the proposed rule, we identified a potentially duplicative notification regarding a laboratory relinquishing LAAF-accreditation; under the proposed rule, the LAAF-accredited laboratory would have to notify the recognized accreditation body and FDA 60 days prior to relinquishing LAAF-accreditation. Additionally, proposed § 1.1123(c)(4) required the recognized accreditation body to notify FDA within 48 hours after it receives notice a LAAF-accredited laboratory intends to relinquish LAAF-accreditation. We have clarified in the final rule that the recognized accreditation body must only provide notice to FDA if the laboratory has not provided notice to FDA 60 calendar days prior to relinquishment as required by § 1.1140 (see § 1.1123(d)(3) of the final rule). For clarity and to align with common conformity assessment terminology, in the final rule we consistently use the verb, ''extend,'' rather than sometimes also using the term, ''expand,'' to refer to the action of adding a method to the scope of LAAF-accreditation. That change is reflected in paragraph (d)(1)(iii) of § 1.1123, (''the effective date of the . . . extension''). We deleted the word ''alleged'' that appeared in § 1.1123(c)(7)(ii) of the proposed rule so that the requirements related to reporting laboratory fraud or false statements to FDA are internally consistent and clearly communicate the requirements for submitting such information; see § 1.1123(e)(2) of the final rule. Finally, we have clarified in § 1.1123(d)(4)(iii) that notification of a reduction of scope or withdrawal of LAAF-accreditation must include the

effective date. We have also made other conforming terminology and minor editorial revisions in this section. Comments regarding this section are discussed below.

(Comment 75) Proposed § 1.1123 listed the reports and notifications that a recognized accreditation body would be required to submit to FDA and contained proposed timeframes for submission of the reports and notifications. In § 1.1123(b) we proposed that a recognized accreditation body must submit results of an internal audit to FDA no later than 45 days after completing the audit. Some comments suggest we extend the deadline to 90 days, contending that 45 days may be insufficient for the resolution of some corrective actions.

(Response 75) Although 45 days may be insufficient time for the complete resolution of some corrective actions, we believe it is sufficient time to complete the investigation required by the corrective action process unless information is needed from an outside source that is not within the control of the accreditation body. Proposed § 1.1123(b)(3) required a description of any corrective action taken and any corrective action that the accreditation body will take; this provision of the proposed rule acknowledged that implementation or monitoring of a proposed corrective action may not have been completed within 45 calendar days but expected that a recommendation for a proposed corrective action should reasonably be completed within the 45 calendar day window. Accordingly, we decline to revise the final rule to extend the deadline to 90 calendar days.

(Comment 76) Section 1.1123(c)(1) proposed to require a recognized accreditation body to immediately notify FDA if the recognized accreditation body was aware of a change that would affect their recognition under this subpart. Comments seek clarification of what we meant by changes that would ''affect recognition.'' Some comments suggest it would be clearer if we require recognized accreditation bodies to submit to FDA reports resulting from evaluations of adherence to ISO/IEC 17011:2017.

(Response 76) The preamble discussed specific examples of ''any changes it is aware of that would affect its recognition'' as referenced in 1.1123(c) of the proposed rule. The changes listed were not exclusively those changes that would be included in the reports resulting from evaluations of adherence to ISO/IEC 17011:2017. As stated in the preamble to the proposed rule, some examples of changes that affect recognition include, but are not limited to, ''changes in the name or operations of a recognized accreditation body, such as the purchase of a recognized accreditation body by a company, as well as changes that would cause the recognized accreditation body to no longer meet the requirements of this proposed program, including if the recognized accreditation body ceases membership in ILAC or is no longer a signatory of the ILAC MRA demonstrating competence to ISO/IEC 17011:2017'' (84 FR 59452 at 59471).

(Comment 77) In § 1.1123(c)(2) through (7), we proposed to require that a recognized accreditation body immediately notify FDA of certain information related to the LAAF-accreditation status of laboratories it LAAF-accredits or laboratories that have sought LAAF-accreditation. Proposed § 1.1123(c)(2) through (6) addressed information related to accreditation or status (*e.g.,* grants or denials of accreditation). Proposed § 1.1123(c)(7) addressed information indicating that a LAAF-accredited laboratory committed fraud or submitted to FDA a material false statement. We proposed a timeframe of 48 hours for a recognized accreditation body to notify FDA of information covered by § 1.1123(c)(2) through (7).

Some comments request clarification of when the 48-hour clock starts for purposes of proposed § 1.1123(c)(2) through (6); comments ask whether the clock starts from the date the LAAF-accreditation decision is made or the date the recognized accreditation body issues the laboratory's certificate of LAAF-accreditation. These comments state that there can be a lag between when the decision is made and when the certificate is issued and appears on the accreditation body's website. These comments recommend that the 48-hour timeframe commence when the LAAF-accreditation certificate is issued to the laboratory.

With regard to proposed § 1.1123(c)(7), some comments familiar with accreditation body practice explain that, if an accreditation body is notified of potential fraud by an accredited laboratory, the accreditation body would conduct a full investigation prior to deciding whether to withdraw accreditation. According to these comments, accreditation bodies may place laboratories on suspension until the investigation is complete. The comments further state that the suspension would be lifted if and when the accreditation body receives evidence of ''sufficient corrective action'' from the laboratory and conducts followup onsite visits.

(Response 77) We understand that some comments ask when the 48-hour notification deadline starts in matters relating to LAAF accreditation. To clarify, the 48-hour window begins when the recognized accreditation body issues the certificate of LAAF-accreditation. Note that in the final rule, we have clarified that within those 48 hours, the recognized accreditation body must notify and submit to FDA the certificate reflecting the scope of LAAF-accreditation (§ 1.1123(d)). When the recognized accreditation body denies LAAF-accreditation for all methods requested by a laboratory, there is no scope certificate, and the 48-hour notification window begins when the recognized accreditation body makes the denial decision.

If a recognized accreditation body places a LAAF-accredited laboratory on suspension while it investigates potential fraud, then both the suspension and the fraud allegation would need to be reported within 48 hours. Any further decision regarding withdrawal of LAAF-accreditation or lifting of the suspension would in turn be an additional change in the laboratory's accreditation status that would trigger the 48-hour reporting requirement.

6. What are the records requirements for a recognized accreditation body (§ 1.1124)?

Proposed § 1.1124 concerned records requirements for recognized accreditation bodies in addition to those required by ISO/IEC 17011:2017. Proposed § 1.1124(a) required recognized accreditation bodies to maintain electronically, for 5 years after the date of creation, certain records related to compliance with this subpart, including records regarding: Applications for LAAF-accreditation; LAAF-accreditation decisions; appeals of adverse LAAF-accreditation decisions; oversight of LAAF-accredited laboratories; oversight of the recognized accreditation body's compliance with this subpart; reports, notifications, and supporting documents required under this subpart; and records of fee payments and direct costs. Records relating to a recognized accreditation body's oversight of laboratories it has LAAF-accredited include records of related to proficiency testing and comparison programs (see § 1.1138(a)(2)). Proposed § 1.1124(b) stated the requirement that a recognized accreditation body make required records available to FDA upon request for copying and inspection or electronically, if requested as such; the recognized accreditation body would be

responsible for submitting an English translation of any records maintained in another language. Proposed § 1.1124(c) stated that a recognized accreditation body must not prevent or interfere with FDA's access to the records of the laboratories it LAAF-accredits.

We have updated the applicable section in the final rule to incorporate revised terminology and to update cross-references. On our own initiative, we made minor editorial changes to the section title to read, ''What are the records requirements for a recognized accreditation body?'' Additionally, we removed the word, ''electronically,'' from paragraph (a) to allow flexibility around how recognized accreditation bodies maintain records. We revised paragraph (a)(2) to specify that records of decisions to suspend or lift the suspension of a LAAF-accredited laboratory must be maintained under this section. We revised paragraph (a)(3) to reflect changes to § 1.1122 of the final rule to incorporate each type of appeal. We also removed the requirement in paragraph (b) to submit an English translation of records electronically since that requirement is covered by § 1.1110 of the final rule. Also, as a result of the new accommodation added to manage conflicts of interest associated with contract assessor activities (see § 1.1119(d) of the final rule), we have added as a required record documentation demonstrating compliance with the requirements for assessment activities by contract assessors with certain financial interests described in § 1.1119(d). See § 1.1124(a)(8) of the final rule. Comments regarding this section are discussed below.

(Comment 78) A few comments request that FDA specify those records that are to be retained for 5 years, and caution that without a clear list, accreditation bodies may be delayed in submitting the documents to FDA. The comments suggest the following records be included in a specific list of records subject to 5-year retention: 1. Assessment report; 2. Corrective actions related to the assessment; 3. Complaints records; 4. Dispute/appeals records; 5. Proficiency testing results.

(Response 78) Proposed § 1.1124(a) lists the records that a recognized accreditation body must maintain for 5 years and remains unchanged in the final rule. We note that the recommended list aligns with our proposed and final requirements.

7. What are the internal audit requirements for a recognized accreditation body (§ 1.1125)?

Section 1.1125 of the proposed rule concerned internal audit requirements for a recognized accreditation body, including the requirements in ISO/IEC 17011:2017 and the requirement to audit compliance with the additional requirements of this subpart for recognized accreditation bodies. We received no comments directly related to this section of the rule. On our own initiative, we revised the section to update cross-references to reflect the reorganized structure of the final rule and made minor revisions to improve clarity and readability, including revising the section title (''What are the internal audit requirements for a recognized accreditation body?'').

G. Comments Regarding FDA Oversight of Recognized Accreditation Bodies

TABLE 8—CHANGES TO SECTIONS REGARDING FDA OVERSIGHT OF RECOGNIZED ACCREDITATION BODIES

Final rule	Proposed rule	Notes
FDA Oversight of Recognized Accreditation Bodies.	Procedures for Recognized Accreditation Bodies.	Revised section title to reflect revised terminology.
§ 1.1130 How will FDA oversee recognized accreditation bodies?	§ 1.1130 How will FDA oversee recognized accreditation bodies?	No changes to the section title.
§ 1.1131 When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?	§ 1.1131 When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation?	Revised section title to reflect opportunity for corrective action and to re-order actions to match the section contents.

1. How will FDA oversee recognized accreditation bodies (§ 1.1130)?

Proposed § 1.1130 concerned FDA oversight of recognized accreditation bodies to determine compliance with this subpart. Proposed § 1.1130(a) stated that FDA's evaluation of a recognized accreditation body would occur by at least 4 years after the date of a recognition for a 5-year term or by the mid-term point for a recognition period less than 5 years. This section stated that FDA oversight could include review of records, an onsite assessment of the recognized accreditation body, and an onsite assessment of one or more laboratories it LAAF-accredits, with or without the recognized accreditation body present. Proposed § 1.1130(b) reserved the right of FDA to conduct additional evaluations of a recognized accreditation body at any time to review compliance with this subpart.

Consistent with the discussion in Response 10, we have updated the section to refer to FDA's actions as ''evaluations'' instead of ''assessments'' to further distinguish the role of FDA from that of a recognized accreditation body. Additionally, we have made explicit that FDA may conduct certain evaluation activities remotely if it will not aid in the evaluation to conduct them onsite. We also restructured and revised this section in the final rule to update terminology and to make minor changes to improve clarity and readability. Comments regarding this section are discussed below.

(Comment 79) Some comments agree that FDA should have the authority to schedule onsite visits to observe recognized accreditation bodies, but they contend FDA should not conduct such site visits unannounced. In their view, it would be unproductive for FDA to make an unannounced onsite visit to a recognized accreditation body, because recognized accreditation bodies need notice to ensure staff will be there to answer FDA questions about the program or else risk wasting Agency time and resources. Comments also state that FDA may review accreditation body records and reports remotely and thus would not gain any further information from unannounced visits.

(Response 79) Onsite evaluations of accreditation bodies are one of several tools we will use for LAAF program oversight. Flexibility to conduct unannounced onsite evaluations will support program integrity as there may be cases where such visits may be the only way the Agency can be assured an accurate assessment of the situation. The Agency recognizes that some personnel may be not be onsite and would necessarily take this into account when planning unannounced visits. We view this as a rare but necessary tool.

(Comment 80) A few comments recommend that it would be preferable for FDA to evaluate a recognized accreditation body's program performance by observing the accreditation body while they are conducting an accreditation assessment for a laboratory. Similarly, some comments recommend that FDA observe the ILAC peer evaluation of accreditation bodies. In the view of these comments, FDA has the right to review all aspects of the accreditation program at any time.

(Response 80) We appreciate these suggestions. As stated in the proposed and final rule, we will make evaluations through a wide variety of means and the recommended approaches could be used.

2. When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body (§ 1.1131)?

Proposed § 1.1131 concerned FDA revocation of recognition and probation of a recognized accreditation body. Proposed § 1.1131(a) and (b) stated the grounds and process for revocation of recognition; FDA would revoke recognition if the accreditation body failed to meet the requirements of this subpart or if FDA determined the accreditation body committed fraud or submitted material false statements to FDA. The proposed process for revocation of recognition included issuance of a notice with a statement of the grounds for revocation and the procedures for requesting a hearing or reinstatement of recognition as well as the requirement for an accreditation body to provide a records point of contact for provision of records once the accreditation body is no longer recognized. Proposed § 1.1131(c) stated that FDA may place a recognized accreditation body on probation if there are deficiencies that are less serious and more limited than those for revocation and the deficiencies are reasonably likely to be corrected within a reasonable amount of time. Under paragraph (d) of this proposed section, we stated that probation would remain in effect until the identified deficiencies are sufficiently addressed or until FDA revokes recognition. Proposed § 1.1131(e) stated the procedures for probation and proposed paragraph (f) stated the effect of probation or revocation: an accreditation body that has had its recognition revoked may not LAAF-accredit laboratories or continue to oversee the laboratories it has LAAF-accredited; a recognized accreditation body on probation would be expected to continue to oversee the laboratories it has LAAF-accredited and permitted to continue to LAAF-accredit laboratories. Paragraphs (g) and (h) of this section stated that FDA would notify impacted LAAF-accredited laboratories of the probation or revocation of recognition of the accreditation body that LAAF-accredits the laboratory and that FDA would provide notice on the public website described in proposed § 1.1109.

We have revised the section title of the final rule to more accurately reflect the contents of the revised section, to read as ''When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?'' We also clarify in § 1.1131(d)(1) of the final rule that in the revocation of recognition procedures, FDA's notice will include the date on which the revocation is effective. We have revised the section to incorporate revised terminology and to update cross-references. We have made several changes in response to comments, discussed below.

(Comment 81) A few comments assert that it is not a usual conformity assessment practice to place an accreditation body on ''probation'' (proposed § 1.1131(c), (g), and (h)), especially if the accreditation body has only demonstrated deficiencies in matters that are less serious and do not raise concerns about the accreditation decisions of the accreditation body. These comments also state that public notice of probationary status, if done without adequate justification, may be undeserved and could potentially damage both the accreditation body and the LAAF program. We understand these comments to be expressing the concern that if the registry indicates an accreditation body is on probation, such a characterization could cause harm to the accreditation body's reputation and business interests. Further, such comments express the view that if probation was undeserved, such harm would be unwarranted. We further understand these comments to be expressing that accreditation bodies may hesitate to participate in this program if they are concerned that they may be characterized unfairly on the registry. Similarly, a few comments recommend that FDA provide an accreditation body with an opportunity to take corrective action before FDA revokes recognition. These comments argue that revocation of an accreditation body's recognition without first providing such an opportunity would adversely impact both the accreditation body and the laboratories it LAAF-accredits and would represent a ''very aggressive approach.''

(Response 81) We agree that it is appropriate to afford a recognized accreditation body the opportunity to take corrective action prior to putting the recognized accreditation body on probation and notifying the public. We have revised § 1.1131 to reflect this position. Although the opportunity for corrective action and probation may be appropriate prior to revocation of recognition, we maintain that some circumstances warrant more immediate revocation of recognition. As described in the proposed and final rule, circumstances that may warrant immediate revocation of recognition include failure to meet the requirements of the subpart or a determination that the recognized accreditation body has committed fraud or submitted material false statements to FDA.

(Comment 82) A few comments request that we clarify exactly when a recognized accreditation body will be placed in probationary status.

(Response 82) We understand from various comments that ''probation'' is not a status term typically utilized in the conformity assessment arena. We intend the status to be an intermediary step after corrective action and before we proceed to revoke our recognition of an accreditation body.

As revised, § 1.1131 provides that if FDA identifies a deficiency, utilizes the recognized accreditation body's complaint process (under ISO/IEC 17011:2017 section 7.12), but determines that the corrective action (under ISO/IEC 17011:2017 section 9.5) is not acceptable, we may place the accreditation body on probation. Section 1.1131(b) states that probation may be appropriate when FDA determines that a recognized accreditation body, ''has not effectively implemented corrective action or otherwise fails to address deficiencies identified.''

Under § 1.1131(b)(1), FDA will notify the recognized accreditation body that it is on probation, will provide the grounds for the probation, and list all deficiencies that must be corrected. Note that under § 1.1131(b)(2), probationary status will be reflected on the online registry described in § 1.1109. Probationary status will endure until either FDA is satisfied with the recognized accreditation body's corrective actions or FDA revokes the recognition under § 1.1131(c) and (d).

H. Comments on LAAF-Accreditation of Laboratories

TABLE 9—CHANGES TO SECTIONS REGARDING LAAF-ACCREDITATION OF LABORATORIES

Final rule	Proposed rule	Notes
LAAF-Accreditation of Laboratories	Accreditation of Laboratories	Revised to reflect new terminology.
§ 1.1138 What are the eligibility requirements for a LAAF-accredited laboratory?	§ 1.1138 What requirements must a laboratory meet to become accredited by a recognized accreditation body? § 1.1146 What are the general requirements for accredited laboratories to remain accredited?	Combined sections in the final rule.
§ 1.1139 How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation?	§ 1.1159 How does a laboratory apply for accreditation or modification of its scope of accreditation by a recognized accreditation body?	Relocated section, revised section title to incorporate new terminology and improve clarity.
§ 1.1140 What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation?	§ 1.1163 What if a laboratory wants to voluntarily relinquish its accreditation?	Relocated the section, revised section title to incorporate new terminology and improve clarity.
§ 1.1141 What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA?	§ 1.1164 What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition?	Relocated the section, revised section title to incorporate new terminology and improve clarity.
§ 1.1142 How does a laboratory request reinstatement of LAAF-accreditation?	§ 1.1165 How does a laboratory request reinstatement of accreditation?	Relocated the section, revised section title to incorporate new terminology.

1. What are the eligibility requirements for a LAAF-accredited laboratory (§ 1.1138)?

In proposed § 1.1138 we stated the baseline requirements for a laboratory to participate in the LAAF program. In paragraph (a)(1)(i) we proposed that a laboratory must demonstrate to a recognized accreditation body that a laboratory is capable of conducting the method(s) it wishes to perform under this subpart by submitting information to demonstrate appropriate verification or validation of each method. In paragraph (a)(1)(ii) we proposed that a laboratory must annually pass a proficiency test (or comparison program, where no proficiency test is available or practicable) for each method. In paragraph (a)(2) we proposed that a laboratory must be accredited to ISO/IEC 17025:2017 and we incorporated that standard by reference; in paragraph (b) we proposed to except certain provisions of ISO/IEC 17025:2017. In paragraph (c) we proposed that a laboratory must demonstrate it is capable of meeting and operating in conformance with all other requirements for laboratories under this subpart.

On our own initiative, we made some organizational changes. The proposed title for the section was, ''What requirements must a laboratory meet to become accredited by a recognized accreditation body?'' We proposed a separate section, § 1.1146, to address the requirements for accredited laboratories to remain accredited. There was significant overlap between the two sections. To improve efficiency and readability, we combined § 1.1146 with this section and made certain editorial changes to effect the merge, including revising the section title to read, ''What are the eligibility requirements for a LAAF-accredited laboratory?''

Proposed § 1.1148 addressed quality assurance requirements for LAAF-accredited laboratories. Proposed § 1.1148(a) required, in brief, annual proficiency testing for each method. Proposed § 1.1148(b) required a LAAF-accredited laboratory to ''[e]nsure its procedures for monitoring the validity of the results of testing it conducts under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.'' There was significant overlap between the proficiency test provisions in proposed § 1.1138(a)(1)(ii) and those in § 1.1148(a). For clarity and efficiency, we merged the proficiency test content from proposed § 1.1148(a) into what is now § 1.1138(a)(2) of the final rule. We also moved to this section the requirement for laboratory quality assurance procedures to include the use of reference materials or quality control samples with each batch of samples tested under this subpart, because we view these tools as vital to a laboratory's demonstration of capability to conduct a method. (Relatedly, we have added quality control results to the required contents of an abridged analytical report; see the discussion of § 1.1153(c)(2), below.)

Also, as explained in our discussion of § 1.1101 above, we moved the language formally incorporating ISO/IEC 17025:2017 from this section to § 1.1101. Finally, we made conforming and minor editorial changes, including specifying calendar days in § 1.1138(a)(2)(iii) (this requirement appeared in § 1.1153(b) of the proposed rule and did not specify ''calendar'' days). We discuss additional changes to the section made in response to comments below.

(Comment 83) Some comments inquire about the laboratory standards we are establishing in this final rule. Some ask which criteria should be set. A few comments appear to ask how FDA would determine which of the many existing food testing laboratories satisfy the standards we are establishing.

Some comments encourage us to ensure that all laboratory requirements are clear and concise. Other comments urge FDA to avoid what they perceive as vague and ambiguous phrases such as ''strongly encourage'' and instead to use clearer language such as ''must.''

(Response 83) The laboratory standards we are establishing are contained in this final rule, specifically in §§ 1.1138 through 1.1142. We agree that clear and concise requirements will benefit the LAAF program and we have done our best to achieve that goal. The task of determining which laboratories satisfy our requirements is the responsibility of the recognized accreditation bodies which will assess laboratories against our standards.

In the proposed rule, after stating that we would not propose to require the accreditation of sampling, we said that we ''strongly encourage all samplers to consider accreditation'' 84 FR 59452 at 59476. When we use such language, we do not intend to state a requirement, nor do we create any obligation. Only the codified section of a rule becomes the regulation. The preamble discussion

represents our current thinking on the matters addressed in the text of the regulation.

(Comment 84) In the proposed rule, a laboratory would be required to demonstrate it is capable of conducting each method it wishes to use in food testing under this subpart by submitting verification or validation information to a recognized accreditation body, as well as a statement that the laboratory was able to properly apply the method. The proposed rule would also have required a laboratory to pass a proficiency test (or comparison program when no proficiency testing is available or practicable) for each method it wishes to use to conduct food testing under this subpart once per year. Some comments express support for these requirements. Some comments state that these requirements are similar to existing ISO/IEC 17025:2017 requirements.

(Response 84) We are gratified that several comments support these requirements.

We agree that these requirements are similar to provisions in ISO/IEC 17025:2017. With regard to validation and verification information, ISO/IEC 17025:2017 requires a laboratory to submit to the accreditation body verification or validation information on each method for which it is seeking accreditation. Our requirement would accomplish the same. However, although the validation information we require a laboratory to send to a recognized accreditation body aligns with information required in ISO/IEC 17025:2017, we specify (in § 1.1151(d)(2)) the verification information in greater detail than does ISO/IEC 17025:2017 (Ref. 3).

At the same time, as discussed above at Response 10, after careful consideration of the comments we are clarifying in this subpart the roles of the FDA and recognized accreditation bodies with respect to LAAF-accredited laboratories. Consistent with our clarified role of reviewing the performance of LAAF-accredited laboratories via individual analytical reports, we have determined that it is appropriate for LAAF-accredited laboratories to submit the verification and validation studies relevant to their analytical reports to FDA (see § 1.1152(c) and discussion at Response 122). This change means FDA will receive the more detailed verification information that, under the proposed rule, we would have required a laboratory to send to the recognized accreditation body. Given that the specified verification information will be submitted to FDA, we are comfortable removing the requirement that it be submitted to the recognized accreditation body.

Having resolved that difference between proposed § 1.1138(a)(1)(i) and ISO/IEC 17025:2017, there remains no substantive difference between the two standards with regard to the validation and verification information to be submitted to an accreditation body. Accordingly, we have removed from the final rule the provision in proposed § 1.1138(a)(1)(i) requiring laboratories to send validation or verification information to the recognized accreditation body and will rely on ISO/IEC 17025:2017 for that requirement.

With regard to the proposed requirement that a laboratory pass a proficiency test for each method (or a comparison program, where no proficiency test is available or practicable) ''once per year,'' the provision in ISO/IEC 17025:2017 is similar. Section 7.7.2 of ISO/IEC 17025:2017 requires a laboratory to monitor its performance by engaging in either proficiency testing or interlaboratory comparisons but does not indicate a frequency (Ref. 3). We remain committed to the frequent nature of this requirement and therefore the final rule requires that a LAAF-accredited laboratory must successfully pass a proficiency test (or where one is not available or practicable, a comparison program) for each LAAF-accredited method at least once every 12 months. For additional discussion of the proficiency testing requirements under this subpart, see Responses 92–94, below.

(Comment 85) Some comments support the proposed policy that LAAF-accreditation should be awarded on a method-by-method basis. In fact, some comments consider method-specific LAAF-accreditation so important that they suggest we communicate that requirement more clearly in the final rule. Some comments encourage us to clarify the use of open or flexible scopes under this subpart.

(Response 85) We agree that it is essential that the competency of laboratories be assessed, and LAAF-accreditation awarded, on a method-specific basis. Test methods vary widely and even within the same discipline, competence to one method does not correlate or imply competence to another method. Further, laboratory competence to the particular method employed is integral to the validity of the test result. Accordingly, we accept the suggestion in the comments summarized above and have revised § 1.1138 to include ''each method'' in paragraph (a) and (a)(1).

ISO/IEC 17011:2017 defines a flexible scope (sometimes referred to as an open scope), as a ''scope of accreditation . . . expressed to allow [laboratories] to make changes in methodology and other parameters which fall within the competence of the [laboratory] . . . as confirmed by the accreditation body.'' (ISO/IEC 17011:2017 section 3.7, (Ref. 2)). Flexible scopes can have flexibility for analytes, matrices, and methods. ISO/IEC 17011:2017 requires accreditation bodies to have written procedures describing how the accreditation body will administer flexible scopes. As relevant to this discussion, these written procedures must include a description of how the accreditation body will maintain for the laboratories they LAAF-accredit certificates of scope that include matrix (materials or products); analyte(s) (component, parameter or characteristic); and method or technology (Ref. 2).

An open or flexible scope is employed when an accreditation body assesses a laboratory's competency in using a particular technology or technique. Once the laboratory proves that competency, it is able to add methods, analytes, or matrices to its scope without the need for an additional assessment by the accreditation body as long as those additions fall within the broader scope of the accredited technology and meet the requirements of ISO/IEC 17025:2017.

Given that ISO/IEC 17011:2017 requires accreditation bodies to maintain certificates of accreditation that communicate which analytes, matrices, and methods are covered by the flexible scope, and § 1.1123(c)(2) requires that a recognized accreditation body must immediately notify FDA when it grants or extends a laboratory's LAAF-accreditation, we are prepared to accommodate open or flexible scopes under this subpart.

(Comment 86) We proposed in § 1.1138(a)(2) that, as a baseline matter, laboratories wishing to conduct testing under this subpart must be accredited to ISO/IEC 17025:2017, and we proposed to incorporate ISO/IEC 17025:2017 by reference into our regulation. We proposed in § 1.1138(b) to exclude three portions of ISO/IEC 17025:2017 from the incorporation by reference, and from the requirements under this subpart. First, we proposed to exclude provisions of ISO/IEC 17025:2017 that relate to the relationship between the laboratory and its customers, to the extent that such provisions establish obligations that conflict with the requirements of this subpart. Second, we proposed to exclude section 7.3

because, we reasoned, it addresses sampling and we did not propose to require the accreditation of samplers. Finally, we proposed to exclude section 7.8, which describes requirements for reporting test results to customers, based on a concern that it might conflict with the test reporting requirements in this subpart (Ref. 3).

Many comments support the baseline laboratory requirement of accreditation to ISO/IEC 17025:2017. Some comments commend the use of this standard, noting that it may be a means to improve the quality of tests, and is accepted globally. Some comments maintain that accreditation to ISO/IEC 17025:2017 increases confidence in a laboratory's data. Some comments indicate that many laboratories that test imported food have already sought ISO/IEC 17025:2017 accreditation voluntarily to improve the quality of their test results. Some comments assert that conformance to ISO/IEC 17025:2017 helps ensure scientific integrity in food testing. Some comments state that relying on ISO/IEC 17025:2017 accreditation will be more efficient for FDA. A few comments express the belief that all private laboratories should be required to be ISO/IEC 17025:2017-accredited.

A few comments agree that ISO/IEC 17025:2017 is currently the predominant standard for the type of laboratory that would conduct testing under this subpart, but encourage FDA to allow more flexibility, stating that over time ISO/IEC 17025:2017 might become less predominant.

Some comments encourage FDA to rely solely and entirely on ISO/IEC 17025:2017; we understand these comments to discourage us from adding any additional requirements or varying at all from ISO/IEC 17025:2017. (To the extent that some comments reference ISO/IEC 17065, which is a conformity assessment standard for bodies that certify products, that standard does not apply here.) These comments express preference for a single uniform accreditation standard and contend that varying standards can present challenges both to laboratories attempting to maintain multiple differing accreditation schemes and to their customers. Some comments state a risk that variations in standards, even different standards based on ISO/IEC 17025:2017, may result in a need for laboratories to be accredited by more than one accreditation body, and encourage FDA to reduce or eliminate redundant accreditations. Some comments encourage FDA to work with leading standard and scientific organizations so that the various standards align and have scientific integrity.

With regard to the ISO/IEC 17025:2017 sections that we proposed to exclude from our requirements, some comments support some or all the exclusions. Some of these comments agree with our proposal not to require the accreditation of samplers and express consequent support for the exclusion of ISO/IEC 17025:2017 section 7.3, which addresses sampling. Some comments concur with our proposed exclusion of customer-related ISO/IEC 17025:2017 provisions, but disagree with the proposed exclusions related to sampling and reporting results because these comments state the belief that FDA should require the accreditation of samplers and better align its reporting requirements with those of ISO/IEC 17025:2017.

On the other hand, many comments encourage us not to exclude certain or any ISO/IEC 17025:2017 provisions. Some comments specifically suggest that we include ISO/IEC 17025:2017 requirements related to customers, as owners and consignees under this rule could be considered the customers of LAAF-accredited laboratories. Some of these comments disagree that the provisions we proposed to exclude conflict with the requirements in this subpart, and suggest that even if they do, any conflicts can be effectively addressed without excluding ISO/IEC 17025:2017 provisions.

Relatedly, some comments state that adherence to certain requirements contained in ISO/IEC 17025:2017 is required only by specific customers; these comments request that we clarify who is the customer of a LAAF-accredited laboratory (*i.e.,* FDA or the owner or consignee). These comments also ask whether ISO/IEC 17025:2017 requirements with which the customer requires adherence will apply to State laboratories that become LAAF-accredited.

A few comments express the belief that documents can be developed to supplement ISO/IEC 17025:2017 accreditation, and that such documents would cover the additional requirements codified in this subpart. Some comments argue that excluding certain parts of the ISO/IEC 17025:2017 standard from our requirements while still labeling a laboratory, ''accredited,'' would cause confusion and would conflict with established business and operational models in laboratories fully compliant with ISO/IEC 17025:2017. Similarly, some comments request that FDA require ISO/IEC 17025:2017 as a baseline matter, and then indicate additional requirements to clarify or expand upon the standard. Comments also state that FDA should stay current with any changes to ISO/IEC 17025:2017.

(Response 86) We remain committed to ISO/IEC 17025:2017 as a baseline requirement for laboratories that wish to conduct food testing under this subpart. Many comments agree with that aspect of the proposed rule and identify various benefits of this policy such as improved test quality; greater scientific integrity; and global acceptance of, and increased confidence in, the test results. We concur. As described in the FRIA (Ref. 4), we also agree that FDA will experience certain efficiencies as a result of this rule. And while we encourage all food testing laboratories to consider becoming accredited to ISO/IEC 17025:2017, we lack the authority to compel such action.

Regarding the possibility that ISO/IEC 17025:2017 may not always be the predominant standard for food testing laboratories, we are confident that ISO/IEC 17025:2017 will be an appropriate baseline for the foreseeable future. Other parts of FDA, and many other Federal Agencies, also rely on ISO/IEC 17025:2017 to establish baseline requirements for their laboratory accreditation programs (*e.g.,* FDA Center for Devices and Radiological Health Accreditation Scheme for Conformity Assessment, CPSC, Department of Defense Environmental Laboratory Program). Every time ISO/IEC updates the 17025 standard, we will consider whether to update this subpart (through notice-and-comment rulemaking) to require accreditation to the updated standard. If during those considerations we conclude that ISO/IEC 17025:2017 is no longer an appropriate baseline for our requirements, we will revise this subpart accordingly (through notice-and-comment rulemaking).

Some comments encourage us to simply rely on ISO/IEC 17025:2017 and neither add nor subtract any requirements. Comments advocating that we not add requirements to ISO/IEC 17025:2017 discuss the advantages of a uniform standard. We do not discount those advantages or the challenges that laboratories face in satisfying varying accreditation schemes. Nevertheless each laboratory requirement that we add to the ISO/IEC 17025:2017 baseline serves an important program purpose. For example, requiring successful proficiency tests for each method at least every 12 months (§ 1.1138(a)(2)) provides increased quality assurance, and requiring at least the creation and retention of the records that comprise a full analytical report will preserve FDA's ability to conduct a meaningful

indepth scientific review of the test (§§ 1.1150(d), 1.1154(a)(2)). As a reminder, all the food testing that takes place under this subpart occurs in the context of heightened public health concern. Laboratories that wish to conduct food testing under this subpart will be required to satisfy requirements in addition to those specified in ISO/IEC 17025:2017 (Ref. 3).

After carefully considering the comments, we have decided not to exclude any provisions of ISO/IEC 17025:2017. Comments successfully argued that our proposed exclusions would unnecessarily complicate the work of the recognized accreditation bodies and LAAF-accredited laboratories and provide limited benefit. We also appreciate the comments remarking that market confusion could result from our exclusion of portions of ISO/IEC 17025:2017 while labeling laboratories ''accredited.'' Although we doubt our proposed exclusion of a small number of ISO/IEC 17025:2017 provisions would result in a need for duplicative accreditation body assessments, we need not belabor that issue raised in the comments, given our decision.

In particular, we are persuaded that we do not need to formally exclude from our regulation ISO/IEC 17025:2017 section 7.3, which addresses sampling, even though we are not requiring sampling accreditation (Ref. 3). Section 7.3 is not necessary to ISO/IEC 17025:2017 accreditation. Indeed, many laboratories are accredited to ISO/IEC 17025 for diverse types of methods and yet not for sampling. When a recognized accreditation body assesses a laboratory for LAAF-accreditation, the recognized accreditation body may simply note section 7.3 as not applicable.

We also proposed to exclude any provisions of ISO/IEC 17025:2017 that relate to the relationship between the laboratory and its customer, to the extent that the provision would conflict with the requirements of this subpart. For example, in the preamble to the proposed rule we expressed concern that including ISO/IEC 17025:2017 section 7.2.1.4, which indicates that the customer may specify the test method, could create a conflict for the laboratory (see 84 FR 59452 at 59477 to 59478). We are now convinced that provisions of ISO/IEC 17025:2017 that mention the customer do not conflict with obligations under this subpart because under ISO/IEC 17025:2017, ''customer'' has a broader meaning than simply the entity who pays the laboratory, and FDA qualifies as a customer alongside the owner or consignee that engages the laboratory (Ref. 3). We appreciate comments noting that the owners or consignees are customers and we should therefore not exclude the ISO/IEC 17025:2017 customer provisions on that basis. We agree that owners and consignees are appropriately considered customers of the laboratory and appreciate that under this subpart, LAAF-accredited laboratories will fulfill their obligations to owners and consignees, as well as their obligations to FDA. This is ensured by the requirement in ISO/IEC 17025:2017 section 5.4 that ''Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition'' (Ref. 3). Regarding the question of whether state or other public laboratories that become LAAF-accredited will be bound by the customer provisions in ISO/IEC 17025:2017, we confirm that they will. The many public laboratories that are or will become ISO/IEC 17025:2017-accredited are required to meet the same requirements of ISO/IEC 17025:2017 as private laboratories, including both customer provisions and the requirements of section 5.4.

Finally, we proposed to exclude ISO/IEC 17025:2017 section 7.8, which addresses reports, based on a concern that it would conflict with the reporting requirements under this subpart. Again, we have come to appreciate that a laboratory's reporting duties under ISO/IEC 17025:2017 do not present any conflict for the laboratory also fulfilling the reporting requirements under this subpart (Ref. 3).

Accordingly, the final rule incorporates ISO/IEC 17025:2017 in its entirety.

(Comment 87) Some comments recommend that FDA allow the bottled drinking water tests in § 1.1107(a)(1)(iii) (*i.e.,* the requirement in § 129.35(a)(3)(i) to test five samples from the same sampling site that originally tested positive for *E. coli*) to be conducted by laboratories certified or accredited to other water-related laboratory accreditation or oversight programs such as the National Environmental Laboratory Accreditation Program, or EPA or State water testing certification programs. From the perspective of these comments, the EPA and State water testing certification programs are an existing laboratory oversight system and FDA should leverage those certifications, in place of LAAF-accreditation, for purposes of the bottled drinking water testing subject to this final rule. These comments predict that if we fail to do so, an insufficient number of laboratories will become LAAF-accredited to conduct the bottled drinking water testing required by § 1.1107(a)(1)(iii). Relatedly, these comments disagree with our proposed conforming revision in the bottled drinking water regulations. Instead of revising the bottled drinking water regulation to require that the testing required in § 129.35(a)(3) be conducted under this subpart, these comments recommend that the bottled drinking water regulations be revised to require that the testing in § 129.35(a)(3) be conducted by a competent commercial water testing laboratory that is EPA or State-certified for *E.coli* testing and sends the results directly to FDA.

(Response 87) For a variety of reasons, we decline this request.

First, FDA lacks the authority under section 422 of the FD&C Act to directly accredit laboratories or otherwise approve them to conduct the food testing described in § 1.1107. FSMA section 202 directed that FDA recognize accreditation bodies, establish standards for laboratories, and create a public registry of recognized accreditation bodies and LAAF-accredited laboratories (section 422(a)(1)(b) and (a)(6) of the FD&C Act). FSMA section 202 describes only the recognized accreditation bodies as having the ability to accredit a laboratory (see, *e.g.,* section 422(a)(1)(B), (a)(2), (a)(5), (a)(6), and (b)(1) of the FD&C Act). In contrast, FSMA section 307 directed FDA to establish a very similar program: ''a system for the recognition of accreditation bodies that accredit third-party auditors'' [9] (Section 808(b)(1)(A)(i) of the FD&C Act). However FSMA section 307 specifically granted FDA authority to directly accredit third-party auditors if, 2 years after establishing the required system, FDA had not recognized an accreditation body (section 808(b)(1)(A)(ii) of the FD&C Act). As Congress specifically provided FDA with authority to directly accredit third-party auditors in FSMA section 307, we presume their decision not to provide FDA with similar authority in FSMA section 202 was intentional. Accordingly, we lack the authority to directly accredit or otherwise approve laboratories for inclusion in the LAAF program generally or the public registry in particular.

The only way a laboratory may conduct the food testing described in

[9] Under that authority we issued the ''Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications Final Rule,'' 80 FR 74569 (Nov. 27, 2015) which established the Accredited Third-Party Certification Program (see *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program*).

§ 1.1107, then, is through a favorable assessment by a recognized accreditation body. In conducting such an assessment, a recognized accreditation body assesses the laboratory against the model laboratory standards we are creating in this final rule. Theoretically we could tailor our model standards to allow for sector-specific standards, if we were confident that those sector-specific standards provided equal rigor and public health protections. For example, theoretically we could allow laboratories that conduct the testing described in § 1.1107(a)(1)(iii) to substitute our laboratory requirements based on accreditation to ISO/IEC 17025:2017 with a sector-specific accreditation standard such as the standard of the National Environmental Laboratory Accreditation Program, or the standard of the EPA water testing certification programs. However, FDA lacks the resources to perform indepth comparisons of various program standards, whether related to bottled drinking water or any other sector, with ISO/IEC 17025:2017 and the remainder of our requirements. Indeed, a prime advantage of relying on an international voluntary consensus standard for our baseline requirement is uniformity. ISO/IEC 17025:2017 is a single standard that addresses technical competency and quality management universally; its requirements mean the same thing in every country and context in which it is used. For those practical and philosophical reasons, we decline the comments' suggestion that we allow bottled drinking water sector-specific laboratory standards in place of the model laboratory standards established in this subpart.

In declining this suggestion, we offer a few additional notes. To the extent a sector-specific standard is also based on ISO/IEC 17025:2017, it should not be difficult or costly for a laboratory accredited to such a sector-specific standard to become LAAF-accredited. Further, the tests described in § 1.1107(a)(1)(iii) (and methods deemed acceptable under § 129.35(a)(3)(ii)) involve analyzing water for the presence of *E. coli,* which is not an uncommon capability among food laboratories accredited to biological methods. Meanwhile, we estimate that there will be one testing occasion per year resulting in five separate tests under § 1.1107(a)(1)(iii). (Ref. 4). We therefore believe it is reasonable to anticipate sufficient capacity among LAAF-accredited laboratories to handle the bottled drinking water testing covered by this final rule.

(Comment 88) Some comments describe the positive features of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) laboratory accreditation standard. These comments state that results from AAVLD laboratories are accepted by Federal Agency laboratory networks focused on disease surveillance, and that AAVLD laboratories already perform research and emergency response work for FDA. These comments further state that the AAVLD standard is aligned with ISO/IEC 17025:2017.

(Response 88) AAVLD-accredited laboratories play a critical role in FDA programs. Many of the veterinary diagnostic laboratories that are part of FDA's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) are AAVLD-accredited. Vet-LIRN laboratories enhance public health by providing testing of food and animal feed products for zoonotic pathogens. These laboratories also perform pathogen and chemical toxin testing in response to foodborne and animal feed-associated illnesses. Vet-LIRN laboratories respond to requests for testing as directed by FDA resulting from consumer complaints, and participate in surveillance studies, method development activities, and proficiency tests. These laboratories primarily analyze animal samples (*e.g.,* stool, urine, blood, tissue) and nonregulatory animal food samples (*e.g.,* leftover opened foods and feed) to help FDA's Center for Veterinary Medicine (CVM) investigate potential problems with CVM-regulated products (such as animal feeds or animal drugs). Use of a LAAF-accredited laboratory is required for those tests described in § 1.1107, but the vast majority of the analyses performed as part of the Vet-LIRN do not fall under § 1.1107. Accordingly, it is not necessary for laboratories participating in the Vet-LIRN to become LAAF-accredited.

To the extent that an AAVLD-accredited laboratory wishes to participate in the food testing described in § 1.1107, it would need to meet all the requirements for a LAAF-accredited laboratory in this subpart. For reasons discussed above in Response 87, FDA cannot admit laboratories meeting other standards into this program. The only way a laboratory may become LAAF-accredited is through a favorable assessment by an accreditation body recognized under this subpart. That construct does not comport with the structure of the AAVLD laboratory accreditation program. AAVLD laboratory accreditation is awarded by AAVLD itself, following an assessment by a committee of laboratory professionals from other AAVLD laboratories. However, AAVLD is not an ILAC–MRA signatory accreditation body that comports with ISO/IEC 17011:2017. Accordingly, it is not eligible for recognition under this subpart.

Moreover, our analysis of the AAVLD standard indicates that although the AAVLD standard is aligned with ISO/IEC 17025:2017, differences remain. For example, the AAVLD standard is designed to assess the laboratory as a whole, rather than particular testing methods. Also, the AAVLD reassessments occur at least once every 5 years, whereas ISO/IEC 17011:2017 section 7.9.3 requires that laboratories be reassessed at least every 2 years (Ref. 2).

For the foregoing reasons, an AAVLD laboratory wishing to conduct the food testing described in § 1.1107 would need to be accredited to ISO/IEC 17025:2017 and satisfy the other laboratory requirements described in this final rule. However, LAAF-accreditation is not required for an AAVLD laboratory to continue to participate in the Vet-LIRN.

(Comment 89) Some comments request that we consider a modified set of requirements for small specialized laboratories such as those that solely analyze DWPE samples to determine the presence of filth and decomposition in seafood. These comments suggest that we not require ISO/IEC 17025:2017 accreditation for small specialized laboratories; instead, such laboratories should be required to provide the laboratory analyst's qualifications, the materials and methods used to conduct the test, and be subject to random FDA audits. A subset of these comments states that, for small specialized laboratories, the ISO/IEC 17025:2017 accreditation requirement would be too onerous for such laboratories to continue operating. Specifically, comments list the cost of initial certification, annual fee, training, internal program writing, and corrective action responses as examples of particularly onerous requirements. These comments emphasize the over-representation of small laboratories in the total number of laboratories that conduct analyses of food subject to DWPE by referring to estimates reported in the preamble to the proposed rule that 84 percent of the current DWPE analyses are performed by 10 laboratories, while about 90 laboratories performed the remaining 16 percent of the analyses. The comments assert that providing modified requirements for small businesses would be consistent with other FSMA regulations.

(Response 89) We decline to provide a modified set of requirements for specialized laboratories of any size. The purpose of the LAAF program is to help ensure quality testing in the context of heightened food safety concerns. To achieve this public health goal, we have determined that without exception, only laboratories that satisfy all applicable laboratory standards may conduct the tests covered by this subpart. We reach the same conclusion when we consider the specific testing mentioned in some of these comments: DWPE testing of seafood for filth and decomposition. FDA places products on DWPE when we have evidence that such products appear to be in violation of FDA's laws and regulations. Moreover, seafood products which were filthy and decomposed have been implicated in past foodborne illness outbreaks (*e.g.,* scombrotoxin fish poisoning; (Ref. 12)). Filth and decomposition are specified as the reasons some seafood products are subject to DWPE (*e.g., https://www.accessdata.fda.gov/cms_ia/importalert_19.html*; *https://www.accessdata.fda.gov/cms_ia/importalert_43.html*). We cannot find any basis for concluding that DWPE testing of seafood for filth and decomposition should be subject to different quality standards.

ISO/IEC 17025:2017 includes technical competency, impartiality, and quality management system standards, and we view these components as critical in the context of testing covered by this subpart. By way of example, section 4.1 of ISO/IEC 17025:2017 provides that laboratory activities must be managed to safeguard impartiality and states that the laboratory may not allow commercial and financial pressures to compromise its impartiality (Ref. 3). The testing covered by this subpart involves heightened food safety concerns, and we can find no basis to justify modifying these standards or the other protections included in ISO/IEC 17025:2017 accreditation.

Next we address the data analysis supporting the proposed rule, which indicated that 96 laboratories conducted about 16 percent of the analyses on food products detained when offered for import because the food was or appeared to be violative (84 FR 59452 at 59457) (Ref. 15). The same data analysis indicated that 34 of those 96 laboratories were accredited to ISO/IEC 17025, and that 44 laboratories already accredited to ISO/IEC 17025 conducted about 95 percent of the analyses. The same data analysis indicated that 62 unaccredited laboratories accounted for the remaining 5 percent of import-related analyses.

To the extent that comments requesting modified standards for specialized laboratories intend to imply that most or all of the 62 unaccredited laboratories that conducted import-related food testing were small, we do not have enough information to reach this conclusion. In addition, we have no way of knowing how specialized these 62 laboratories are; some may conduct only DWPE testing, but we cannot tell the range of analyses each conducts.

Even if we assume a high proportion of small, specialized laboratories that focus on DWPE testing, we expect the costs for such laboratories to become ISO/IEC 17025:2017-accredited to be less than the costs for larger laboratories and those with a more diverse set of testing capabilities. Reasoned assumptions which may reduce the cost of ISO/IEC 17025 accreditation for small, specialized laboratories include: (1) The ability to efficiently manage data collection and maintenance using relatively simpler in-house databases, particularly for seafood filth and decomposition testing, which generates discrete data; (2) lower onsite assessment costs since an accreditation body necessarily will spend less time assessing a smaller scope of accreditation (*e.g.,* 1–3 methods); [10] and (3) reduced costs for equipment and proficiency samples due to the small number of methods performed.

All testing covered by this subpart, including filth and decomposition testing in seafood for DWPE purposes, is of critical public health significance. As described above, we estimate that the costs of ISO/IEC 17025:2017 accreditation generally should be lower for laboratories with very few methods in their scope. On balance, we do not think the costs of requiring relatively small laboratories that conduct specialized testing to become ISO/IEC 17025:2017-accredited to perform covered testing outweigh the benefits that will be derived from doing so.

For these reasons, we decline the request to modify LAAF program standards for certain laboratories.

(Comment 90) Some comments recommend that FDA require laboratories wishing to conduct food testing under this subpart to be accredited to both ISO/IEC 17025:2017 and the supplemental document, ''AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2017'' (the AOAC 17025 Guidelines) (Ref. 13). Other comments maintain that the AOAC 17025 Guidelines are not appropriate for laboratories that test only animal food or feed, and not human food. Instead, these latter comments suggest that for laboratories testing animal food or feed, FDA should require the accreditation to ISO/IEC 17025:2017 and ''Quality Assurance/Quality Control Guidelines for Feed Laboratories,'' the guidance on interpreting ISO/IEC 17025:2017 issued by the Association of American Feed Control Officials (AAFCO) (Ref. 14). For laboratories that test both human food and animal food or feed, these comments recommend FDA require accreditation to both supplemental guidelines.

(Response 90) In several places in the preamble to the proposed rule, FDA took note of how a matter is addressed in the AOAC 17025 Guidelines. For example, in our discussion of our proposed requirement that laboratories pass a proficiency test (or a comparison program if no proficiency test is available or practicable) annually for each method to which they are LAAF-accredited, we noted that the AOAC 17025 Guidelines contain a similar requirement and exception (84 FR 59452 at 59477). It appears that some readers may have misunderstood these discussion points, and mistakenly believed that we proposed to require laboratories to comply with all AOAC 17025 Guidelines or to be accredited to both ISO/IEC 17025:2017 and the AOAC 17025 Guidelines. Although we found it instructive to consider the approach taken by the AOAC 17025 Guidelines on certain matters, we did not propose that laboratories must be accredited to both ISO/IEC 17025:2017 and the AOAC 17025 Guidelines. In addition, we acknowledge the AAFCO guidelines provide equally useful supplemental information in animal food testing matters. The AAFCO guidelines share best practices which would assure that data of appropriate quality are generated by laboratories for feed programs and may be useful for producing reliable and defensible analytical test results. After careful consideration, we decline the suggestion to require either the AOAC or AAFCO guidelines in this subpart, but agree that both provide useful supplemental information. We do not presently perceive a need for such a requirement, and as some comments have pointed out, there may be challenges around the breadth of the AOAC 17025 Guidelines considering the wide variety of tests required to be conducted by LAAF-accredited laboratories under this subpart.

[10] A laboratory that is ''specialized'' necessarily performs a narrow range of methods.

(Comment 91) A few comments seek clarification of the roles of Federal, State, and local regulatory laboratories with respect to this rule. Some comments seek clarification on whether State and local regulatory laboratories that are already accredited to ISO/IEC 17025:2017 by an ILAC–MRA signatory and may have agreements with FDA for testing related to food safety inspections, will need to do anything differently as a result of this rule. Some comments posit that only a few public laboratories are conducting the testing covered by this subpart, and those laboratories may already operate under quality management systems, and perhaps even ISO/IEC 17025:2017.

Some comments suggest that Federal laboratories (*e.g.,* a laboratory within a Federal Agency) should be considered equivalent to LAAF-accredited laboratories. Stated differently, these comments recommend that if an owner or consignee uses a Federal laboratory, the result should be acceptable to FDA even if the laboratory is not LAAF-accredited.

(Response 91) Federal, State, and local regulatory laboratories perform the vital function of testing product samples of human food, and animal food and feed, collected by public health officials either in the course of an investigation or as part of routine market surveillance. Over the years great strides have been made at all levels of government to build an integrated food safety system; improving coordination with and among public regulatory laboratories has been an important part of that work. This subpart does not impact those tests and so it may be irrelevant to many public regulatory laboratories.

On the other hand, in addition to testing samples collected by public health officials, some public regulatory laboratories may also currently conduct some of the food testing that is covered by this subpart. For full details see § 1.1107, but the bulk of the testing covered by this subpart falls within the categories of certain tests of bottled drinking water, shell eggs, and sprouts; testing to support removal from import alert; and testing to support admission of an imported food product detained at the border because FDA has determined that the food is, or appears to be, adulterated or misbranded. Once this subpart is fully implemented, all testing covered by this rule must be conducted by a LAAF-accredited laboratory. Public regulatory laboratories may become LAAF-accredited laboratories; indeed, the statute specifically contemplates public laboratories participating in this program (''laboratories, including independent private laboratories and laboratories run and operated by a Federal Agency (including the Department of Commerce), State, or locality'' (section 422(a)(2) of the FD&C Act)). All laboratories, including public regulatory laboratories, that wish to become LAAF-accredited must satisfy the requirements of this subpart.

Similarly, an array of laboratories throughout the Federal government conduct a variety of tests in service to the missions of their organizations. Any Federal laboratories that wish to become LAAF-accredited to conduct the testing covered by this subpart will need to satisfy the requirements of this subpart.

(Comment 92) We received several comments regarding the frequency with which we should require proficiency testing (or a comparison program, where no proficiency test is available or practicable). Some comments applaud the proposed requirement for an annual proficiency test for each method (or comparison program, where no proficiency test is available or practicable). Some comments suggest that the annual frequency be set as a minimum requirement, as even more frequent proficiency testing would allow for trending of results. Other comments suggest FDA defer to ISO/IEC 17025:2017 for proficiency testing frequency. Some of these comments seek to clarify how the FDA will handle the annual proficiency testing requirement in the case of open or flexible scopes. Some comments express that it is hard to find a proficiency test provider that includes all analytes for such a method. Other comments state that owners or consignees may have a difficult time finding laboratories that are both ISO/IEC 17025:2017-accredited and have performed a proficiency test for the analyte/method combination within the last year for emerging issues, new methods, or novel matrices being sampled and tested.

(Response 92) Proficiency testing is a quality assurance mechanism provided by an independent provider that results in an indication of a laboratory's performance of a method. A successful proficiency test round indicates that a laboratory can competently analyze samples by that method whereas an unsatisfactory result indicates that the laboratory needs to investigate and correct the cause(s) of the unsatisfactory result.

Although participation in proficiency testing provided by an outside, independent provider is desired for all testing, we recognize that it is not available for all test methods, specific analytes, or matrices; or that, where available, it may not occur at the required frequency. Therefore, we allow as an option a similarly designed comparison program which will provide a demonstration of the laboratory's competence to perform a method not covered by an available proficiency test program. The comparison program should be an independent or blind test of the laboratory's performance of a method that is evaluated against the expected performance of the method resulting in a conclusion of the laboratory's performance as acceptable or unacceptable. All the testing covered by this subpart is occurring in the context of heightened public health concern. We must therefore be assured that LAAF-accredited laboratories are producing accurate test results. For example, the results of testing conducted under § 1.1107(a)(4) are used as evidence to overcome an appearance that a product detained at the border violates FDA laws and regulations.

We agree that requiring LAAF-accredited laboratories to successfully complete an annual proficiency test (or a comparison program, where no proficiency test is available or practicable) for each LAAF-accredited method is important to support the testing under this subpart. We have determined that deferring to the proficiency test requirement in ISO/IEC 17025:2017 will not meet the needs of this program, given the context of heightened public health concern. As noted in the proposed rule, our proficiency testing frequency requirement is similar to that of the AOAC 17025 Guidelines.[11] Although even more frequent proficiency testing may be instructive, we are not requiring it under this subpart. Accordingly, we are finalizing the requirement that a LAAF-accredited laboratory must successfully complete a proficiency test or comparison program for each method every 12 months. We avoid stating the requirement must be satisfied every ''year,'' to avoid implying that the proficiency tests or comparison programs requirement applies per calendar-year.

In light of the comments, and considering the critical role that proficiency testing plays in the context of this final rule to help ensure both the integrity of specific tests conducted under this subpart and this laboratory accreditation program as a whole, we are revising the proficiency testing provisions so that positive results are

[11] Some comments explain that although we stated in the proposed rule that section 5.9.1 of the AOAC 17025 Guidelines addresses proficiency testing, the AOAC 17025 Guidelines have been updated. The updated AOAC 17025 Guidelines address proficiency testing in section 7.7.2. FDA appreciates the comments.

explicitly required. In the language of the proposed rule LAAF-accredited laboratories were required to ''participate'' and ''conduct'' a proficiency test annually, per method. The final rule requires that a proficiency test for each method must be ''successfully passed'' within a 12-month cycle, unless one is not available or practicable. § 1.1138(a)(2)(i). In that case, the final rule requires that the LAAF-accredited laboratory ''demonstrate competency through participation in [a] comparison program.'' § 1.1138(a)(2)(ii). As we discuss further below in (Response 96, the LAAF-accredited laboratory must submit all proficiency test and comparison program results, regardless of outcome, to the recognized accreditation body within 30 calendar days of receipt. § 1.1138(a)(2)(iii).

For laboratories LAAF-accredited to an open or flexible scope, the requirement would be for a proficiency test or comparison program within 12 months for each method within the open or flexible scope.

With regard to comments expressing concern that it may be hard for an owner or consignee to find a laboratory that is ISO/IEC 17025:2017-accredited and meets our proficiency test requirements, we note that we will be maintaining an public registry of all LAAF-accredited laboratories (and recognized accreditation bodies) online; see § 1.1109 for additional discussion of the public registry.

(Comment 93) Some comments express confusion regarding whether FDA expects each analyst performing a method in the LAAF-accredited laboratory to annually fulfill the proficiency testing requirement for that method. These comments reference the requirement proposed at § 1.1152(g)(12)(iv) that a full analytical report include, ''[i]ndividual proficiency test worksheets'' and suggest that we clarify our requirement.

(Response 93) The requirement is for the laboratory to successfully pass a proficiency test for each LAAF-accredited method within the last 12 months. We have revised the full analytical report requirement to clarify; for more information see the discussion of § 1.1152, below.

(Comment 94) Some comments express confusion regarding whether FDA expects the LAAF-accredited laboratory to inform the recognized accreditation body that the laboratory has determined that a proficiency test is either not available or practicable, and so the laboratory intends to participate in a comparison program instead. Comments speculate regarding whether FDA might have intended that the recognized accreditation body review such determinations when it audits the laboratory.

(Response 94) The LAAF-accredited laboratory's determination that a proficiency test is not available or practicable must be approved by its recognized accreditation body; we revised the proficiency test provisions of the final rule to clarify this requirement; see § 1.1138(a)(2)(ii). The LAAF-accredited laboratory's proposed alternative to a proficiency test also must be approved by its recognized accreditation body, prior to the laboratory's participation in the alternative.

We consider quality assurance measures vital to the integrity of the LAAF program and the testing that occurs under this subpart. Although one aspect of that quality assurance is requiring proficiency testing for each LAAF-accredited method within each 12-month period, an additional aspect is having the recognized accreditation body concur with both the laboratory's determination that no proficiency test is available to the laboratory, and the alternative proposed by the laboratory.

(Comment 95) In the proposed rule, we noted that ISO/IEC 17043:2010 ''Conformity Assessment—General Requirements for Proficiency Testing'' (Ref. 16) provides specific standards for proficiency test providers. We requested comment on whether FDA should require the use of proficiency test providers accredited to ISO/IEC 17043:2010.

Some comments support the proposed requirement that proficiency testing providers must be ''competent,'' and do not recommend that we specify accreditation to ISO/IEC 17043:2010. Some comments state that many proficiency test providers that are not accredited to the ISO/IEC 17043:2010 standard have equivalent quality systems and are established programs in the industry or in government organizations. Some comments state that international proficiency test providers are less likely to be accredited to ISO/IEC 17043:2010 as this standard is not utilized very much outside of the United States. Some comments suggest that recognized accreditation bodies can institute processes for determining equivalency for such proficiency test providers.

Other comments recommend that we require the use of proficiency test providers accredited to ISO/IEC 17043:2010. Some assert that accreditation of proficiency test providers provides assurances regarding both the accuracy of the proficiency test and the technical competence of the laboratories that successfully participate. Some comments suggest that FDA could require the use of ISO/IEC 17043:2010 accredited proficiency test providers when available. Other comments suggest that the FDA adopt the stance taken in AOAC 17025 Guidelines section 7.7.2 which states that an ISO/IEC 17043 accredited proficiency test provider should be given preference. Some comments ask FDA to clarify which steps should be taken if we require ISO/IEC 17043:2010 accreditation for proficiency test providers, but where none is available for certain methods.

(Response 95) FDA appreciates the detailed responses to our question on this matter.

Having considered the comments, we have decided against requiring the use of proficiency test providers accredited to ISO/IEC 17043:2010. We agree with the specification in the AOAC 17025 Guidelines that such providers should be given preference, and we encourage laboratories to seek providers with such accreditation. However, at the present time there are many methods for which no proficiency test provider exists at all, let alone one accredited to ISO/IEC 17043:2010. Given the importance of an independent, third-party evaluation of a laboratory's competence—as provided by a proficiency test within every 12-month cycle—we have decided to allow a wide selection of proficiency test providers to cover as many of the testing methods covered by this regulation as possible. Although the use of an ISO/IEC 17043:2010 accredited proficiency test provider may give the laboratory confidence in the quality and consistency of the proficiency test material and the evaluation of laboratory test results, at the present time, the breadth of testing covered by ISO/IEC 17043:2010 providers is not sufficient to support making this a requirement.

(Comment 96) Some comments disagree with the proposed requirements in § 1.1153(b)(1) and (2) that within 30 days of receipt, the LAAF-accredited laboratory must submit proficiency test results to the recognized accreditation body and that failing proficiency test results must also be submitted to the FDA; comments state that this deviates from current ISO/IEC 17025:2017 procedures. Comments explain that proficiency test results for an ISO/IEC 17025:2017-accredited laboratory are assessed annually by an accrediting body. Comments further explain that ISO/IEC 17025:2017-accredited laboratories address unsatisfactory results by conducting a

root cause analysis and taking corrective action.

Some comments agree with proposed § 1.1153(b)(2), which required the LAAF-accredited laboratory to submit failing proficiency test results to FDA within 30 days of receipt. Other comments state that requiring recognized accreditation bodies to review proficiency test results without specified timeframes is not efficient, and the 30-day timeframe may not provide enough time for the laboratory to complete its corrective action process. Comments express concern that failing results submitted to the recognized accreditation body and FDA could be used against the laboratory without consideration of the laboratory's corrective action procedures.

Comments state that FDA should defer to ISO/IEC 17025:2017 proficiency test reporting requirements and that recognized accreditation bodies can submit non-conforming laboratory results to the FDA during their onsite assessments. Comments also state that some accreditation bodies require that the proficiency testing data be submitted directly to the accreditation body from the proficiency test provider and that procedures already are in place for review of proficiency testing schemes. A few comments have asked FDA to clarify what would be considered a ''questionable'' or failing proficiency test result. Comments state that some proficiency test providers consider consecutive questionable results when determining a laboratory's proficiency test performance and comments ask for clarification on how FDA would evaluate consecutive questionable results.

(Response 96) We have moved the proficiency test result reporting requirements from § 1.1153(b) to § 1.1138(a)(2)(iii) so that they appear alongside the main proficiency test requirements.

After considering the comments, we have decided to revise the requirements regarding LAAF-accredited laboratories' sharing results of proficiency tests (or a comparison program, where no proficiency test is available or practicable) with the recognized accreditation body and FDA. First, we have determined that it is sufficient for the LAAF-accredited laboratory to share results with the recognized accreditation body and have therefore deleted the requirement that failing results also be submitted to FDA. Upon consideration of the comments on these provisions, the comments encouraging greater delineation of FDA's role, and the requirements in § 1.1138(a)(2)(ii) that recognized accreditation bodies must concur in both the determination that no proficiency test is available and the alternative chosen, we conclude that it better suits the role of the accreditation body to review proficiency test results.

We acknowledge that current ISO/IEC procedures only require the accreditation body to review a laboratory's proficiency test results annually, and that reviewing all results, and on an ongoing basis, will not be as efficient for the accreditation body. (According to the comments, some accreditation bodies go beyond what is required under the ISO/IEC standard and so, may already receive results of all proficiency test results, sometimes directly from the proficiency test provider itself; our requirements may not be as much of a change for those accreditation bodies.) However, we view proficiency testing (or comparison programs, where no proficiency test is available or practicable) as a very important tool to either reflect the continued competence of a laboratory with regard to a particular method or provide an opportunity for the laboratory to determine why it did not receive a fully acceptable result and address any related need for process improvements. We believe that providing the recognized accreditation body with proficiency test results on an ongoing basis will allow the recognized accreditation body to maintain greater and more timely awareness of a laboratory's competency.

At the same time, we take the point of the comments stating that if the result is less than fully acceptable, it is unlikely that the LAAF-accredited laboratory will complete its corrective action process within 30 calendar days of receiving the result. In addition, as explained above, we want recognized accreditation bodies to be in possession of additional information about laboratory competency in a timelier fashion than annual reviews provide. Therefore in the final rule we are retaining the 30 calendar day timeframe for submission to the recognized accreditation body of the results of the proficiency test (or comparison program, where no proficiency test is available or practicable).

We note that a LAAF-accredited laboratory must successfully pass a proficiency test (or comparison program, if a proficiency test is not available or practicable) as described in § 1.1138(a)(2) to gain or maintain LAAF-accreditation for a particular method.

Finally, with regard to the proposed requirement that a LAAF-accredited laboratory submit to FDA results of ''failed'' proficiency tests, comments request that we clarify what would be considered a failing result. We acknowledge and agree with comments indicating that proficiency test results generally are phrased in terms such as ''satisfactory'' or ''fully acceptable,'' or ''unsatisfactory'' or ''questionable.'' We have revised the requirement in the final rule to require that a laboratory submit all proficiency test and comparison program results, regardless of outcome, to the recognized accreditation body within 30 calendar days of receipt (see § 1.1138(a)(2)(iii)).

(Comment 97) We received several comments regarding the quality assurance requirements in proposed § 1.1148. Some comments agree with the proposed requirement that reference materials or quality control samples be used with each test conducted under this subpart. Some comments ask that FDA provide more details of the requirements for a quality assurance process, including how quality is assured and by whom, who performs audits and how they are issued, and, regarding proposed § 1.1148, who is accountable for findings and corrective action. Some comments include for FDA's consideration examples of how quality assurance is defined and implemented in other organizations, including mention of the AOAC 17025 Guidelines' treatment of reference materials and quality control samples.

(Response 97) FDA considers quality assurance to be vital to the integrity of this program and the testing that occurs under this subpart. We have included various requirements throughout this subpart that address quality assurance precisely because confidence in LAAF-accredited testing is essential. One example is the requirement that LAAF-accredited laboratories ensure that policies and procedures for monitoring the validity of the results of testing they conduct under this subpart include the use of reference materials or quality control samples with each batch of samples tested under this subpart (§ 1.1138(a)(3)), a policy that aligns with the AOAC 17025 Guidelines (Ref. 13). Relatedly, we have revised the final rule to require submission of quality control results even with abridged analytical reports, again, because of the importance we place on quality assurance. ISO/IEC 17025:2017 similarly contains quality assurance requirements, and not as a stand-alone provision, but integrated throughout the standard (Ref. 3).

In our view, quality assurance is most effective when it is not treated as a distinct activity or addendum, but rather as a commitment that should be

reflected in many facets of laboratory operations. Accordingly, we decline the invitation to include a definition of ''quality assurance.'' We do not believe a definition would significantly advance the degree to which LAAF-accredited laboratories pursue and conduct quality assurance.

Commenters interested in additional details about the quality assurance process under this subpart need only become more familiar with its provisions. Both the recognized accreditation bodies and LAAF-accredited laboratories are subject to requirements that we believe will promote quality assurance.

(Comment 98) We received many comments regarding whether FDA should require LAAF-accreditation for the entities that collect the samples that get tested under this subpart.

In the proposed rule we chose not to include requirements for the accreditation of samplers. We acknowledged the importance of proper sampling procedures and that accreditation for sampling could potentially help ensure the collection of representative samples. We stated that although only laboratories were eligible for ISO/IEC 17025 accreditation under the 2005 version of that standard, the 2017 version of the standard allows for the accreditation of entities that only collect and do not analyze samples (''stand-alone sampling entities'') (see 84 FR 59452 at 59476). As the revision was relatively new at the time of the proposed rule, we were not able to adequately assess the accreditation of such entities. We solicited comments on several related issues, such as the capacity of accredited samplers (both laboratories and stand-alone sampling entities), which international voluntary consensus standard would serve as the optimal basis for a consensus sampling standard, and which standards are currently employed to assess samplers and whether such standards are effective and sufficient. We proposed instead, in § 1.1149, to require LAAF-accredited laboratories to develop or obtain certain sampling documents that would allow FDA to exercise oversight of the sampling conducted as part of this program. Comments on proposed § 1.1149 are addressed below.

Several comments endorse not requiring the accreditation of samplers at the present time. Some of these comments contend samplers are adequately qualified and therefore an accreditation requirement is not warranted. These comments consider that the FDA oversight of samples made possible by proposed § 1.1149 will provide adequate assurance of samplers' qualification and will provide helpful flexibility in allowing different entities to collect the sample. Some comments claim that for many food facilities, the preventive controls regulations already require that sampling activities be performed by a qualified individual and be overseen by a person with specialized training in food safety preventive controls (*i.e.,* a preventive controls qualified individual).

We understand some comments to argue that without substantive sampling protocols to which samplers could refer, it would be difficult for accreditation bodies to accredit samplers to ISO/IEC 17025:2017 or assess against proposed § 1.1149. These comments recommend that, at a minimum, FDA should provide a mechanism whereby samplers could verify sampling protocols with FDA. See discussion of this point with respect to § 1.1149, below.

Some comments agree with our assessment in the proposed rule that accreditation of stand-alone samplers is still relatively new. Some comments agree that we should review this issue in the future. Some comments contend that requiring the accreditation of samplers would necessitate significant investments of time and expense by industry to obtain such accreditation but would not result in significant public health benefit.

Other comments disagree with FDA's proposed decision and instead argue that the final rule should require the accreditation of samplers. Some of these comments contend that the statute requires samplers to be accredited under this subpart; comments specifically quoted or referenced section 422(a)(6)(A)(iv) and (b)(1) of the FD&C Act.

Some comments contend that allowing sampling by unaccredited entities would fail to provide the clarity needed for proper sample collection, which can have a significant impact on the quality of the test results and related uncertainty. These comments state that analysis of an improper sample can invalidate the test results, and argue that requiring accredited samplers is crucial to the integrity of both the sample itself and the resulting test data. A few comments claim that requiring the accreditation of samplers would ensure traceability, which we understand to mean the ability to connect the sample back to a lot or shipment.

Some comments contend that aspects of ISO/IEC 17025:2017 are necessary to ensure quality sampling. Some comments reason that, if samplers are not required to be ISO/IEC 17025:2017-accredited, there is a risk they may be connected to owners and consignees, and thus have an interest in the outcome of the sampling and food testing. These comments express the concern that allowing unaccredited samplers may lead to the analysis of biased, substituted, or manipulated samples. Comments suggest that accreditation to the ISO/IEC 17025:2017 standard would protect against such conflict of interest concerns. Some comments also champion the value of ISO/IEC 17025:2017 to establish standards for sampler qualifications.

Some comments disagree with the Agency's assessment in the proposed rule that ISO/IEC 17025:2017 accreditation for stand-alone sampling entities is relatively new and the FDA does not have enough information to assess their accreditation. Comments disagree that accreditation bodies do not have the experience or bandwidth to satisfy a requirement under this subpart that samplers be ISO/IEC 17025:2017-accredited.

Regarding current capacity among ISO/IEC 17025:2017-accredited samplers, some comments assert that there is more than sufficient accredited-sampler capacity to conduct all the DWPE sampling that would be required under this subpart. They claim that current ISO/IEC 17025:2017-accredited sampling providers can expand their workforce as needed to meet increased demand. They also contend that if we were to require the accreditation of samplers under this subpart, we would be creating additional incentive for sampling entities to become ISO/IEC17025:2017-accredited, which would further increase capacity. Other comments seem to suggest that accredited sampling capacity will increase over time for market reasons (as accreditation generates revenue), regardless of whether we incentivize by requiring sampling accreditation under this subpart.

Certain comments suggest that the sampling requirements in ISO/IEC 17025:2017 in conjunction with FDA's Investigations Operations Manual (IOM) (Ref. 17) would provide comprehensive standards for sampling. Comments also maintain that ILAC is in the process of considering the circumstances in which it may be appropriate to require accredited sampling.

(Response 98) As discussed at some length in the proposed rule, proper sampling procedures are essential to meaningful test results. Accordingly, it is important that this subpart address samplers' training and procedures. After careful consideration of the comments, we have decided that the most appropriate way to support those goals at the present time is through the

oversight provisions at § 1.1149 rather than by requiring ISO/IEC 17025:2017-accreditation of samplers.

Although we have decided not to require the accreditation of sampling at this time, it should be noted that with the adoption of ISO/IEC 17025:2017 without exclusions, those laboratories that include sampling on their scope of accreditation will be assessed by their accreditation body to the requirements of ISO/IEC 17025:2017 section 7.3 on sampling. Even though many sampling entities are not part of an ISO/IEC 17025:2017-accredited laboratory, we conclude that the general requirements in ISO/IEC 17025:2017 section 7.3 are sufficiently addressed in § 1.1149 (Ref. 3). There currently is no other consensus standard specific to sampling of which we are aware; nor is there a single, widely accepted sampling standard for us to incorporate or on which to rely. Instead, there are several publications that address the appropriate statistical sampling that is required to obtain the representative sample referred to in § 1.1149. Some comments suggest that the FDA IOM could serve as the substantive standard. However, while the FDA Compliance Programs [12] and the IOM define the general process for all sampling to ensure that the sample is representative of the entire lot and in conformance with FDA sampling procedures and methods, many of the instructions in these documents are specific to FDA operations and would not be appropriate for incorporation within this subpart. We also acknowledge the point of the comments that argue that the 2017 version of ISO/IEC 17025 is not still ''new,'' and the comments that maintain that accreditation bodies have the capacity to accredit entities for sampling. Nevertheless, in the absence of any other consensus standard specific to sampling of which we are aware; nor a single, widely accepted standard on sampling criteria and specifications, we believe more time is needed for industry to flesh out, and for us to assess, the ISO/IEC 17025:2017 accreditation of entities (including non-testing entities) for sampling. Additionally, due to the absence of a predominant substantive sampling standard, we do not agree with the position expressed in comments that accreditation alone would provide sufficient clear direction on sampling protocols to ensure proper sample collection. For additional discussion regarding FDA substantive sampling resources, see FDA Compliance Programs and IOM Ch. 4.

Despite the contentions of some comments, the statute does not specify that FDA must require the accreditation of samplers in this subpart. Comments point to section 422(a)(6)(A)(iv) and (b)(1) of the FD&C Act to support the argument that sampling accreditation is necessary. Section 422(a)(6)(A)(iv) of the FD&C Act states that the model standards established in this subpart must include methods to ensure that (among other things), ''individuals who conduct the sampling and analysis are qualified by training and experience to do so.'' This language does not mention accreditation; instead, it provides (in relevant part) that FDA require samplers to be qualified. We are fulfilling that obligation in § 1.1149. Section 422(b)(1) of the FD&C Act lists the tests that must be covered by this subpart; the introductory text reads (in relevant part), ''food testing shall be conducted by Federal laboratories or non-Federal laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies.'' This provision refers to accreditation, but the ''or'' is important; by stating ''sampling or analytical testing methodology,'' the statute allows for the satisfaction of just one type of accreditation. Thus, this language explicitly allows for testing to be conducted by laboratories accredited for just the appropriate test method.

As we stated in the proposed rule, in the 2-year period from 2016–2017, about 63 percent of DWPE sampling was conducted by 5 entities accredited for sampling under ISO/IEC 17025:2017 (see 84 FR 59452 at 59476). About 37 percent of DWPE sampling was conducted by more than 300 entities not accredited for sampling (see id.). In the proposed rule, we specifically solicited feedback regarding the current capacity of accredited samplers. Some comments respond that there is sufficient capacity among already-accredited samplers to conduct all DWPE sampling, and that it would be relatively easy for such entities to expand capacity much further. We appreciate the time taken by commenters to thoroughly address our specific inquiries.

This subpart reaches beyond testing to support removal from import alert, and entities focused on the sampling and testing needs at ports of entry may not be convenient choices for non-import related owners and consignees needing the services of a LAAF-accredited entity. We note incidentally that some of the non-import sampling needs under this subpart are unique; there are serious biosecurity concerns that would need to be addressed by any outside entity collecting the shell egg samples the testing of which is covered by this subpart under § 1.1107(a)(1)(ii). See, *e.g.,* Biosecurity Basics for Poultry Growers (Ref. 18). We did not receive any comments describing the current capacity of accredited samplers to collect non-import samples, though as stated, some comments express the view that it would be relatively easy to expand capacity, and some comments make the point that if we require the accreditation of samplers we would be creating an incentive to become accredited for sampling.

Some comments suggest that there is no indication current samplers are unqualified. For current purposes it is sufficient to acknowledge that the statute directs FDA to address sampler qualifications in this subpart. Some comments claim that sampling that takes place pursuant to the FSMA preventive controls regulations is already required to be conducted by a trained individual, and overseen by another person with specialized food safety preventive controls training. (See the definition of preventive controls qualified individual in §§ 117.3 and 507.3.) It is true that each of those regulations requires sampling to be conducted by an individual qualified by education, training, or experience to carry out such sampling (§§ 117.3, 117.4(b); §§ 507.3, 507.4(b)), but the preventive controls regulations only require a preventive controls qualified individual to prepare or oversee the preparation of the food safety plan that would detail the sampling regimen, not to oversee the sampling activity (§§ 117.180, 507.53). In addition, very few of the samples that must be tested by a LAAF-accredited laboratory would be collected from registered food facilities subject to either of the preventive controls regulations; we estimate that almost all of the laboratory analytical reports submitted in accordance with this subpart will be related to sprouts (see § 1.1107(a)(1)(i)), shell eggs (see § 1.1107(a)(1)(ii)), and imports under section 801(a) (see § 1.1107(a)(4), (5)) (Ref. 4).

Some comments raise concerns about biased sampling. These comments contend that the conflict of interest provisions in ISO/IEC 17025:2017 protect against samplers that have an interest in the outcome of the test from submitting unrepresentative (*e.g.,* ''cherry picked'' or manipulated) samples. Although we also appreciate that ISO/IEC 17025:2017 contains conflict of interest provisions, the requirements in § 1.1149(a)(2) and (3)

[12] For more information on FDA Compliance Programs, see *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-guidance-manual-cpgm.*

for a sampling plan and collection report will ensure that the sample collection procedures and preparation techniques, as well as the chain of custody including controlling for the representative nature of the sample, are documented and reviewed by FDA. For more information on the sampling documentation required by this final rule, see the discussion of § 1.1149, below.

Regarding sampler qualifications, ISO/IEC 17025:2017 section 6.2 requires accredited entities to document (among other things) the educational, training, and experiential needs of each position and ensure that personnel possess the necessary competence to perform their function (Ref. 3). Although we do not dispute that these aspects of ISO/IEC 17025:2017's quality management system are valuable, we are addressing sampler qualifications, albeit using a different approach, in this rule. Section 1.1149(a)(1) requires the qualifications of each sampler to be submitted to FDA. Reviewing the documentation of samplers' training and experience will provide FDA with a means of helping to ensure that each sampler possesses qualifications sufficient for the task.

A few comments claim that requiring the accreditation of samplers would facilitate connecting a sample back to a lot or shipment. However, the requirements in § 1.1149(a)(1) through (3) for the written documentation of the sampler's qualifications by training and experience, the written sampling plan used to conduct the sampling, and the collection report combined should include the information required to allow for tracing back to the lot or shipment.

A number of pending developments may cause us to revisit this issue. Contrary to the assertion of some comments, our understanding is that ILAC is not considering developing standards or advice regarding the circumstances in which it would be appropriate to require sampling accreditation. However, a number of other developments may cause us to revisit this issue, including our experience administering this program, which will include reviewing sampling documents from both LAAF-accredited laboratories and unaccredited samplers. Any change we propose to this subpart will be effected through rulemaking and include an opportunity for public comment.

2. How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation (§ 1.1139)?

This topic appeared in § 1.1158 of the proposed rule. In the proposed rule, paragraph (a) of this section directed a laboratory seeking LAAF-accreditation to apply to a recognized accreditation body. It also noted that a laboratory that had previously been disqualified from the program by FDA or had its LAAF-accreditation withdrawn by a recognized accreditation body must meet additional requirements to be reinstated; those requirements are contained in § 1.1142 of the final rule (proposed § 1.1165).

In the proposed rule, paragraph (b) of this section stated that a laboratory seeking LAAF-accreditation may use documentation of conformance with ISO/IEC 17025:2017 in meeting the requirements of this subpart.

In the proposed rule, paragraph (c) of this section provided that LAAF-accreditation endures as long as the laboratory maintains compliance with all requirements of this subpart, unless the laboratory relinquishes its LAAF-accreditation, FDA disqualifies the laboratory from the program, or the recognized accreditation body withdraws the laboratory's LAAF-accreditation.

On our own initiative, we specified the relevant paragraph in the cross-reference to § 1.1142 and made other conforming and minor editorial changes. Conforming terminology changes include adding the phrase, ''reduced in scope,'' and the term, ''disqualified'' to the list of ways LAAF-accreditation may end, in paragraph (c). Whereas in the proposed rule, the words, ''withdrawn'' and ''revoked'' included ''in part'' withdrawal or reduction, in the final rule we use the word, ''reduce,'' to mean that some (but not all) methods are removed from the scope of LAAF-accreditation and we use ''disqualify'' to refer to the action FDA takes with respect to a LAAF-accredited laboratory. Additionally, we have revised the section to remove reference to ''modification of scope,'' instead referring to extension of scope in the final rule. We also revised the section title accordingly to read, ''How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation?'' Comments regarding this section are discussed below.

(Comment 99) We received a few comments on this section; they concern paragraph (c). Comments state that as proposed, LAAF-accreditation would continue indefinitely, and accreditation bodies may approach this policy differently. Some accreditation bodies take a proactive approach and prompt laboratories to begin the renewal accreditation process for ISO/IEC 17025:2017 well in advance of expiration.

(Response 99) We acknowledge that accreditation bodies vary in their approaches to the duration and renewal of ISO/IEC 17025:2017 accreditation. Nevertheless, we are comfortable with the policy that LAAF-accreditation for a particular method endures indefinitely for a variety of reasons including that ISO/IEC 17011:2017 section 7.9.1 prescribes that ISO/IEC 17025:2017 accreditation may be for a maximum of 5 years (Ref. 2); § 1.1120(e) of this subpart requires recognized accreditation bodies to conduct an onsite assessment of a sample of the laboratory's scope every 2 years; and we have included various quality assurance requirements in this subpart such as the requirement in § 1.1138(a)(2) for a successful proficiency test at least every 12 months for each method to which a laboratory is LAAF-accredited.

3. What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation (§ 1.1140)?

This topic appeared in § 1.1163 in the proposed rule. We proposed to title this section, ''What if a laboratory wants to voluntary relinquish its accreditation?'' For precision and in keeping with the terminology changes described above at Response 10, the title has been reworded to read, ''What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation?''.

In the proposed rule, paragraph (a) of this section provided that a LAAF-accredited laboratory must notify FDA and its recognized accreditation body at least 60 days before relinquishing its LAAF-accreditation either in whole or in part. We proposed that the notice must include the date on which the relinquishment will occur, and if the laboratory is relinquishing its LAAF-accreditation in whole, certain information on a records custodian.

In the proposed rule, paragraph (b) stated that FDA will provide notice of the relinquishment on the public registry described in § 1.1109.

On our own initiative, we made a few changes to this section. First, we removed the language requiring the notice of relinquishment to be electronic and in English; requirements for submitting information to FDA under this subpart are now addressed in § 1.1110. We also removed mention of the fact that the relinquishing laboratory must make its records available to FDA as required by § 1.1153 because it was superfluous. We also made minor editorial changes and specified ''calendar'' days in paragraph (a).

We received no comments solely related to this section and made no further changes to it.

4. What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA (§ 1.1141)?

This topic appeared in § 1.1164 in the proposed rule. We proposed to title this section, ''What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition?'' We rephrased the title for efficiency and in keeping with the terminology changes described above at Response 10 so that it now reads, ''What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA?''.

In the proposed rule, paragraph (a)(1) of this section explained the actions a LAAF-accredited laboratory must take if its recognized accreditation body departs the program. Within 30 days of FDA issuing a notice informing the LAAF-accredited laboratory of the recognized accreditation body's departure, the laboratory must submit to FDA its most recent internal audit (see § 1.1154(a)(5) of the final rule), documentation showing compliance with the conflict of interest requirements in § 1.1147, and documentation of the most recent proficiency test for each method to which the laboratory is LAAF-accredited (see proposed § 1.1148(a), (b)). Proposed paragraph (a)(2) stated that within 1 year of receiving FDA's notice informing the laboratory of its accreditation body's departure from the program, the laboratory must become LAAF-accredited by a recognized accreditation body.

In the proposed rule, paragraph (b) provided that the laboratory need not comply with paragraph (a) if, within 15 days of receiving FDA's notice informing the laboratory of its accreditation body's departure from the program, the laboratory initiates relinquishment of its LAAF-accreditation in whole (see proposed § 1.1163, final rule § 1.1140) with the relinquishment to occur within no more than 90 days.

In addition to changes made in response to comments discussed below, we made several changes to this section on our own initiative in the final rule. We restructured the section to change proposed paragraph (a) to a chapeau introducing paragraphs (a) and (b) of the final rule and reordered the language of the chapeau to match the order in which the notifications are listed in the final rule. On our own initiative we replaced the phrase, ''30 days after FDA issues the notice to the accredited laboratory'' with, ''30 calendar days after receiving the notice,'' because these notices do not always come from FDA and it is clearer to specify ''calendar'' days here and in paragraph (b) of this section. In the case of a recognized accreditation body that chooses to allow its recognition to expire or voluntarily relinquishes its recognition, § 1.1116(b) requires the recognized accreditation body to notify the laboratories it has LAAF-accredited. We also updated cross-references to the sections requiring notice to the LAAF-accredited laboratories. In addition, we corrected the reference to the section addressing a recognized accreditation body allowing expiration of, or voluntarily relinquishing, its recognition. Comments regarding this section are discussed below.

(Comment 100) Comments state that the 15-day timeframe proposed in § 1.1164(b), during which time a LAAF-accredited laboratory ''orphaned'' by its recognized accreditation body may inform FDA that the laboratory intends to relinquish its LAAF-accreditation, instead of taking the actions required by paragraph (a), is inconsistent with the timeframes established in the section on relinquishment (see § 1.1140 of the final rule). Section 1.1140 of the final rule states that a LAAF-accredited laboratory that chooses to voluntarily relinquish its LAAF-accreditation must provide at least 60 calendar days advance notice of the intention to relinquish. Comments indicate that the 15-day timeframe in proposed § 1.1164(b) seems irrelevant because a laboratory could decide to depart the program on the 25th day after receiving FDA's notice and still comply with the timeframes established in § 1.1140.

(Response 100) We agree with these aspects of the comments and so have revised the introduction of this section to provide that the LAAF-accredited laboratory has 30 calendar days to either provide to FDA the required documentation (*i.e.,* its most recent internal audit (see § 1.1154(a)(5)), documentation showing compliance with the conflict of interest requirements in § 1.1147, and documentation of the most recent proficiency test for each method to which the laboratory is LAAF-accredited (see § 1.1138(a)) or inform FDA of its intent to relinquish under § 1.1140(a).

5. How does a laboratory request reinstatement of LAAF-accreditation (§ 1.1142)?

This topic appeared in § 1.1165 in the proposed rule. In the proposed rule, paragraph (a) of this section provided that a laboratory that had any portion of its LAAF-accreditation withdrawn by the recognized accreditation body or was disqualified by FDA for any portion of its LAAF-accreditation, may seek reinstatement by submitting a new application for LAAF-accreditation. We also proposed that the laboratory take additional actions: Notify FDA of certain information prior to submitting the application to the recognized accreditation body and demonstrate to the recognized accreditation body to which the laboratory is newly applying that the grounds for the withdrawal or disqualification have been resolved and the laboratory has implemented measures to prevent recurrence.

In the proposed rule, paragraph (b) of this section stated that a LAAF-accredited laboratory that voluntarily relinquished any portion of its LAAF-accreditation may seek reaccreditation by submitting a new application to a recognized accreditation body.

We revised the section and section title to reflect updated terminology and made other conforming and minor editorial changes within the section. In this section and throughout the final rule, we removed ''legal'' as a modifier for certain names required to be submitted (for example, names of the laboratory and recognized accreditation body in this section and the analyst names in other sections) as the distinction was unnecessary and inconsistently used in the proposed rule. We also removed ''valid'' as a modifier for contact information in § 1.1142(a)(1) as it was also unnecessary. We received no comments solely related to this section.

I. Comments Regarding Requirements for LAAF-Accredited Laboratories

TABLE 10—CHANGES TO SECTIONS REGARDING REQUIREMENTS FOR LAAF-ACCREDITED LABORATORIES

Final rule	Proposed rule	Notes
Requirements for LAAF-Accredited Laboratories.	Requirements for Accredited Laboratories	Revised to reflect new terminology.

TABLE 10—CHANGES TO SECTIONS REGARDING REQUIREMENTS FOR LAAF-ACCREDITED LABORATORIES—Continued

Final rule	Proposed rule	Notes
N/A	§ 1.1146 What are the general requirements for accredited laboratories to remain accredited?	Merged contents of proposed section with § 1.1138.
§ 1.1147 What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?	§ 1.1147 What impartiality and conflict of interest requirements must accredited laboratories meet?	Revised to reflect new terminology and to improve clarity.
N/A	§ 1.1148 What quality assurance requirements must accredited laboratories meet?	Removed this section and relocated content to § 1.1138.
§ 1.1149 What oversight standards apply to sampling?	§ 1.1149 What oversight standards apply to sampling?	Section title remains the same.
§ 1.1150 What are the requirements for analysis of samples by a LAAF-accredited laboratory?	§ 1.1150 What requirements apply to analysis of samples by an accredited laboratory?	Revised to reflect new terminology and to improve clarity.
§ 1.1151 What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart?	§ 1.1151 What requirements apply to the methods of analysis an accredited laboratory uses to conduct food testing under this subpart?	Revised to reflect new terminology.
§ 1.1152 What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA?	§ 1.1152 What notifications, results, and reports must accredited laboratories submit to FDA?	Revised to reflect new terminology and include ''studies''.
§ 1.1153 What are the requirements for submitting abridged analytical reports?	New section	Created new stand-alone section for the portions of § 1.1152 related to abridged reports.
§ 1.1154 What other records requirements must a LAAF-accredited laboratory meet?	§ 1.1153 What other records requirements must an accredited laboratory meet?	Relocated records section and revised to reflect new terminology.

1. What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory (§ 1.1147)?

In the proposed rule, § 1.1147(a) required LAAF-accredited laboratories to generally prohibit employees, contractors, and agents involved in food testing and related activities from accepting any money or other item of value from the owner or consignee of the food that is being, or will be, tested by the laboratory. Proposed paragraph (b) excepted from the general prohibition the payment of fees for testing services; reimbursement of direct costs associated with the testing; and for laboratories owned by the owner or consignee, payment of salary. Proposed paragraph (c) required that payment by the owner or consignee for the testing service, and any direct reimbursement related to the testing, must be independent of the test outcome.

On our own initiative we revised paragraph (b)(1). In the proposed rule, paragraph (b)(1) excepted, ''payment of fees for food testing services.'' In the final rule, it excepts, ''[p]ayment of fees for food testing under this subpart and related services,'' because owners and consignees may pay a LAAF-accredited laboratory for services incidental to testing, such as to collect a sample or for shipping and handling costs.

We have revised the text of this section to update terminology and to make other conforming and editorial changes. We also revised the section title to read, ''What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?'' We discuss additional changes to the section made in response to comments below.

(Comment 101) We proposed to allow laboratories owned by the owner or consignee (''in-house'' laboratories) to become LAAF-accredited. We received several comments regarding this proposed policy.

Some comments express support for the proposed policy. These comments state that the LAAF-accreditation process and other requirements in the proposed rule would protect against potential conflicts of interest. Some of these comments express the view that although in-house laboratories should be permitted to become LAAF-accredited, they should not be required to do so.

Some comments oppose the proposed policy. Some of these comments contend in-house laboratories cannot be free from conflicts of interest. Some comments contend that this conflict of interest may place public health at risk since owners or consignees testing their food would have a vested interest in the outcome of the food testing; some comments cite a widely-publicized foodborne illness outbreak and state that the risk of our proposed policy is the recurrence of such situations. Some comments also seem to argue that in-house laboratories do not, or inherently cannot, satisfy the conflict of interest provisions in ISO/IEC 17025:2017. These comments may have been attempting to address our statement in the proposed rule that we were unaware of any information indicating that laboratories owned by owners or consignees are less able to become LAAF-accredited than independent laboratories.

Some comments opposing the proposed policy argue that the statute precludes in-house laboratories from conducting at least import-related testing under the LAAF program. These comments disagree with FDA's interpretation of ''on behalf of'' in 422(b)(1)(B) of the FD&C Act. These comments argue that when Congress used such language it was clearly Congress's intent to prohibit in-house laboratories from testing their own products under that 422(b)(1)(B) of the FD&C Act.

In the proposed rule, we said that reading the statute such that in-house laboratories would be ineligible for import-related testing under this program could raise potential concerns under U.S. international trade obligations. (see 84 FR 59452 at 59461 through 59462). We tentatively concluded that such a reading would not comport with section 404 of FSMA, which states that nothing in the FD&C Act shall be construed in a manner inconsistent with the agreement establishing the WTO or any other treaty or international agreement to which the United States is a party. Some comments that oppose the proposed policy disagree with our proposed reasoning, and state that there is insufficient evidence that treaties or international agreements apply in this instance or that they are sufficient to

justify, according to these comments, risking public health by allowing in-house laboratories to be eligible for LAAF-accreditation.

(Response 101) After considering the comments and reviewing the statute, we are retaining the proposed policy such that in-house laboratories may become LAAF-accredited to conduct any of the testing described in § 1.1107 as long as those laboratories meet all the laboratory requirements of this subpart.

We acknowledge that opportunities may exist for owners and consignees to exert undue influence over an in-house laboratory; owners and consignees generally do not have the same amount of power and control over an independent or third-party laboratory. However, as we discussed in the proposed rule, ISO/IEC 17025:2017 contains several requirements relevant to conflict of interest and impartiality (see 84 FR 59452 at 59478). For example, ISO/IEC 17025:2017 section 4.1 requires the laboratory to conduct its activities impartially and to be structured and managed so as to safeguard impartiality, to not allow commercial, financial, or other pressures to compromise its impartiality, and, if a risk to impartiality is identified, the laboratory must be able to demonstrate how the laboratory eliminates or minimizes the risk (Ref. 3). We are aware that in-house laboratories are accredited to ISO/IEC 17025:2017, indicating that accreditation bodies have found sufficient safeguards in place to allow such laboratories to be impartial. We have no basis to question those accreditation body determinations.

To further protect the integrity of the testing conducted under this subpart, § 1.1147 imposes on laboratories impartiality and conflict of interest requirements that supplement those contained in ISO/IEC 17025:2017. With limited exceptions, we require laboratory employees, contractors, and agents not to accepts gifts or other items of value from owners or consignees whose food is tested by the laboratory. We also require that the owners' or consignees' payment to the laboratory be independent of the testing outcome. This final rule also contains oversight provisions which allow accreditation bodies to assess, and FDA to review, the performance of, laboratories. Recognized accreditation bodies and FDA both have the authority and the responsibility to exercise their oversight to help ensure that laboratories comply with the requirements of this subpart including the requirements of § 1.1147.

Some comments point to a widely publicized foodborne illness outbreak case as an example of the risk presented by in-house laboratories. In that case, several executives and employees were convicted and sentenced for Federal crimes related to selling peanut butter products that the defendants knew had tested positive for *Salmonella.* Among other misdeeds, the defendants fabricated test results. That is, the testing accurately indicated that the product contained *Salmonella* but the owners produced fraudulent test certificates stating the opposite. In addition, the firm did not use an in-house laboratory; rather, it sent its product to two different independent laboratories for analysis. Accordingly, the facts of that case have no direct bearing on the integrity of in-house laboratories. Furthermore, section 422(b)(2) of the FD&C Act, implemented by § 1.1152(b) of this final rule, requires laboratories to send the results of all tests covered by this subpart directly to FDA, thus protecting against the opportunity for owners or consignees to fabricate test results of independent or third-party laboratories.

We disagree that the statute precludes in-house laboratories from conducting any or all testing covered by this subpart. Section 422(b)(1) of the FD&C Act contains two paragraphs. Paragraph (A) states that certain testing ''by or on behalf of an owner or consignee'' must be conducted by a LAAF-accredited laboratory; this paragraph describes specific followup testing required by existing FDA regulations and testing ''as the Secretary deems appropriate,'' in both cases to address an identified or suspected food safety problem. Paragraph (B) states that certain testing, ''on behalf of an owner or consignee'' must be conducted by a LAAF-accredited laboratory; paragraph (B) describes testing in support of admission of detained imported food.

First, section 422 of the FD&C Act explicitly contemplates the participation of in-house laboratories when it states that ''food testing shall be conducted . . . by or on behalf of an owner or consignee'' (section 422(b)(1)(A)). As we discussed in the proposed rule, section 422(b)(1)(B) of the FD&C Act is silent with respect to testing conducted on imports by owners or consignees. Under one possible interpretation, the absence of ''by or'' in paragraph (B) would mean that only independent laboratories may be accredited to conduct food testing on detained imports (84 FR 59452 at 59461 through 59462).[13] Under this interpretation, laboratories owned by owners or consignees would be prohibited from conducting such import-related food testing, but laboratories owned by owners or consignees would be eligible to conduct food testing under section 422(b)(1)(A) of the FD&C Act. That would raise the prospect that section 422(b)(1) would not apply equally to domestic and foreign goods (section 422(b)(1)(A) of the FD&C Act would generally apply to domestic owners or consignees and potentially foreign owners or consignees). Such a difference in treatment could raise potential concerns under U.S. international trade obligations. In this regard, we note that section 404 of FSMA provides that nothing in the FD&C Act shall be construed in a manner inconsistent with the agreement establishing the WTO or any other treaty or international agreement to which the United States is a party.

In considering section 422(b)(1)(B) of the FD&C Act and section 404 of FSMA together, we finalize the proposed conclusion that it is reasonable to interpret section 422(b)(1)(B) of the FD&C Act to allow laboratories owned by owners or consignees to conduct food testing that falls under section 422(b)(1)(B) of the FD&C Act, provided that such laboratories meet the accreditation requirements proposed.

We understand some comments to question whether treaties or international agreements are relevant to the food testing circumstances covered by this subpart. Other comments appear to question whether the existence of such treaties or international agreements justifies permitting in-house laboratories to participate despite the purported public health risks posed by such participation. It is undisputed that the United States is a party to the WTO, and two WTO agreements are relevant to FDA's regulatory authorities: (1) The Agreement on the Application of Sanitary and Phytosanitary Measures and (2) the Agreement on Technical Barriers to Trade. More significantly, however, we believe we have addressed the fundamental issue at the heart of the opposing comments, *i.e.,* the concern that allowing in-house laboratories (whether foreign or domestic) to become LAAF-accredited jeopardizes public health because in-house laboratories have such a vested interest in vouching

[13] Under another possible interpretation of section 422(b)(1), the phrase, ''on behalf of'' may be read as sufficiently broad to encompass in-house laboratories (*i.e.,* an in-house laboratory conducts testing on behalf of the entity that owns the laboratory). In that case, the absence of ''by or'' is inconsequential, and we would again reach the conclusion that allowing in-house laboratories to conduct any testing under this subpart is consistent with the statute.

for their products that their test results are inherently suspect. Above, we have explained our view that robust requirements in ISO/IEC 17025:2017 and in the final rule address conflict of interest and impartiality such that in-house laboratories may qualify to become LAAF-accredited. We also have explained our view that the statute appropriately may be read to permit participation by such laboratories. We therefore conclude that owners or consignees may become LAAF-accredited as long as they satisfy all the relevant requirements of this subpart.

Finally, to clarify, no laboratory is required to participate in this program; it is entirely voluntary for both accreditation bodies and laboratories.

(Comment 102) Some comments agree with the requirement in § 1.1147(c) that payment for laboratory services must be independent of the testing result; these comments indicate that it is routine commercial practice to require payment in advance of testing to prevent non-payment for violative samples.

(Response 102) We appreciate comments concurring with the proposed provision and are pleased that it is common practice for laboratories to require payment prior to conducting the test. On our own initiative and because the section discusses impartiality and conflict of interest requirements for a LAAF-accredited laboratory, we have clarified in § 1.1147(c) of the final rule that the LAAF-accredited laboratory must require the owner's or consignee's payment to be independent of the outcome of the test results.

2. What are the quality assurance requirements for LAAF-accredited laboratories (§ 1.1148)?

Proposed § 1.1148 concerned the quality assurance requirements beyond those in ISO/IEC 17025:2017 for LAAF-accredited laboratories. Paragraph (a) described the annual proficiency test requirement and provided for the opportunity to use a comparison program if an annual proficiency test for the method was not available or was otherwise impracticable. Paragraph (b) provided that LAAF-accredited laboratories ensure procedures for monitoring the validity of the results of testing conducted under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.

On our own initiative, we determined that the requirements in proposed § 1.1148 are more appropriately categorized as eligibility requirements for LAAF-accredited laboratories. As such, these provisions are in § 1.1138 of the final rule.

3. What oversight standards apply to sampling (§ 1.1149)?

In the proposed rule, § 1.1149(a) required a LAAF-accredited laboratory to develop (if the laboratory collected the sample) or obtain (if the laboratory was not the entity responsible for collecting the sample) certain documents related to sampling, prior to analyzing the sample. Proposed paragraph (b) provided that if the sampling documentation requirements were not met, we might consider the test to be invalid.

Proposed paragraph (a)(1) required documentation of the sampler's qualifications by training and experience. We proposed that such qualification documentation need only be obtained the first time an individual collects a sample, unless the qualifications had changed significantly. Proposed paragraph (a)(2) required a written sampling plan that identified the sampler and listed factors the sampler would control to ensure sample validity. Proposed paragraph (a)(3) required a written sample collection report to include at least the following five elements: The product code or, if collecting an environmental sample, the location and a description of the environment; the date of sampling; the size, identity, and quantity of the sample; documentation of the sample collection procedures and any sample preparation techniques; and documentation of the chain of custody and measures taken to secure the validity of the subsequent test, including controlling for the representational nature of the sample. On our own initiative, we added, ''lot number'' to the information required in a sample collection report. This information is consistent with the other types of information required in a sample collection report and will provide us with better visibility into how the sample was collected, as well as additional information to allow us to trace the sample back to its origin.

In terms of the requirement that the sample collection report include a product code, for domestic products we mean the product code assigned by the manufacturer, packager, or labeler, as applicable. In the import context, a product code is a string of letters and numbers that represent certain information such as which industry produced the item. For more information on product codes for imports, see *https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder#whatcode.* On our own initiative, we moved the provisions addressing the advance notice of sampling from proposed § 1.1152(i) to a new paragraph (c) in § 1.1149 of the final rule. In the proposed rule, these provisions required that in certain circumstances FDA may require a LAAF-accredited laboratory to request and obtain from a sampler advance notice of sampling. We proposed that we may require advance notice of sampling if we determine that sampling may materially differ from the sampling documented in the associated sampling plan or sample collection report, or, if we determine that the sampling may otherwise have been improper.

When we require advance notice of sampling, either the LAAF-accredited laboratory must submit, or it must require the sampler to submit, the notice to FDA 48 hours before each of that sampler's next 10 LAAF program sampling collections. We proposed that the notice must contain:

- A unique identification code for the advance notice of sampling;
- The name of the accredited laboratory that will conduct analysis of the sample;
- The name and street address of the sampler that will conduct the sampling;
- A primary contact (name and phone number) for the sampler;
- The reason(s) why the food product or environment will be sampled;
- The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled;
- As applicable, the U.S. Customs and Border Protection entry and line number(s) and the FDA product code(s) of the food; and
- The date and approximate time the sampling will begin.

We also proposed that FDA may, as appropriate, specify the type of food product or environment that requires advance notice of sampling. We proposed that we might specify an amount of time other than 48 hours advance notice is required, between 24 hours and 7 business days. We proposed that we might require a number of sampling occasions other than 10, between 1 and 20. Finally, we proposed that we might notify the LAAF-accredited laboratory that additional advance notice is not required.

As discussed previously in Response 22, we added the term, ''sampling firm'' in § 1.1102 and defined it to mean an entity that provides sampling services. We have updated the references to sampler in § 1.1149 to more accurately distinguish between requirements for the sampler and the sampling firm.

On our own initiative, for clarity, we added the phrase, ''at least'' before ''48 hours.'' We clarify in § 1.1149(c)(2)(i) that FDA may, as appropriate, specify that the requirement regarding the advance notice of sampling applies to samples collected by a particular sampler. We also deleted the word, ''code,'' after, ''identification,'' because it was unnecessary and inconsistent with other uses of ''identification'' in this subpart. We also clarify in the final rule that ''the FDA product code(s) of the food'' contained in proposed § 1.1152(i)(3)(vii) must include the product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled). See § 1.1149(c)(3)(viii) of the final rule. Finally, we made terminology, conforming, and minor editorial changes to this section. We discuss changes made in response to comments below.

(Comment 103) Some comments ask FDA to clarify what constitutes an acceptable sampling plan. Some comments state that our sampling requirements are different for different types of commodity and test, that FDA commonly rejects results due to sampling variations, and that we should publish all FDA Laboratory Information Bulletin methods and refer to them in import alerts as applicable. Some comments recommend that we align sampling requirements under this subpart with certain existing documents that describe a scientific approach to creating or assessing sampling protocol: The AAFCO/Association of Public Health Laboratories/Association of Food and Drug Officials documents ''GOODSamples'' (Ref. 19) and ''GOOD Test Portions'' (Ref. 20).

(Response 103) As we discussed in the proposed rule, proper sampling procedures are essential to meaningful test results and it is therefore important that this subpart address the training and procedures of samplers. After careful consideration of the comments, we have decided that the most appropriate way to support those goals at the present time is through the oversight provisions in this section, rather than by requiring ISO/IEC 17025:2017-accreditation of samplers. Accordingly, we are not establishing model standards for sampling in this subpart. For more information on our decision not to require the accreditation of samplers, see (Response 98.

Regarding comments' suggestion that FDA publish all Laboratory Information Bulletin methods, we note that although we have published some (see *https://www.fda.gov/science-research/field-science-and-laboratories/laboratory-information-bulletins*), Laboratory Information Bulletins typically do not include sampling collection information. However, there are a variety of other publicly available FDA resources concerning sampling. Generally applicable sampling procedures and methods are described in the FDA Food Compliance Programs (*https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs*) and the sampling chapter of the IOM, Ch. 4. The IOM section 4.3.7.2 addresses random sampling. A random representative sample should reflect the average composition of the entire lot to ensure that analytical results are meaningful. This is particularly imperative when potential foodborne adulterants that pose a public health risk are not homogeneous in the product.

FDA also provides more specific information on sampling in certain circumstances.

Some import alerts contain more customized information on sampling (see *https://www.fda.gov/science-research/field-science-and-laboratories/private-laboratory-testing*). Sampling for the testing of bottled drinking water, shell eggs, and sprouts required under § 1.1107(a)(1) is impacted by the product-specific regulations and/or may be informed by product-specific guidance. See *e.g.,* §§ 118.7 (addresses shell egg sampling); 129.35(a)(3)(ii) (addresses bottled drinking water sampling); and ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Draft Guidance for Industry,'' available at *https://www.fda.gov/media/102430/download* (addresses product and environmental sampling for sprouts). When finalized, this guidance will represent FDA's current thinking on this issue.

FDA appreciates the suggestion that we consult reputable industry sampling guidance documents. We note that the ''GOODSamples'' and ''GOOD Test Portions'' documents were generally written for use by State and local regulatory laboratories and not for private laboratory use. Nevertheless, we are aware of these documents and agree they are helpful resources.

(Comment 104) Some comments disagree with, or request additional clarification about, certain provisions within § 1.1149. Some comments express concern that requirements in § 1.1149(a) for documentation before analyzing the sample will lead to delays in testing and obtaining results, and some comments express concern that the delay could interfere with the sample's integrity. Some of those comments suggest that instead, FDA should have a mechanism in place to approve the sampling method or plan prior to sample collection.

A few comments ask FDA to clarify how a laboratory is to evaluate the effectiveness of a sampling plan. Comments also request that FDA clarify what would constitute a ''significant change'' in a sampler's qualifications and how a laboratory would learn about such a change.

Some comments contend that FDA should not collect all the proposed sampling documentation in § 1.1149(a) in every instance, and argue that the documentation need not be collected if the sample is collected at a domestic food facility, because such entities are subject to preventive controls regulations and we could allow the preventive controls qualified individual to attest to the sufficiency of the sampler's qualifications and the sampling procedures.

Other comments suggest the documentation in § 1.1149(a) should be submitted to the laboratory's recognized accreditation body. Some comments express the view that recognized accreditation bodies are noticeably absent from the sample document collection process and this could be rectified by either requiring that samplers be accredited or by establishing clear substantive sampling requirements against which recognized accreditation bodies could assess sampling documents.

(Response 104) The submission to FDA of the sampler's qualifications, the sampling plan, and the sampling collection report will allow the Agency to exercise oversight over the sampling that occurs under this subpart. We acknowledge that the proposed rule could have been clearer on this point, but there is no requirement that the sampling documents be submitted to or approved by FDA prior to the LAAF-accredited laboratory conducting the test. Nor does the LAAF-accredited laboratory need to evaluate the documents or do anything with them prior to conducting the test; the laboratory need only submit the documents to FDA with the analytical report, after the testing is complete (see § 1.1152(c)). As long as the LAAF-accredited laboratory possesses the documents, it can proceed to conduct the test, and we presume that in most instances the documents will either be developed by the laboratory (if it collected the sample) or delivered with the sample (if another entity collected

the sample). Either way, once the LAAF-accredited laboratory possesses the sample we expect it will usually also possess the documentation required under § 1.1149(a). Relatedly, at the present time the Agency does not perceive a need to require or create a pathway for routine preapproval of the sample method or plan prior to sampling.

After considering the comments, we are removing from the final rule the requirement that the LAAF-accredited laboratory obtain documentation of an individual sampler's qualifications more than once if that person's qualifications have ''significantly changed.'' We no longer view the information as necessary and agree that often the LAAF-accredited laboratory would be unaware of it. We have also clarified that a LAAF-accredited laboratory may refer to the previously submitted qualifications if the LAAF-accredited laboratory has previously submitted them to FDA under § 1.1152(c). We do not expect many samples collected under this program to come from food facilities subject to the preventive controls regulations and so decline the invitation to create an exception to § 1.1149(a) for such establishments. We discourage samplers and LAAF-accredited laboratories from submitting to us an individual's social security number, or other unnecessary personally identifiable information.

For the reasons discussed above at Response 98, we have decided not to require the accreditation of samplers at the present time, and we also do not perceive a reviewing role for the recognized accreditation bodies with regard to the documents required under § 1.1149(a). As noted above, submission of those documents to FDA is the mechanism whereby we may exercise oversight of the sampling that occurs under this subpart.

(Comment 105) Some comments express concern with the proposed provisions on advance notice of sampling. Comments ask for clarification regarding how these requirements might work in the context of the directed food laboratory order and the other testing conducted under this subpart. Comments also indicate that delays associated with this requirement could lead to significant losses for entities, particularly regarding perishable foods. A few comments suggest that requiring advance notice of sampling may not be appropriate when resolving a food safety issue that needs rapid testing and that it is commercially and logistically impractical to regularly specify an exact date and approximate time of sampling.

(Response 105) FDA has concluded it is reasonable for public health reasons to require advance notice of sampling when the Agency suspects a sampler previously has failed to follow proper protocols. Again, utilizing appropriate sampling techniques is essential to generating a representative sample, which is in turn essential to producing a meaningful test result. FDA generally will require the advance notice of sampling to be submitted to us at least 48 hours prior to collection of the sample(s) to allow us time to determine whether to observe the sampling or to take an audit sample and assign appropriate personnel to the task. However, under § 1.1149(c)(2)(iii), we may require an amount of time other than 48 hours, perhaps as little as 24. In tailoring the requirements to a particular situation, we would consider a variety of factors including product shelf life.

It is possible that we could require advance notice of sampling in connection with any test required to be conducted by a LAAF-accredited laboratory, including a directed food laboratory order. As the circumstances in which we might require advance notice of sampling vary widely, it is impossible to predict or generalize regarding how these requirements will be implemented, *e.g.,* depending on the provision of § 1.1107 under which the testing falls. However, FDA will take into consideration such factors as the type of product, its shelf life, timing requirements of the test method, public health context for the testing, etc., and will use the options under § 1.1149(c)(2) to customize the requirements accordingly.

(Comment 106) Some comments recommend that FDA clarify how we will notify a LAAF-accredited laboratory that a sampler must provide advance notice of sampling under § 1.1149(c) (proposed § 1.1152(i)), and how we will track the subsequent 10 samples from that sampler. Some comments suggest that we share with owners or consignees the pending requirement for advance notice of sampling. Some comments emphasize the logistical and operational challenges of several entities coordinating around the collection of a sample. With regard to the requirements in § 1.1149(c)(3)(iii) (proposed § 1.1152(i)(3)(iii)) that the advance notice include the sampler's name and street address, some comments seek clarification as to why we would require the sampler's street address. Some comments recommend that we clarify that the requirement is for a business name and address for the sampling entity, and not an individual's name and address. In addition, these comments suggest we clarify that the primary contact required by § 1.1149(c)(3)(iv) (proposed § 1.1152(i)(3)(iv)) should be the individual managing the sampling operation.

(Response 106) First, we note that under § 1.1149(c), the LAAF-accredited laboratory is not simply communicating a requirement to the sampler. Instead, the LAAF-accredited laboratory is the entity required either to obtain the advance notice of sampling from the sampler and submit it to FDA itself, or to require the sampler to submit the notice directly to FDA.

In terms of our communications with LAAF-accredited laboratories regarding § 1.1149(c), such communications may occur by email but regardless, will be tailored to the circumstances. Further, we may use a variety of methods to track subsequent collections by a sampler identified under § 1.1149(c); one method will be to review the documents we receive under § 1.1149(a).

Regarding the suggestion that we inform owners and consignees when we will require advance notice of sampling from a particular sampler, we have revised the codified text to state that we may, as appropriate, notify the owner or consignee that advance notice of sampling applies to food testing conducted on its behalf. Such notification is consistent with current FDA practice in the context of reviewing import-related private laboratory analytical packages (PLAPs), which we have been doing for years. If FDA identifies a deficiency in a PLAP, we routinely inform the owner or consignee the basis for FDA's concern (*i.e.,* we would inform the owner or consignee if we identified a sampling problem that may have impacted the test result).

FDA has experience auditing samplers and we acknowledge that it can be a logistical challenge. Nevertheless, when we have cause for concern with a particular sampler, especially given the public health context in which testing under this subpart occurs, it is reasonable to require advance notice of sampling.

Finally, after considering the comments regarding the sampler's name and address required by § 1.1149(c)(3)(iii) and the primary contact required by § 1.1149(c)(3)(iv), we note that we have revised this section to incorporate the new term, ''sampling firm'' (see § 1.1102). We have revised these sections to refer instead to the sampling firm information in the final rule.

Our general purpose in requiring a sampling entity's address in an advance

notice of sampling is to clearly identify the commercial operation responsible for conducting the sampling. Again, we would only require an individual sampler's name and street address if that person has been contracted to provide sampling services for testing conducted under this subpart. If an individual has assumed responsibility for that task, then we have an interest in ensuring that we can properly identify that individual and a street address helps us to do so. We again emphasize that all the tests required to be conducted by a LAAF-accredited laboratory occur in the context of heightened public health concern. Although we are not requiring the accreditation of samplers, we nevertheless require that any individuals collecting samples under this subpart be properly qualified. Owners and consignees risk having us reject test results if the sample that was analyzed, was collected using improper sampling methods or procedures. If we have cause to believe that past sampling conducted by an individual has, for example, materially differed from the sampling described in the sample collection report, this may constitute a reasonable need to clearly identify that individual and may also provide a reasonable basis on which to audit that person's future sampling activities.

4. What are the requirements for analysis of samples by a LAAF-accredited laboratory (§ 1.1150)?

Proposed § 1.1150 concerned requirements for analysis of samples by a LAAF-accredited laboratory. Paragraph (a) required analysis to be conducted on the sample received from the sampler or a representative sample of the sample received from the sampler. Paragraph (b) provided requirements for the analyst conducting the analysis: (1) To be qualified by appropriate education, training or experience; (2) to have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and (3) be in compliance with the conflict of interest requirements in this subpart. Paragraph (c) required that the method used to conduct food testing meet the requirements of § 1.1151. Paragraph (d) stated that the LAAF-accredited laboratory must document testing information and test results to account for all the information that is required to be included in a full analytical report. We note that this requirement concerns all testing under this subpart, regardless of whether the LAAF-accredited laboratory submits full or abridged analytical reports (see §§ 1.1152 and 1.1153 of the final rule).

We have made revisions to the section to update terminology and cross-references to reflect the reorganization of the final rule. We revised the section title to read, ''What are the requirements for analysis of samples by a LAAF-accredited laboratory?'' and made minor editorial changes to the section. We received no comments specific to this section and made no further changes.

5. What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart (§ 1.1151)?

Proposed § 1.1151 concerned requirements for methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart. Paragraph (a) required that analysis conducted under this subpart must be conducted using a method of analysis that is fit for purpose, within the laboratory's scope of LAAF-accreditation, and has been appropriately validated and verified for use in such food testing. In paragraph (b), we stated that if a method is prescribed by the FD&C Act or implementing regulations for the testing under § 1.1107(a)(1), or by the directed food laboratory order for the testing under § 1.1107(a)(2), then that method must be used to conduct food testing under this subpart. Paragraph (c) stated that a LAAF-accredited laboratory must validate methods and record the information. Paragraph (d) stated that before a LAAF-accredited laboratory conducts food testing under this subpart using a method for a specific intended use for which the method has been validated, but for which the laboratory has not previously applied the method under this subpart, the LAAF-accredited laboratory must have verified it can properly perform the method for the specific intended use. Further, a LAAF-accredited laboratory performing verification of a method under this subpart must record the method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the accredited laboratory is able to properly perform the method. Paragraph (e) provided that a LAAF-accredited laboratory may submit a request to FDA to use a method outside its scope of LAAF-accreditation. FDA may approve the request if: (1) A new method has been developed and validated, but no reasonably available laboratory has been accredited to perform the method and (2) use of the method is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

We made several revisions to this section on our own initiative to improve clarity and readability of the section. We also have updated terminology and revised cross-references throughout the section, including the section title. Comments regarding this section are discussed below.

(Comment 107) Some comments ask FDA to identify the criteria that will be used to assess whether a method is ''fit for purpose'' in § 1.1151(a)(1). Other comments request that FDA provide a list of validated methods deemed fit for purpose. These comments state that since there may be more than one method that could be classified as such, there may be inconsistent test results from use of different methodologies.

In the proposed rule, we referenced a page on our website that lists methods currently being used for food and feed safety programs: *https://www.fda.gov/food/science-research-food/laboratory-methods-food* (84 FR 59452 at 59481). Some comments argue that this website is often outdated or incomplete, and that FDA should publish a complete list and reference it in import alerts. Other comments urge FDA to specify methods in import alerts. These comments state that some import alerts cover perishable food items such as produce, and it would be impossible to validate a new method quickly enough to test such perishable goods.

(Response 107) As a preliminary matter, we describe some key terms. Validation is meant to demonstrate that a method is suitable for the intended purpose, and verification is meant to show that the laboratory can properly apply the method for a specific intended use, and meet the performance criteria of the method for the matrix and analyte being tested. When we say a method is ''fit for purpose,'' we mean that it may only be applied for the food testing to which it is intended to apply, for the purpose for which it is validated, and that the method performance is suitable for the intended use—specifically with respect to the limit of detection or probability of detection, specificity, reproducibility, and accuracy. Due to the broad range of testing under this subpart, it is not possible for us to provide a more specific set of criteria for determining whether a method is fit for purpose. (See also, section 7.2.1.4 of ISO/IEC 17025:2017 (Ref. 3).)

Standard methods must be verified and non-standard methods or a standard method applied outside its original scope (for example, applied in a different food matrix) must be validated.

If a LAAF-accredited laboratory wishes to use a method that is already validated, the laboratory must verify that the laboratory is able to run the method and achieve an acceptable detection limit. If a method validation was not performed on a particular food category (*i.e.,* validation performed on dairy but the new matrix is fruit or vegetables) then the laboratory will need to perform a ''matrix extension'' either through a single laboratory validation or an independent validation study. We will review laboratory analytical reports to determine whether the food matrix tested fits into a validated matrix, and if not, the laboratory will need to perform a matrix extension. (For additional discussion of matrix extensions, see Response 108.) FDA guidelines for validations can be found at: *https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines.* LAAF-accredited laboratories may use these guidelines in performing validation studies, or they may use other established and recognized protocols, such as those published by AOAC. We request that a LAAF-accredited laboratory cite the protocol used when submitting a validation.

Regarding the request that FDA provide a list of validated methods deemed fit for purpose, we decline to provide a list or to include specific methods in import alerts. It is simply not practical for FDA to try and provide an exhaustive list of all methods that may be appropriate in food testing circumstances. The website provided above (and in the proposed rule) is one example of a potential resource for methods of analysis; we endeavor to keep it current. Also, a method prescribed for use in a compliance program is considered to have already been validated. (See *https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs* and *https://www.fda.gov/animal-veterinary/compliance-enforcement/cvm-compliance-programs*.) However, laboratories are not required to use these methods.

Regarding specifying methods in import alerts, in most cases it not necessary to limit testing to a single specific method where there are multiple acceptable methods of analysis. Further, we do not agree with the comments expressing concern that use of different methodologies may produce inconsistent results; validated methods that are fit for purpose and conducted properly by a laboratory should yield consistent results. Indeed, that concept lies at the base of all validation studies; if the new method works properly, the result should be consistent with the result produced using the standard method.

Finally, we agree that validating a new method takes time. It is anticipated that products under import alert will already have appropriate methods available. For import alerts concerning time-sensitive products, we expect that owners and consignees will refer to the online registry described in § 1.1109 (once it is up and running) to locate a LAAF-accredited laboratory that is able to conduct the desired test promptly.

(Comment 108) Many comments agree with the requirements in proposed § 1.1151(a)(3) and (4) that methods used under this rule must be appropriately validated or verified. However, some comments state that it would be very onerous for a laboratory to validate every single potential food matrix. Some of these comments discuss the example in the preamble to the proposed rule regarding chloramphenicol in shrimp (see 84 FR 59452 at 59480) and assert that this example conflicts with FDA validation guidance and use of the AOAC Food Matrix Triangle to group like foods into one validation. Other comments request that we clarify when a matrix extension or further validation would be necessary, especially if other validated methods are available.

(Response 108) Appropriate method validation and verification, as just discussed in Response 107, is critical to data acceptability. Although tools such as the AOAC Food Triangle are commonly used to group like foods, there are sometimes limits to this approach as provided in the example of the chloramphenicol analysis that performs differently for fish and shrimp which are similar matrices within the same food group. Though it is generally assumed that the more closely related a new food matrix is to a previously validated matrix from the same food group for the detection of a defined analyte, the greater the probability that the method will perform similarly with the new matrix, the method must nonetheless be verified for all new matrices. This is to ensure that the new matrix will neither produce high false positive rates (*e.g.,* matrix is free from cross reactive substances) nor high false negative rates (*e.g.,* matrix is free of inhibitory substances). As we agree that it would be onerous for a laboratory to validate every single potential food matrix, an acceptable approach for a matrix verification within the same food group as the validated matrices is the use of spiked samples and blank matrix (if available) as described in the ''matrix extension'' sections of the validation guidance documents provided at: *https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines.* Note that matrices falling within food groups not previously validated cannot use this approach and will require validation.

Some comments asking about our requirements for verification and validation studies reference the portion of the PRIA in which we estimated the cost of requiring LAAF-accredited laboratories to submit additional verification studies to be between 1 percent and 5 percent of the costs for verification and validation activities required to maintain ISO/IEC 17025:2017 accreditation. To the extent that such comments are questioning why we would estimate between 1 percent and 5 percent of the costs for verification and validation studies over and above verification and validation costs required to maintain accreditation to ISO/IEC 17025:2017, we note that the additional costs acknowledge the possibility of differing requirements for matrix extensions between this subpart and ISO/IEC 17025:2017 on a case-by-case basis.

Finally, we agree that in most cases it is not necessary to limit testing to a single specific method where there are multiple acceptable methods of analysis.

(Comment 109) A few comments state that proposed § 1.1108(b) provided that the directed food laboratory order would specify, among other things, ''the manner of the food testing, such as the methods that must be used'' whereas proposed § 1.1151(b)(2) stated that ''if the [directed food laboratory] order prescribes a test method, that is the only appropriate method. . . .'' These comments explain that, read in conjunction, these proposed sections indicate that FDA may not specify a method in the directed food laboratory order and may allow a LAAF-accredited laboratory to use an appropriate method within its scope of LAAF-accreditation.

(Response 109) As discussed above in Response 54, in a directed food laboratory order, we would specify the method to the owner or consignee and, in some circumstances, may provide flexibility to use equivalent methods, so that an owner or consignee may have access to a greater number of LAAF-accredited laboratories that could conduct the testing. If a directed food laboratory order allows for flexibility to use equivalent methods, a LAAF-accredited laboratory could use an appropriate method within its scope of LAAF-accreditation which meets the requirements of this section.

(Comment 110) Proposed § 1.1151(e) implemented the waiver provision of

section 422(b)(3) of the FD&C Act and stated that a LAAF-accredited laboratory could submit a written request to FDA requesting permission to use a method outside its scope of LAAF-accreditation. The proposed rule went on to state that FDA may approve the request if two conditions were met: (1) A new method had been developed and validated but no reasonably available laboratory had been accredited to perform the method and (2) the use of the new method is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

Some comments agree that FDA should decide whether to allow a LAAF-accredited laboratory to use a method outside its scope; they state, however, that the recognized accreditation body is not involved in the decision and should be notified. Other comments urge FDA to clearly define ''reasonably available'' to avoid improper use of this exception and an unfair barrier to competition among laboratories if, for example, one LAAF-accredited laboratory is not reasonably available due to a longer turnaround time than another.

(Response 110) We appreciate the supportive comments. Given the narrow circumstances in which the statute contemplates FDA waiving the requirements of this subpart (*e.g.,* new method and either a food emergency or a foodborne illness outbreak), we disagree that a definition of ''reasonably available,'' is necessary to avoid our abuse of this provision. Further, we hesitate to limit our authority to rely on this subpart in the context of either an outbreak or an emergency.

We expect that in most circumstances, we would notify a recognized accreditation body if we authorize a laboratory it has LAAF-accredited to use a method outside the scope of the laboratory's LAAF-accreditation. However, because food emergencies and outbreaks may necessitate fast action, we decline to add to the final rule a commitment that we will notify the recognized accreditation body in every situation.

6. What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA (§ 1.1152)?

Proposed § 1.1152 concerned the notifications, results, and reports a LAAF-accredited laboratory must submit to FDA. Note that in the final rule we devote a separate section to abridged analytical reports (§ 1.1153), and so the content from proposed § 1.1152(d), (e), and (f) is now located in § 1.1153 of the final rule. In the final rule we also relocated the contents of § 1.1152(i), on advance notice of sampling, to § 1.1149.

In the proposed rule, paragraph (a) of § 1.1152 stated general requirements such as that all LAAF-accredited laboratory notifications, results, reports, and studies must display a unique identification (*e.g.,* an alphanumeric identifier unique to each analytical report, to clarify which pages comprise the report), and that the LAAF-accredited laboratory must submit corrected versions if the LAAF-accredited laboratory becomes aware that the originals were in some way inaccurate.

Briefly, in proposed paragraph (b) we stated that test results must generally be submitted by the LAAF-accredited laboratory directly to FDA via a destination we will specify on the website described in § 1.1109. Also briefly, in paragraph (c) we listed the documentation required to be submitted to FDA with each test result: All sampling documentation required by § 1.1149, a full analytical report unless permitted to submit an abridged analytical report, validation or verification information required by § 1.1151 unless submitted to the recognized accreditation body under proposed § 1.1138, and a signed certification from the laboratory's management that the submissions are true, accurate, and include the results of all the tests conducted under this subpart. Note that in the final rule, we moved the requirement for submission of justification and authorization for deviating from or modifying the method of analysis to paragraph (c). In the proposed rule, that requirement was stated once for abridged analytical reports (§ 1.1152(f)(2)) and also referenced for full analytical reports (§ 1.1152(g)(1)); for efficiency and clarity it is now stated once in § 1.1152(c).

Proposed paragraph (g) listed the required contents of a full analytical report, such as documentation of references to the test method used, identification and qualifications of the analyst(s), calculations, and identification of any software used. Proposed paragraph (h) stated that if the LAAF-accredited laboratory used a method not published in a reputable standard or that is otherwise not publicly or readily available, the LAAF-accredited laboratory must submit documentation of the method to FDA upon request. Proposed paragraph (j) required LAAF-accredited laboratories to immediately (within 48 hours) notify FDA and the recognized accreditation body of any changes that affect LAAF-accreditation. Proposed paragraph (k) provided that if FDA does not receive all the information required in § 1.1152, we may consider the related testing to be invalid.

On our own initiative, we made several revisions to this section in the final rule. We revised the title of the section to include ''studies'' to more accurately reflect the contents of the section. We revised paragraph (a) to remove the requirement here for notifications, results, and reports to be submitted electronically and in English; the requirement remains and is now in § 1.1110 of the final rule. We have also revised the list of general requirements for all notifications, results, reports, and studies required to be submitted to FDA in paragraph (a)(1) to improve clarity and readability. We revised paragraph (b) to clarify that a LAAF-accredited laboratory must identify on the test results the name and street address of the owner or consignee for which the testing was conducted and, as appropriate, the U.S. Customs and Border Protection entry number and line number(s). The entry and line numbers link import-related tests with related product shipments; they are inapplicable in the domestic context. Although ISO/IEC 17025:2017 provides that test reports include the name and contact information for the customer, FDA needs the level of detail we have specified in the final rule so that we may precisely identify the entity and/or article of food to which the test results relate. We have also revised the section to reflect revised terminology, to update cross-references, to improve the clarity and readability of the section, and to make minor editorial changes. We discuss additional changes made in response to comments below.

(Comment 111) Some comments recommend that FDA establish uniform analytical data requirements by adopting international accreditation standards and appropriate national scientific technical standards as the main basis for qualifying laboratories and sampling organizations to sample and submit analytical data to FDA.

(Response 111) We agree with the aspects of these comments stating that it can be beneficial to rely on international standards in the right circumstances. Accordingly, we are relying on the international voluntary consensus standards ISO/IEC 17025:2017 and ISO/IEC 17011:2017 as the foundational requirements for laboratories and accreditation bodies, respectively, under this subpart. Further, we agree with the aspects of comments stating that the LAAF program will benefit from uniform requirements for test records and the data, analysis, and information supporting the test result. However, we

do not agree that such requirements in a voluntary consensus standard or national scientific technical standard alone would meet the unique needs of the LAAF program. Accordingly, we have established in §§ 1.1152, 1.1153, and 1.1154 the notifications, results, records, and reports that a LAAF-accredited laboratory must create, maintain, and submit under this subpart.

For our discussion regarding the decision not to require ISO/IEC 17025:2017 accreditation of samplers, see Response 98.

(Comment 112) Some comments express the mistaken impression that results from tests conducted under this subpart will be made publicly available.

(Response 112) Information on the recognized accreditation bodies and LAAF-accredited laboratories participating in the LAAF program will be made available via the online registry described in § 1.1109. However, test results will not be made public. All the testing conducted under this subpart is initiated by an owner, such as a food producer or a consignee, such as an importer of food. The owner or consignee contracts with a LAAF-accredited laboratory to conduct a food test. Due to the public heath significance of the test, various provisions of the FD&C Act grant FDA the authority to require the test results and associated records and reports to be submitted to us, but these documents contain confidential business information. FDA will treat such information in accordance with the requirements of applicable information disclosure laws, such as FOIA and its implementing regulations.

(Comment 113) Some comments recommend clarifications to proposed § 1.1152(b). As proposed, section 1.1152(b)(1) stated that, ''the results of any and all tests conducted by an accredited laboratory under this subpart must be submitted directly to FDA''; some comments contend that this provision could be misinterpreted to mean that all testing from a LAAF-accredited laboratory must be submitted to FDA. These comments recommend that this section be revised to clearly state that LAAF-accredited laboratories only need to send test results to FDA if the testing is conducted under this subpart.

Other comments urge FDA to address when LAAF-accredited laboratories should send test results to the owner or consignee of the product, *e.g.,* at the same time as the results are submitted to FDA. Comments state that given the importance of the results, owners and consignees need this information to make informed decisions about the products to protect public health.

(Response 113) Proposed § 1.1152(b)(1) was intended to apply only to the results of tests required to be conducted by LAAF-accredited laboratories under this subpart. We have revised the provision as follows: ''The LAAF-accredited laboratory must submit the results of all testing required to be conducted under this subpart directly to FDA via the location specified by the website described in § 1.1109, unless another location is specified by FDA regarding testing conducted under § 1.1107(a)(2) or (a)(3).'' See § 1.1152(b)(1) of the final rule.

We decline to address the timing of when a LAAF-accredited laboratory sends results to the owner or consignee. Section 422(b)(2) of the FD&C Act states that testing results under this subpart shall be sent directly to FDA. Nothing in section 422 of the FD&C Act addresses sharing test results with an owner or consignee. Therefore, we decline to regulate or opine on this matter. In short, the issue of when the LAAF-accredited laboratory shares test results with the food owner or consignee is strictly a matter of negotiation between those two parties. We note that nothing in the final rule would prohibit the LAAF-accredited laboratory from sending the results of testing required to be conducted under this subpart to the owner or consignee at the same time results are sent to FDA in accordance with this subpart.

(Comment 114) Regarding the testing described in § 1.1107(a)(1) (explicit followup testing requirements in existing FDA regulations), some comments express concern that requiring such tests to be conducted by LAAF-accredited laboratories may delay products moving into commerce. We understand these comments to reason that the use of different methods by different laboratories may result in confusion and therefore delay the release of product being held pending the test results. These comments recommend that FDA specify testing requirements and timelines for each product subject to testing under § 1.1107(a)(1). These comments also request that we provide owners and consignees with guidance on any product hold requirements during testing.

(Response 114) Section 1.1107(a)(1) requires that certain followup tests required by existing product-specific FDA regulations be conducted by a LAAF-accredited laboratory. There are three commodities for which existing FDA regulations require followup testing that is covered under this subpart: Sprouts, shell eggs, and bottled drinking water. Producers of these three commodities have been required to conduct the particular followup tests referenced in § 1.1107(a)(1) for years; under this final rule, the new requirement is for producers to have the tests conducted by a LAAF-accredited laboratory.

There is no reason to suspect that LAAF-accredited laboratories will be slower than other laboratories, nor is there any reason to suspect that test results from LAAF-accredited laboratories will be more confusing than results from other laboratories. In fact, we anticipate less confusion with results from LAAF-accredited laboratories because such laboratories must meet the standards we are establishing in this rule. For example, all LAAF-accredited laboratories will be ISO/IEC 17025:2017-accredited and will participate in the proficiency test and other quality assurance activities required under this subpart.

Further, wide variation in test methods is less probable in the context of testing under § 1.1107(a)(1). Existing sprouts, shell eggs, and bottled drinking water regulations and guidances address the test methods for the tests referenced in § 1.1107(a)(1) (see §§ 129.35(a)(3)(ii) (bottled drinking water), 118.8 (shell eggs), 112.152 (sprouts)).

For the foregoing reasons, there is no need for us to further specify testing requirements and timelines for these products, nor is additional guidance on these specific test requirements necessary as a result of this rulemaking.

(Comment 115) Some comments disagree with proposed § 1.1152(h), which stated that LAAF-accredited laboratories that use non-standard methods that are not publicly available in a reputable international or national standard must submit documentation of the method to FDA upon request and caution that laboratories may be hesitant to provide proprietary method information to the FDA. Others question whether we should allow use of non-standard methods for testing under this subpart at all, arguing that results generated for regulatory purposes should be transparent to the regulated industry and the public.

Other comments agree with the requirement to submit documentation of a non-standard method in proposed § 1.1152(h) but believe the information would be redundant since it would be included on the certificate of analysis. Comments also contend that FDA does not have a mechanism for reviewing the requested information on non-standard methods.

(Response 115) First, we note that this provision appears in § 1.1152(e) in the final rule.

We decline to prohibit use of non-standard methods in the LAAF program. First, given the breadth of food testing covered by this rule, it is not practical to rely solely on standard methods. Moreover, test methods, test results, and analytical reports submitted to FDA under this program will not be made publicly available regardless of whether a standard method was applied; accordingly we do not believe use of non-standard methods is problematic. Therefore, LAAF-accredited laboratories can use any validated and verified method within the scope of their LAAF-accreditation. LAAF-accredited laboratories are not limited to using methods FDA has developed or uses; they can use any properly validated and verified method as long as the method achieves the same performance specifications as the FDA method. Any standard or FDA official methods need verification to ensure that the LAAF-accredited laboratory is capable of performing the analysis, and all non-standard and laboratory-developed methods need method validation. If a standard method has been modified significantly, it requires revalidation. We acknowledge the concerns regarding submitting proprietary information method information to FDA and will protect such information.

We disagree that the information FDA would request under § 1.1152(e) is redundant. The certificate of analysis includes a reference to the method used; for published or standard methods, FDA can use the reference to determine the technology and methods used without requesting additional information. Section 1.1152(e) will allow FDA to request documentation of a non-standard method and will ensure that we have access to the same type of information on which to base our review as we would for published or standard methods.

We also disagree that FDA does not have a mechanism for reviewing requested information on non-standard methods. For decades, FDA field scientists have been assessing the scientific credibility, reliability, and validity of each analytical testing result, and the analytical methods used to obtain these results, as part of reviewing the PLAPs submitted to FDA (see ORA Laboratory Manual Volume II, ORA–LAB.5.4.5 ''Methods, Method Verification and Validation'' (Ref. 21)).

(Comment 116) Comments suggest that it is unnecessary and burdensome for FDA to request that the qualifications of the laboratory analyst be submitted as part of a full analytical report in proposed § 1.1152(g)(12), as the recognized accreditation body would have already reviewed and vetted the analyst as part of their accreditation process. A few comments question how FDA will use the analyst information requested in the full analytical report. Other comments state that personal analyst information is not needed if individual proficiency testing worksheets are collected. Several comments seek clarification on how FDA intends to use such information and how FDA will protect individual analyst information from disclosure.

(Response 116) Under final § 1.1152(d)(12), we are requiring that certain information on the qualification of individual analysts be submitted to FDA the first time that analyst conducts testing under this subpart and to account for any significant changes (*e.g.,* new competencies gained). Briefly, we require the analyst's curriculum vitae, training records for the methods that the analyst is qualified to perform, and any other documentation of the analyst's ability to perform the method properly (see § 1.1150(b)). Note that in the final rule we are not requiring individual proficiency test worksheets as part of the full analytical report; for that discussion see Response 93, and we have clarified that analyst training information is limited to the applicable methods (we are not requiring submission of all an analyst's training records).

Analyst-specific information is essential to our review of the LAAF-accredited laboratory's performance; it allows us to verify the technical competence of the individual conducting the test. Further, while recognized accreditation bodies assess LAAF-accredited laboratories every 2 years (see § 1.1120), there may be significant analyst turnover and changes in responsibilities in the interim. We note that analyst-specific information is not required for abridged analytical reports (see § 1.1153(c) of the final rule).

We have been routinely collecting information on individual analysts as part of the PLAPs submitted to support admission of an article of imported food and removal from import alert. FDA is critically aware of protecting individual personally identifiable information, and FDA information technology systems have safeguards in place to ensure this information remains confidential. Having said that, we discourage LAAF-accredited laboratories from submitting to us an individual analyst's social security number or any other unnecessary personally identifiable information.

(Comment 117) Several comments express concern with FDA collecting and reviewing test results and analytical reports. Some comments state concern with the resources required for the Agency to review test results and analytical reports and the mechanisms to ensure consistent review across FDA.

(Response 117) FDA has been collecting and reviewing the private laboratory test results and analytical packages used to support admission of an article of imported food and removal from import alert for decades. To implement the LAAF program described in section 422 of the FD&C Act, FDA will collect and review additional test results and analytical packages as well (*e.g.,* shell egg testing) (see § 1.1107). This program is designed to further protect the U.S. food supply and FDA is committed to implementing this program and realizing the public health benefits associated with the improved confidence in these test results. See the FRIA (Ref. 4) for additional discussion of the estimated costs (and cost savings) to FDA associated with this rule.

For discussion of how we ensure consistent review of analytical reports, please see Response 132.

(Comment 118) Some comments ask whether the justification for any modification to or deviation from the method of analysis and the recognized accreditation body's authorization therefore should be submitted as an extra document or as part of a full or abridged analytical report.

(Response 118) ISO/IEC 17025:2017 requires the laboratory to justify and authorize any method deviation or modification (*e.g.,* sections 5.6.b and 5.6.c require personnel to have the authority and resources to identify and prevent or minimize deviations; section 7.2.1.7 requires deviations to be technically justified and authorized) (Ref. 3). Final § 1.1152(c)(5) requires the LAAF-accredited laboratory to submit documentation of any such justification and authorization to FDA as part of the documentation required to be submitted with test results. Regarding the method of submission, the justification and authorization should be a distinct document, clearly marked, within the analytical report.

Again, note that in the final rule this requirement appears at § 1.1152(c)(5), which is the provision detailing information required with every analytical report (whether full or abridged); in the proposed rule the requirement was repeated in the separate lists of what is required in a full and what is required in an abridged analytical report.

(Comment 119) Some comments state that the reporting requirements under § 1.1152 should be modified, suggesting that they are duplicative, onerous, and can create unnecessary delays and increases in both laboratory administrative time and FDA review. Under the proposed rule, laboratories would be required to be accredited by recognized accreditation bodies that are full members of the ILAC (see § 1.1113); some comments state this means that FDA should require less documentation under § 1.1152. Some comments state that testing procedures within the scope of LAAF-accreditation are assessed by auditors and that certificates of analysis of test medium and equipment calibration are reviewed before LAAF-accreditation is granted. Further, comments question the need for the analyst name and signature for each analytical step. Comments overall question the added value of collecting what they view as a large amount of information.

Some comments express concern over the burden of submitting the full analytical reports as required under proposed § 1.1152(g). To decrease this burden, the comments recommend that FDA reduce the level of detail in each report since ISO/IEC 17025:2017 already includes periodic audits by the accreditation body for many of these analytical report requirements, such as proficiency testing and verification and validation studies required by proposed § 1.1152(c). The comments also suggest that the frequency of reporting to FDA could be adjusted and reduced based on risk.

A few comments also suggest that an official certificate of analysis from a laboratory accredited by a recognized accreditation body and submission of an analytical report meeting the requirements of ISO/IEC 17025:2017 should be sufficient to serve as the full analytical report required in proposed § 1.1152(g).

Some comments express the belief that certain documents listed below should not be required to be submitted to FDA with each test result under proposed § 1.1152:

- All sampling plans and sample collection reports related to food testing conducted and written documentation of the sampler's qualifications (proposed § 1.1152(c)(1) and (2));
- Certification from one or more members of the accredited laboratory's management certifying that test results, notifications, reports and studies are true and accurate (proposed § 1.1152(c)(7));
- Documentation of references for the method or methods of analysis used (proposed § 1.1152(g)(2));
- Identification of the analyst(s) who conducted each analytical step, validation step, and verification step, including analyst(s) legal name and signature (proposed § 1.1152(g)(3));
- Calculations (proposed § 1.1152(g)(4));
- References, in color, of chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra (proposed § 1.1152(g)(5));
- Copy of the label from any immediate container sampled and any additional labeling needed to evaluate the product (proposed § 1.1152(g)(7));
- All original compilations of raw data secured in the course of analysis, including discarded, unused, or reworked data, with the justification for discarding or reworking such data, corresponding supporting data, and quality control results all identified with unique sample identification (proposed § 1.1152(g)(8));
- Any other relevant additional supporting information, storage location of analyzed samples, and appropriate attachments such as instrument printouts, computer generated charts and data sheets, photocopies or original labels for the product analyzed (proposed § 1.1152(g)(9));
- Curriculum vitae of testing analysts, training records for analyst(s), including dates of training, name of trainer; any other documentation of the analyst(s)' ability to perform the method properly in the context of the food testing (proposed § 1.1152(g)(12);
- ''Documents related to the accredited laboratory's grant'' (proposed § 1.1153(a)(1)).

A few comments support the submission of the remaining items in proposed § 1.1152(a), (c), and (g), with the exception of the modifiers ''all'' and ''any'' throughout § 1.1152 since comments contend the language is unclear and may put participating laboratories at unreasonable risk.

(Response 119) After considering the comments, FDA is making limited changes to the required contents of a full analytical report. We note that documents related to the LAAF-accredited laboratory's grant of LAAF-accreditation are not required to be submitted as part of an analytical report. Next, we note that we have removed the individual proficiency test worksheet requirement from among the documents to be submitted as part of a full analytical report. Also, we have clarified in the final rule that analyst training information is only for the applicable methods, not all training records. We also added a parenthetical clarification after ''quality control results,'' which states, ''including the expected result and whether it is acceptable.'' Note that we have added corresponding text to the required contents of an abridged analytical report; see our discussion of § 1.1153 below.

According to some comments, FDA is asking for too much information in a full analytical report or is asking for LAAF-accredited laboratories to prepare and maintain too much information or documentation for each test. The reason we disagree with both contentions is based on our mission of protecting the public health from adulterated food products; namely, in order for FDA to responsibly carry out its duties with regard to the food testing described in § 1.1107, we need to be able to assess the scientific credibility, reliability, and validity of each test result. When a LAAF-accredited laboratory submits a full analytical report, we are able to conduct a meaningful scientific review of the LAAF-accredited laboratory's work. When a laboratory submits an abridged analytical report, we must be able to promptly access the information that would facilitate our substantive scientific review; hence, we require its creation and maintenance under this subpart (see § 1.1150(d)).

To the extent that we are allowing for the submission of abridged analytical reports under this subpart, we are allowing laboratories that have been LAAF-accredited by a recognized accreditation body to submit less documentation under this rule than we have routinely accepted for import-related PLAPs. We do not agree with comments arguing that because a recognized accreditation body reviews some laboratory documentation during its biennial assessment, we should decline to review documentation related to individual test results; the purpose of an assessment by a recognized accreditation body is entirely different than the purpose of our review of analytical reports and naturally the scope and depth of the two activities will reflect those differences.

With regard to the particular documents the comments suggest we should not require:

- The information related to the sampling plan, sample collection, and sampler qualifications are required since the accreditation of sampling is not required under this rule; therefore, FDA uses this documentation to ensure that sampling was performed correctly.
- The certification of results is a requirement of ISO/IEC 17025:2017 section 6.2.6.c (''authorization'');

however since this is not one of the required reporting elements in ISO/IEC 17025:2017 section 7.8, it is specified as a required document in this rule to ensure that FDA receives the information (Ref. 3).

- Where standard methods have not been referenced on a report, it is critical for FDA to be able to determine the test method used and therefore we require that the reference method is listed in order to make that determination.
- Identification of analysts performing specific steps are a requirement for an audit trail in laboratory records.
- The calculations are needed for the review of data to ensure that no errors affecting the reported results occurred due to math errors.
- The compilation of all raw data along with the chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra and other attachments such as instrument printouts, computer generated charts and data sheets requested are records that are required by ISO/IEC 17025:2017 to be retained as technical records and should be readily accessible by the laboratories. This information provides the necessary evidence to support the analytical conclusion of the test results. Note that, as long as a record of the processed data file is submitted, we do not consider instrument data files maintained on the instrument computer as originally obtained to be ''raw data'' and so do not require their submission (or their maintenance under § 1.1154(a)(3)).
- The requirement for the label from any immediate container sampled and any additional labeling needed to evaluate the product as well as photocopies or original labels for the product analyzed are important components for any analysis in making a determination on the acceptability of the specific product tested in relationship to the test result obtained.
- The storage location of the sample is important to assure that samples were stored in a manner which protected the integrity of the sample prior to and during analysis so that test results were not adversely impacted.
- Curriculum vitae, training records, and other records of analyst competence are discussed in Response 116.

Finally, while FDA agrees that use of the words, ''any'' (*e.g.,* ''any other relevant supporting information'') and ''all'' (''all original compilations of raw data'') is broad, we have retained their use in this section of the final rule because it is not possible to generate a full list of the potential information or data that might be needed to review the testing data due to the broad scope of analysis covered by this rule. The intent is for the LAAF-accredited laboratory to submit any records needed for a thorough technical review of the testing data.

(Comment 120) A few comments ask for FDA to define ''individual proficiency testing worksheets'' in proposed § 1.1152(g)(12)(iv) and to clarify whether each analyst who submits test results must have participated in proficiency testing each year on the method used.

(Response 120) As discussed in Response 92, the requirement that a LAAF-accredited laboratory must meet the proficiency test requirements on an annual basis for each method within the scope of LAAF-accreditation is on a per laboratory basis. Also, we have revised the final rule to delete from the full analytical package the relevant proficiency test worksheets. The recognized accreditation bodies will be reviewing proficiency testing results and any related corrective actions under § 1.1138(a)(2)(iii) of the final rule.

(Comment 121) A few comments recommend that FDA modify the language requiring a copy of the container label to be submitted to FDA as part of a full analytical report under § 1.1152(g)(7) of the proposed rule to include the qualifier, ''if available,'' as foods taken from bulk containers may not have a label.

(Response 121) We appreciate this suggestion and have revised the final rule to include ''if available'' (see § 1.1152(d)(7)).

(Comment 122) A few comments request clarification of what is required to be submitted to the recognized accreditation body or FDA as part of analytical method verification or validation studies in proposed § 1.1152 (c)(4) through (6). These comments recommend that, at a minimum, accuracy, precision, recovery, detection limits and in-matrix studies be included.

(Response 122) Note that under the final rule, all validation and verification studies required by § 1.1151(c) and (d) are required to be submitted to FDA (see § 1.1152(c)(3) and (4)). In the proposed rule, we proposed to require that some validation and verification studies be submitted to the recognized accreditation body; specifically, those validation and verification studies that were necessary for the recognized accreditation body to assess competence to the method for purposes of granting LAAF-accreditation. However, we believe it better clarifies the role of FDA as distinct from the role of the recognized accreditation body if we do not share the responsibility of reviewing those studies. When FDA reviews validation and verification studies, it is for the purpose of determining whether such a study, such as a matrix extension, demonstrates laboratory performance sufficient to support the particular analytical report under review. In contrast, recognized accreditation bodies review validation and verification studies for the purpose of assessing whether to award accreditation. Therefore, upon further consideration, in light of the comments, and in keeping with our role as reviewer of the performance of LAAF-accredited laboratories, we have determined it to be appropriate for all such studies to be submitted to FDA as a component of an analytical report.

Note that because of the differences in types of testing (chemical, biological, or physical) and the purpose of the testing, it is not practical to provide a single concise list of elements needed in a specific validation or verification study. In terms of clarifying what a LAAF-accredited laboratory needs to submit to FDA as part of a validation or verification study, we direct interested parties to the existing FDA Food Program's guidelines on performing validation and verification studies located at the following web link: *https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines.* Laboratories may use these guidelines in performing validation studies or they may use other established and recognized protocols such as AOAC. Please identify the protocol that is being used when submitting a validation.

7. What are the requirements for submitting abridged analytical reports (§ 1.1153)?

Proposed § 1.1153 covered records requirements for LAAF-accredited laboratories; we have relocated those provisions to § 1.1154 in the final rule. Section 1.1153 in the final rule addresses abridged analytical reports and is comprised of provisions that appeared in § 1.1152(d) through (f) in the proposed rule.

In the proposed rule, an abridged analytical report was comprised of most of the information required in a report by ISO/IEC 17025:2017 and the justification and documented authorization for any modification to or deviation from the method used. Note that in the proposed rule, the justification and authorization information was also required as part of a full analytical report. On our own initiative and for efficiency and clarity, we moved this requirement to

§ 1.1152(c), which is the provision describing documentation required to be submitted with test results (whether full or abridged analytical reports).

Additionally, in the final rule we have added a component to the abridged analytical report contents: Quality control results (including the expected result and whether it is acceptable). The addition of quality control results to the abridged analytical report will provide FDA with important contextual information for the certificate of analysis and may reduce our need to request other documentation or a full analytical report pursuant to § 1.1153(d). Finally, in § 1.1153(e) of the final rule, we reiterate that we may consider the testing to be invalid if the LAAF-accredited laboratory fails to submit all required testing-related documentation. This appeared in § 1.1152(k) of the proposed rule and applied to all analytical reports; it appears in § 1.1152(g) of the final rule as it applies to full analytical reports and all other information required to be submitted to FDA under § 1.1152.

Briefly, in the proposed rule a LAAF-accredited laboratory would have gained permission to submit abridged analytical reports after submitting 10 successful consecutive full analytical reports to FDA. Of the full analytical reports, at least one would have needed to be from each of the major food testing discipline for which the laboratory sought permission. LAAF-accredited laboratories that failed to submit 10 successful consecutive analytical reports would be required to wait a minimum of 2 years before again attempting to submit the 10 successful consecutive analytical reports. Similarly, if an abridged analytical report contained material substantive shortcomings or repeated administrative deficiencies, that laboratory would be required to wait a minimum of 2 years before reapplying for permission to submit abridged analytical reports. Comments regarding the abridged analytical report provisions of the proposed rule are discussed below.

(Comment 123) Many comments support allowing laboratories to submit shorter and simpler abridged analytical reports to FDA after meeting certain requirements, as outlined in proposed § 1.1152(d). These comments suggest that FDA may be able to more quickly review abridged analytical reports. A few comments request clarification on whether the requirements for abridged analytical reports apply to governmental accredited laboratories and if not, whether FDA would consider developing a similar process for them. Some comments state that the opportunity to submit abridged analytical reports should apply to all accredited laboratories, public and private.

A few comments contend that the ability to submit abridged analytical reports to FDA is of limited benefit because LAAF-accredited laboratories would have to submit a full analytical report to FDA within 48 hours if requested, as proposed under § 1.1152(e)(1). Some comments also recommend that the timeframe for providing FDA with the full analytical report should be at least 72 hours, as 48 hours is not enough time to compile the large amount of information needed for a full analytical report.

Other comments mention that the circumstances necessitating the exceptions described in the preamble to the proposed rule, (''. . . [for] the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program . . . .'' (84 FR 59452 at 59484)) are vague and request that FDA clarify the standard it will use in requesting full analytical reports.

(Response 123) We appreciate the support for the proposal to allow the submission of abridged analytical reports and we agree that this approach may promote certain efficiencies for LAAF-accredited laboratories and FDA.

As a threshold matter, the final rule requirements regarding abridged analytical reports apply to all LAAF-accredited laboratories conducting food testing under this subpart. Government laboratories may apply to a recognized accreditation body to become LAAF-accredited to conduct food testing under this subpart and may request permission to submit abridged analytical reports as described in § 1.1153.

Regarding the 48-hour timeframe in which laboratories permitted to submit abridged analytical reports may need to produce and submit to FDA a full analytical report, we are making two changes in response to comments. First, we are changing the timeframe in which a LAAF-accredited laboratory would need to submit a full analytical report pursuant to the exception from 48 to 72 hours to provide additional time to prepare documents for submission to FDA. Second, we are clarifying that we may request one or more additional documents up to a full analytical report under the exception. This will enable the Agency to tailor the request to the specific circumstances and likewise will reduce the burden on LAAF-accredited laboratories under this exception.

With those changes, we are maintaining the exception as it remains an important tool by which we may audit abridged analytical reports and otherwise protect public health and LAAF program integrity (see discussion at 84 FR 59452 at 59484). Under this exception and as stated in the preamble to the proposed rule, we may request additional documentation or a full report under this exception at our discretion, which may be based on the underlying public health risk of the analyte, if we have a question about something in the abridged analytical report, something in the abridged analytical report appears to be amiss, or on a random basis to spot-check LAAF-accredited laboratory performance. We estimated making these requests for no more than 10 percent of abridged analytical reports submitted, but at least once per year (see 84 FR 59452 at 59484).

Finally, we note that the analytical steps should not change when producing an abridged analytical report, only the amount of information submitted to FDA (see § 1.1150(d)).

(Comment 124) Several comments state that FDA should simplify the process for granting permission to submit abridged analytical reports as it is overly burdensome on both LAAF-accredited laboratories and FDA and diverts resources away from protecting public health. These comments recommend that FDA consider as few as one or two full analytical reports per major food testing discipline. These comments contend that the proposed process, requiring 10 full reports, would give larger LAAF-accredited laboratories an advantage and that these larger laboratories are better able to absorb the increased cost of full analytical reports without the need to pass the higher cost on to the owner or consignee.

Many comments argue that the proposed disqualification periods from submitting abridged analytical reports or even the failure to gain permission would be detrimental to LAAF-accredited laboratories and overly punitive. These comments state that corrective action to address deficiencies would be more appropriate and would afford the LAAF-accredited laboratory due process. Some comments recommend that FDA issue a warning letter to LAAF-accredited laboratories with material substantive shortcomings so that corrective action could be taken in response. Comments state further that FDA should meet with the LAAF-accredited laboratory and recognized accreditation body or allow for an appeals process prior to taking further action to use probation or disqualification especially since this could be based on minor repeated

administrative deficiencies yet would result in a long disqualification period.

Comments also request additional details regarding ''material substantive shortcomings'' and ''administrative deficiencies'' and argue that interpretation of these terms, if not clearly defined, could be inconsistently applied when reviewing abridged analytical reports. Further, comments express concerns that, as proposed, repeated administrative deficiencies could become a material substantive shortcoming and lead to disqualification, which would have a large financial impact on LAAF-accredited laboratories. These comments urge FDA to consider what public health benefit, if any, would accrue from focusing on administrative deficiencies and the resulting burden on LAAF-accredited laboratories.

Some comments indicate that permission to submit abridged reports represents a direct relationship between FDA and LAAF-accredited laboratories where the recognized accreditation body is not involved. Other comments contend that the LAAF-accreditation process should be considered evidence of a laboratory's ability to submit full analytical reports and ultimately reduce or eliminate the number of full analytical reports required to be submitted to gain permission from FDA to submit abridged analytical reports.

(Response 124) We agree with comments regarding the need to simplify the proposed process for seeking permission to submit abridged analytical reports and the need to revisit the consequences of deficiencies in abridged analytical reports. We have made significant changes to both aspects of the abridged analytical report process in the final rule. In simplifying the process, we decline the recommendation to rely on recognized accreditation bodies to evaluate a LAAF-accredited laboratory's ability to submit abridged analytical reports. We agree that recognized accreditation bodies will play a crucial role with respect to LAAF-accrediting laboratories and continuing oversight of the laboratories they LAAF-accredit; however, FDA's role is to review the performance of those laboratories and in particular, to do so by reviewing analytical reports. Moreover, we maintain that FDA's experience with LAAF-accredited laboratories' full analytical reports and the Agency's confidence in reliance on such analytical reports to make regulatory decisions are imperative factors in the decision to grant permission to submit abridged analytical reports. Therefore, although we have revised the processes related to abridged analytical reports, it remains FDA, rather than the recognized accreditation bodies, that will have the authority to grant permission to submit abridged reports.

In terms of gaining permission to submit reports, on request of the LAAF-accredited laboratory, FDA will review the last five full analytical reports for a major food testing discipline (biological, chemical, and physical) to determine whether the LAAF-accredited laboratory will be granted permission to submit abridged analytical reports for that major food testing discipline. In reviewing the last five analytical reports, FDA will check that the reports contain no shortcomings that call into question the validity of the test result or repeated administrative errors. Additionally, FDA will confirm that the LAAF-accredited laboratory requesting permission is not on suspension or probation for any method within the major food testing discipline for which the laboratory is requesting permission and that the laboratory has successfully implemented any required corrective action (see §§ 1.1121 and 1.1161). FDA will notify the LAAF-accredited laboratory if permission has been granted or denied.

The revised process for requesting permission should reduce the burden for both FDA and LAAF-accredited laboratories and will still ensure that there is requisite experience with full analytical reports for each major food testing discipline for which permission to submit abridged analytical reports is sought. We recognize that the proposed process of submitting 10 full analytical reports and granting permission for the major food testing disciplines included in those 10 reports could result in a grant of permission for a major food testing discipline based on as few as 1 full analytical report if it was included among a group of 9 other full analytical reports for another major food testing discipline. Changing the process to review five full analytical reports per major food testing discipline provides for more equal oversight of, and experience with, full analytical reports, reduces the potential competitive advantage of larger laboratories, and reduces the overall barrier to permission. It also alleviates the need for a separate process for adding a major food testing discipline as proposed (see § 1.1152(d)(3) of the proposed rule). Finally, in response to comments and on our own initiative, we have revised and simplified the oversight process for abridged analytical reports to leverage existing program oversight tools, including corrective action, described in § 1.1161 as opposed to relying on the separate process proposed. Thus, we have removed disqualification periods specific to issues with submitting abridged analytical reports (see proposed § 1.1152(d)(2) and (d)(4) through (6)). Section 1.1153(b) of the final rule describes the process by which FDA will review and communicate issues with abridged analytical reports and when FDA may require corrective action, probation, or may revoke permission to submit abridged analytical reports. We believe the revised process will be fairer and more transparent for LAAF-accredited laboratories and easier for FDA to implement.

In response to concerns that a LAAF-accredited laboratory's failure to gain permission to submit abridged analytical reports will negatively impact the laboratory, we note that, as discussed above in Response 57, permission to submit abridged analytical reports will not be included on the public registry described in § 1.1109.

We decline the request to define the terms, ''material substantive shortcomings'' and ''repeated administrative deficiencies''; however, we have made the following modifications which we believe will address the underlying concerns: We revised the final rule to specify that substantive shortcomings are those that call into question the validity of the results and clarified the section to refer to repeated administrative errors. In addition, we have specified that FDA will notify the LAAF-accredited laboratory of any deficiencies as described in § 1.1153(b)(2).

8. What other records requirements must a LAAF-accredited laboratory meet (§ 1.1154)?

The other records requirements for a LAAF-accredited laboratory appeared in § 1.1153 of the proposed rule but appear in § 1.1154 of the final rule. In paragraph (a) we proposed that LAAF-accredited laboratories be required to maintain electronically for 5 years, records created and received under this subpart, such as documents relating to the grant of LAAF-accreditation and documentation of testing conducted under this subpart. In paragraph (b) we proposed that within 30 days of the receipt of proficiency testing results, the LAAF-accredited laboratory submit the results to the recognized accreditation body and, if the laboratory failed the test, to FDA. Proposed paragraph (c) stated that a LAAF-accredited laboratory must make records available for FDA inspection and copying upon written request, and addressed related details.

Proposed paragraph (d) stated that a LAAF-accredited laboratory must ensure that significant amendments to records can be tracked to previous and original versions, and addressed related details.

We have revised the section to update terminology and cross-references and to make other minor editorial changes to improve the clarity and readability of the section. We also have made several conforming changes to reflect changes elsewhere in the final rule: We have revised paragraph (a)(1) to specify proficiency test and comparison program records; this information was previously required by proposed § 1.1153(b)(1). Accordingly, paragraph (b) has been removed and the requirement to submit proficiency test results to the recognized accreditation body has been incorporated in § 1.1138(a)(2)(iii). We removed reference to the English language and English translation requirement and electronic submission as this is now included in § 1.1110 of the final rule. Additionally, we removed the word, ''electronically,'' from paragraph (a) to allow flexibility around how LAAF-accredited laboratories maintain records and to align with the same revision for recognized accreditation bodies in § 1.1124(a). We revised paragraph (a)(3) so that it now says, ''associated correspondence between the LAAF-accredited laboratory . . . and the owner or consignee'' rather than, ''associated correspondence by the LAAF-accredited laboratory . . . with the owner or consignee;'' to clarify that correspondence to the laboratory related to food testing under this subpart is among the records the laboratory must maintain. Finally, we clarify in § 1.1154(a)(2) that the documentation of food testing that a LAAF-accredited laboratory conducted under this subpart must account for all information required by § 1.1152(d) of the final rule. This addition better clarifies the contents of the cross-reference to § 1.1150(d) in the proposed and final rule. We discuss additional changes made in response to comments below.

(Comment 125) Some comments agree that the requirement to maintain records for 5 years is reasonable and agree with the 10-business day record submission requirement in proposed § 1.1153(c).

A few comments request that FDA clarify that food testing records required in proposed § 1.1153(a)(2) are limited to records related to testing covered by this subpart and would not apply to routine testing that is performed outside the scope of the rule. Some comments request clarification as to why all requests for food testing from an owner or consignee are necessary as stated in proposed § 1.1153(a)(4).

(Response 125) We appreciate the supportive comments and agree that records a LAAF-accredited laboratory must maintain under this rule (proposed § 1.1153, final rule § 1.1154) are only those related to food testing covered by this subpart. Per the request from comments, we clarify in the final rule that LAAF-accredited laboratories maintain all requests for food testing from an owner or consignee that would be conducted under this subpart. These records would help FDA ascertain compliance with the requirement to submit all test results to FDA (under § 1.1152(b)).

J. Comments Regarding FDA Oversight of LAAF-Accredited Laboratories

TABLE 11—CHANGES TO SECTIONS REGARDING FDA OVERSIGHT OF LAAF-ACCREDITED LABORATORIES

Final rule	Proposed rule	Notes
FDA Oversight of LAAF-Accredited Laboratories.	Procedures for Accreditation of Laboratories ..	Revised to reflect new terminology and reorganization of the final rule.
§ 1.1159 How will FDA oversee LAAF-accredited laboratories?	§ 1.1159 How will FDA oversee accredited laboratories?	Revised to reflect new terminology.
§ 1.1160 How will FDA review test results and analytical reports?	§ 1.1160 How will FDA review submitted test results and analytical reports?	Minor editorial change.
§ 1.1161 When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?	§ 1.1161 When will FDA put an accredited laboratory on probation or revoke the accreditation of a laboratory?	Revised to reflect new terminology and revised contents of the section.
§ 1.1162 What are the consequences if FDA puts a LAAF-accredited laboratory on probation or disqualifies a LAAF-accredited laboratory?	§ 1.1162 What are the consequences if FDA puts an accredited laboratory on probation or revokes the accreditation of a laboratory?	Revised to reflect new terminology.

1. How will FDA oversee LAAF-accredited laboratories (§ 1.1159)?

This section of the proposed rule described three broad mechanisms FDA might employ to oversee LAAF-accredited laboratories. First, in proposed paragraph (a) we stated that we ''may assess accredited laboratories at any time to determine whether . . . there are deficiencies . . . that, if not corrected, would warrant . . . revocation of its accreditation.''

In proposed paragraph (b), we listed various records and information that we may review in evaluating the performance of a LAAF-accredited laboratory, such as records the laboratory is required to maintain under this subpart. Proposed paragraph (c) stated that we may conduct an onsite ''assessment'' of the LAAF-accredited laboratory. Proposed paragraph (d) stated that we will report our observations and findings to the recognized accreditation body.

As discussed above at Response 10, FDA has revised terminology throughout this rule to clarify that our role with regard to LAAF-accredited laboratories is not to ''assess'' them but is to review their performance, primarily by reviewing analytical reports and test results. In final § 1.1159 we revised the language accordingly, to more clearly communicate our role. This section now consistently refers to FDA reviewing the performance of a LAAF-accredited laboratory and explicitly includes analytical reports and test results submitted to FDA among the things we may review in § 1.1159(b)(5).

We have also revised paragraph (c) of the final rule to explicitly state that certain FDA review activities may be conducted remotely if it will not aid in the review to conduct them onsite. For example, records reviews or auditing filth plates are common review activities that may be conducted remotely. The ability to conduct remote reviews of LAAF-accredited laboratory performance under this subpart will provide a more efficient, cost-effective, and less intrusive option for reviews. This may also allow for continued

oversight of LAAF-accredited laboratories when onsite visits are otherwise impracticable.

We also made other conforming and minor editorial changes to this section and section title, including deletion of the phrase, ''of food subject to food testing under this subpart'' in proposed § 1.1159(b)(5) because the phrase is included in the definition of owner or consignee in § 1.1102 and therefore need not be repeated; see § 1.1159(b)(6) if the final rule. Comments regarding this section are discussed below.

(Comment 126) A few comments state that FDA onsite reviews under § 1.1159(c) should be limited to work performed under this subpart and should not extend to other work conducted by the LAAF-accredited laboratory, even work related to other FDA regulations (*e.g.,* testing under part 117). These comments further contend that when FDA conducts onsite reviews, we may not examine privileged or proprietary records or laboratory practices not directly related to this subpart.

(Response 126) We agree that an onsite review of a LAAF-accredited laboratory and any review activities conducted remotely would be limited to work performed under this subpart. We have revised § 1.1159(c) to further clarify that FDA's onsite review is limited to a LAAF-accredited laboratory's performance under this subpart. As such, it would not include review of privileged or proprietary records or laboratory practices outside the scope of this final rule.

(Comment 127) Some comments encourage FDA to communicate with the recognized accreditation body if during the course of our review of a LAAF-accredited laboratory we obtain information causing us to place the LAAF-accredited laboratory on probation or disqualify the LAAF-accredited laboratory from conducting food testing under this subpart. The recognized accreditation body could then perform an assessment of its own related to the laboratory's ISO/IEC 17025:2017 accreditation and LAAF-accreditation status.

(Response 127) Section 1.1159(d) of the final rule states that ''FDA may report any observations and deficiencies identified during its review of LAAF-accredited laboratory performance under this subpart to the recognized accreditation body.'' This would include information that causes us to place the LAAF-accredited laboratory or disqualify the laboratory from conducting testing under this subpart.

(Comment 128) Some comments express concern that the proposed rule did not communicate more detailed information about the processes around FDA review of LAAF-accredited laboratories. These comments ask what the impact would be if FDA found a deficiency in the course of its review; for example, whether FDA would invalidate past test results and, if so, how far back in time the invalidation would extend.

(Response 128) The impact of any deficiency identified in the course of an FDA review of a LAAF-accredited laboratory's performance under this subpart would depend on the deficiency found. Section 1.1160 describes what would happen if FDA finds a deficiency in an analytical report. As described in § 1.1161(a) of the final rule, FDA may require corrective action to address any deficiencies identified. In the case of certain serious deficiencies such as those described in § 1.1161(c) of the final rule, FDA may disqualify a LAAF-accredited laboratory from submitting analytical reports for one or more methods within the scope of LAAF-accreditation. The consequences of probation or disqualification are described in § 1.1162 of the final rule. Paragraph (c) states in relevant part that FDA may refuse to consider specific food testing results if the basis for disqualification of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

2. How will FDA review test results and analytical reports (§ 1.1160)?

Proposed § 1.1160(a) through (c) described how FDA would proceed if it finds deficiencies in any test result, analytical report, related documents (*e.g.,* related to sampling), or the associated analysis indicates that any aspect of the testing under this subpart is not being conducted in compliance with the requirements of this subpart. In paragraph (a), we proposed that we may consider the analysis to be invalid and/or will notify the LAAF-accredited laboratory and may also notify the owner or consignee, of the deficiency. The LAAF-accredited laboratory would be required to respond to FDA within 30 days. Proposed paragraph (b) stated that we may report our determination of a deficiency to the recognized accreditation body. Proposed paragraph (c) stated that if the deficiency demonstrates a material substantive shortcoming in the related food testing, or demonstrates repeated administrative deficiencies, we may also consider disallowing the LAAF-accredited laboratory from submitting abridged analytical reports, or other actions under this subpart. Proposed paragraph (d) noted that nothing in this subpart limits FDA's ability to review and act upon information received about food testing.

We revised this section to incorporate updated terminology, to make conforming changes, and to improve clarity and readability. We discuss additional changes made in response to comments below.

(Comment 129) Some comments indicate that proposed § 1.1160(b) did not state that recognized accreditation bodies ''will'' be informed when FDA finds a deficiency as a result of reviewing a LAAF-accredited laboratory's test results, analytical reports, related documents, or the associated analysis; instead we used the word, ''may.'' These comments urge FDA to inform the recognized accreditation body of findings of deficiency. Other comments appear to encourage us to notify the recognized accreditation body when we learn of a possible deficiency, before we reach a conclusion that a deficiency has occurred. Comments generally urge FDA to have transparent communication with recognized accreditation bodies regarding the LAAF-accredited laboratories.

(Response 129) We agree that communication between the FDA and the recognized accreditation bodies will be beneficial for this program. At the same time, we do not want to overwhelm a recognized accreditation body with details concerning analytical reports that are unlikely to be relevant to their oversight of a LAAF-accredited laboratory. To that end, final § 1.1160(b) provides FDA with discretion regarding which observations and deficiencies we will report to a recognized accreditation body. We anticipate deciding on a case-by-case basis which deficiencies are significant enough to warrant notifying a recognized accreditation body. By way of two examples, while a deficiency such as failure to run quality control samples as required in § 1.1138(a)(3), that would call into question the validity of the test result, likely would be reported to the recognized accreditation body, a deficiency that does not call into question the validity of the test, such as FDA requesting a missing document, generally would not require notification of the recognized accreditation body. Relatedly, we have clarified in § 1.1160(a) that we may require that a laboratory correct the test result, analytical report, related documents, or the associated analysis. Such correction would not require additional corrective action; however, FDA may require corrective action for certain deficiencies.

(Comment 130) Some comments request that in the event that FDA identifies a deficiency in an analytical report, FDA not notify the owner or consignee if the deficiency can be immediately resolved and human health is not directly affected.

(Response 130) The potential circumstances surrounding FDA identification of a deficiency in a test result, analytical report, or related documents are numerous and varied. It would be imprudent for us to try to categorize deficiencies and establish different notification requirements for the various categories. Instead, we will approach each instance of deficiency under § 1.1160(a) on a case-by-case basis, in terms of determining whether it is appropriate to inform the owner or consignee. We do take the point of the comment, though, and agree that owners or consignees need not always be informed when FDA identifies a deficiency in a test result, analytical report, or related documents. Accordingly, we are retaining the conditional language of the proposed rule in § 1.1160(a) of the final rule by stating that FDA ''may'' report such deficiencies to the owner or consignee.

(Comment 131) Some comments state that FDA should expedite review of analytical reports and test results from all LAAF-accredited laboratories. These comments contend that this will benefit both importers and their customers and will result in more efficient use of FDA resources during review.

(Response 131) We acknowledge these comments and intend to review analytical reports in a timely fashion.

(Comment 132) Some comments express the concern that FDA's review of analytical reports submitted in relation to testing to support removal from import alert has been inconsistent, both between FDA regions and within single facilities. Comments contend that over time FDA has required increasing amounts of information. Comments express frustration that it has been difficult to gain clarity from FDA regarding what our standards are for the documents comprising a full analytical report. Comments recommend that FDA develop a document that clearly communicates to FDA staff as well as laboratories submitting reports, our requirements for each component of a full analytical report; comments assert this should be done before holding laboratories accountable for failure to satisfy such requirements.

Other comments express frustration regarding working with FDA to resolve issues identified in analytical reports submitted in relation to testing to support removal from import alert. These comments assert that such resolution requires the participation of more than one office within FDA's Office of Regulatory Affairs. In the view of these comments, the cumbersome FDA resolution process results in delayed admissibility decisions.

Other comments request that we clarify how we will ensure that analytical reports are reviewed by qualified FDA personnel.

(Response 132) The review of the laboratory analytical reports and test results is a very structured process. Reviewers complete technical reviews using the Laboratory Manual Volume III Section 7—Private Laboratory Guidance, corresponding import alerts, and other appropriate guidance documents ensuring that the technical reviews are consistent across reviewers and that testimony submitted contains all pertinent elements needed for the specified analysis to assure FDA that the scientific data is credible, reliable, and valid. Reviewing personnel are highly qualified and have gone through extensive training to perform these reviews. The use of technical lead review panels further aids in preventing inconsistencies and in standardizing the review process by insuring a uniform, systematic, and effective approach to package review across the FDA. The periodic auditing of the technical review process in accordance with FDA's quality system and Laboratory Manual Volume III Section 7—Private Laboratory Guidance (*https://www.fda.gov/media/73540/download*) provides another layer of consistency to the process. Average turnaround time for a review is generally 2 days including the technical lead review assignments. The required elements for full and abridged analytical reports, along with the documents required to be submitted with test results, are set forth in this final rule. This process is designed to mitigate inconsistencies.

Finally, it is true that more than one FDA office may have a role to play when we work with laboratories to resolve questions regarding an analytical report. We endeavor to work efficiently across the involved FDA offices to resolve such issues and communicate the resolution to impacted internal and external entities.

3. When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports (§ 1.1161)?

Proposed § 1.1161 described the grounds necessary for FDA to place a LAAF-accredited laboratory on probation or disqualify it from the program and the processes for taking such action. In paragraph (a) we stated that we may disqualify a laboratory in whole or in part for good cause and when the recognized accreditation body fails to withdraw LAAF-accreditation. We stated that the reasons may include demonstrated bias or lack of objectivity in testing, performance that calls into question the validity or reliability of testing, or other failure to substantially comply with this subpart.

In proposed paragraph (b) we described the grounds for probation as deficiencies that are less serious and more limited than those identified in paragraph (a), when it is reasonably likely that the LAAF-accredited laboratory will be able to correct them within a specified period of time. We stated that under such circumstances we would temporarily place the laboratory on probation and request appropriate corrective action. In proposed paragraph (c) we clarified that we may disqualify a LAAF-accredited laboratory in part (for just some methods).

In proposed paragraph (d) we stated that a LAAF-accredited laboratory's probationary status would last either until the deficiency is corrected or FDA determines that disqualification is warranted. In proposed paragraph (e) we described the notice of disqualification that we would provide to a LAAF-accredited laboratory. In proposed paragraph (f) we described the notice of probation that we would provide to a LAAF-accredited laboratory. In proposed paragraph (g) we stated that if we place a LAAF-accredited laboratory on probation and determine that the laboratory is not implementing appropriate corrective actions we may disqualify the laboratory in whole or in part. In proposed paragraph (h) we stated that probationary status and disqualification will be noted on the public registry described in § 1.1109.

We revised the section to incorporate updated terminology and to specify that probation can be method-specific, to be consistent with disqualification which is also method-specific (see § 1.1161(b) of the final rule). We also revised the section title to more accurately reflect the section contents of the final rule (''When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?'') We discuss additional changes made in response to comments below.

(Comment 133) Some comments disagree with the processes we proposed in § 1.1161 regarding how FDA would follow up with a LAAF-accredited laboratory if we identify a

concern with the laboratory's performance. Some comments disagree with the ordering of our actions because in the proposed rule, we described first notifying a LAAF-accredited laboratory that we were placing it on probation, and then allowing an opportunity for the laboratory to correct. Some comments assert that such a process is not consistent with processes in the conformity assessment arena.

Several comments state that under the proposed rule, probationary status would be publicly noted on the online registry; several comments argue that sharing that status publicly could impede the LAAF-accredited laboratory's business. Comments contend that professional courtesy and due process should dictate that the Agency provide notice before imposing any status changes or restrictions on a LAAF-accredited laboratory. These comments argue it would be unfair of FDA to imply on the public registry that the laboratory's performance had been unacceptable without first allowing the laboratory an opportunity to take corrective action.

Several comments recommend that, instead, FDA should notify the LAAF-accredited laboratory of our concern and provide an opportunity for the laboratory to correct, before the Agency imposes any status changes. In particular some comments recommend that, if FDA has a concern with the LAAF-accredited laboratory's performance, FDA should utilize the laboratory complaint process (required by ISO/IEC 17025:2017 section 7.9 (Ref. 3)). In the view of these comments, if FDA's concern has not yet been adequately addressed via the LAAF-accredited laboratory's complaint process, then the matter should be raised to the recognized accreditation body. For example, some comments suggest that if FDA is not satisfied with a LAAF-accredited laboratory's corrective action, then there should be a meeting between FDA, the LAAF-accredited laboratory, and the recognized accreditation body to try and resolve the issue, before FDA proceeds to probation or disqualification. Some comments suggest that, after FDA places a LAAF-accredited laboratory on probation, the laboratory be afforded an additional opportunity to remedy the deficiency.

Some comments maintain that LAAF-accredited laboratories should have an opportunity to defend against a potentially ''hypercritical review'' that raises only minor problems or mistakes that do not impact the test results. These comments further contend that such problems or mistakes should not impact the laboratory's LAAF-accreditation status.

Finally, comments encourage FDA to establish a single process for following up on concerns with the performance of a LAAF-accredited laboratory, and that process should lead only to potential probation or disqualification. In this view, potential or actual deficiencies in the performance of a LAAF-accredited laboratory should not impact the laboratory's eligibility to submit abridged analytical reports.

(Response 133) After considering the comments, we agree that a LAAF-accredited laboratory should be afforded the opportunity to take corrective action on FDA notification of a deficiency prior to being placed on probation by FDA. Thus, we have revised § 1.1161 of the final rule to reflect this position. Specifically, § 1.1161(a) describes a corrective action process which relies on the complaint and corrective action processes required by ISO/IEC 17025:2017 sections 7.9 and 8.7, respectively. As stated in § 1.1161(b) of the final rule, FDA will only proceed to probation if ''FDA determines that a LAAF-accredited laboratory has not effectively implemented corrective action or otherwise fails to address deficiencies identified.'' Similarly, FDA will only proceed to disqualify a laboratory from the LAAF program if we determine that ''a LAAF-accredited laboratory on probation [failed] to effectively implement correction action or otherwise address identified deficiencies.'' Id. at (c)(2). Thus, a LAAF-accredited laboratory will have at least two opportunities to respond to FDA regarding an identified deficiency before FDA disqualifies the laboratory from submitting analytical reports under the LAAF program.

Some comments suggest that if the initial complaint and corrective action process fails to satisfy FDA, FDA should involve the recognized accreditation body. FDA agrees and accordingly, final § 1.1161(b)(1) provides that FDA will notify both the LAAF-accredited laboratory and its recognized accreditation body if we have grounds for probation. It is possible that a meeting between the FDA, the recognized accreditation body, and the LAAF-accredited laboratory may be beneficial at that stage, but as deficiency circumstances will vary greatly, we will consider that option on a case-by-case basis.

We accept the point made in some comments that minor deficiencies should not result in probationary status, and agree that a small number of administrative errors would not form the basis for FDA to require corrective action. However, in the case of submissions from a LAAF-accredited laboratory that evidence a pattern of inattention with regard to any requirements, it may not be unreasonable for FDA to grow concerned that the laboratory may also be failing to observe other, more substantive, details.

Finally, after considering the comments we agree that it will be clearer and more efficient to forego a separate set of disciplinary actions regarding permission for a LAAF-accredited laboratory to submit abridged analytical reports. Accordingly, final § 1.1161 describes the single path of actions that FDA can pursue against a LAAF-accredited laboratory. For more information on permission to submit abridged analytical reports, see above discussion of § 1.1153 at Response 124.

(Comment 134) Several comments express concern with FDA's proposed use of the words, ''probation'' and ''revoke'' in § 1.1161. Some comments advise that FDA should better distinguish between actions the FDA may take against a LAAF-accredited laboratory under this subpart, and the actions an accreditation body might take against a laboratory with regard to that laboratory's ISO/IEC 17025:2017 accreditation. Some comments suggest that, because FDA lacks authority to impact a laboratory's ISO/IEC 17025:2017 accreditation, we should clarify that if we place a LAAF-accredited laboratory on probation, the impact of our action is limited to this subpart, and not the laboratory's ISO/IEC 17025:2017 accreditation.

(Response 134) We agree that FDA authority under this subpart does not directly impact or relate to the laboratory's ISO/IEC 17025:2017 accreditation. We have made changes throughout the final rule to clarify that actions taken under this subpart against LAAF-accredited laboratories by recognized accreditation bodies are limited to impacting a laboratory's LAAF-accreditation and actions taken by FDA are limited to impacting the laboratory's ability to conduct the tests described in § 1.1107. Additionally, we have revised the language used in § 1.1161 to better distinguish FDA and recognized accreditation body actions under this subpart. For example, we use the terms, ''reduce the scope'' and ''withdraw'' to describe the actions a recognized accreditation body may take with respect to LAAF-accreditation and we use the word, ''disqualify'' to describe the action FDA may take with regard to a laboratory's eligibility to conduct the testing described in § 1.1107. For a full discussion of

terminology revisions in the final rule, see Response 10, above.

(Comment 135) A few comments request clarification of exactly when a LAAF-accredited laboratory would be placed on probation. We understand these comments to be expressing confusion over what ''probation'' means in this context, because it is not a familiar concept in the realm of conformity assessment (*e.g.,* neither ISO/IEC 17011:2017 or ISO/IEC 17025:2017 contemplate probation).

(Response 135) We first note that in light of the comments, FDA changed several terms in the final rule. We are now using separate terms for actions taken by FDA and recognized accreditation bodies with regard to LAAF-accredited laboratories, to better delineate the roles of FDA and the recognized accreditation bodies under this subpart. In the final rule, FDA may place a LAAF-accredited laboratory on ''probation'' but the recognized accreditation body ''suspends'' a laboratory's LAAF-accreditation.

Also in light of the comments, we substantively revised the grounds for probation of a LAAF-accredited laboratory. In the proposed rule, probation was reserved for less serious laboratory deficiencies than the deficiencies that might lead to FDA disqualification of the LAAF-accredited laboratory. In the final rule, FDA will use a single path for all laboratory deficiencies and that single path will typically involve at least a three-step process: Corrective action, then probation if the corrective action is not effective, followed by disqualification if additional actions taken during probation are ineffective. Thus, final § 1.1161(b) provides that probation may occur when ''FDA determines that a LAAF-accredited laboratory has not effectively implemented corrective action or otherwise fails to address deficiencies identified.'' Note, however, that we reserve the option to disqualify a LAAF-accredited laboratory without prior corrective action or probation in certain egregious cases described in § 1.1161(c)(1) of the final rule.

4. What are the consequences if FDA puts a LAAF-accredited laboratory on probation or disqualifies a LAAF-accredited laboratory (§ 1.1162)?

Proposed § 1.1162 describes the consequences of FDA placing a LAAF-accredited laboratory on probation or disqualifying the laboratory from submitting analytical reports under the program. Proposed paragraph (a) stated that the disqualified laboratory is immediately ineligible to conduct testing under this subpart either in part or in whole, depending on the extent of the disqualification, and a laboratory on probation may continue to conduct testing under this subpart.

Proposed paragraph (b) stated that FDA may refuse to consider testing conducted prior to disqualification if the basis for the disqualification indicates that the specific food testing previously conducted may not be reliable. Proposed paragraph (c) provided that a disqualified laboratory must notify FDA of a records custodian within 10 days. Proposed paragraph (d) stated that a laboratory on probation or that has been disqualified must notify any owners or consignees for whom it is conducting testing under this subpart, that it is on probation or has been disqualified.

We have updated this section of the final rule to incorporate updated terminology and to make other conforming changes to denote that probation and disqualification by FDA can be on a method-specific basis. On our own initiative, we relocated the requirement that the laboratory notification regarding the records custodian be submitted to FDA electronically and in English in § 1.1162(c) of the proposed rule to § 1.1110 in the final rule. We also made minor editorial changes to improve clarity and readability of the section. We received no comments solely related to this section.

K. Comments Regarding Requesting FDA Reconsideration or Regulatory Hearings of FDA Decisions Under This Subpart

TABLE 12—CHANGES REGARDING REQUESTING FDA RECONSIDERATION OR REGULATORY HEARINGS OF FDA DECISIONS UNDER THIS SUBPART

Final rule	Proposed rule	Notes
Requesting FDA Reconsideration or Regulatory Hearings of FDA Decisions Under This Subpart.	Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under This Subpart.	Revised to reflect the contents of the sections included.
§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?	§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?	No changes to the section title.
§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the accreditation body's recognition or disqualify a LAAF-accredited laboratory?	§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the recognized accreditation body's recognition or revoke the accredited laboratory's accreditation?	Revised to reflect new terminology.
§ 1.1174 How does an owner or consignee request a regulatory hearing on a directed food laboratory order?	§ 1.1174 How does an owner or consignee request a regulatory hearing on a food testing order?	Revised to reflect new terminology.

(Comment 136) Some comments suggest that regulatory hearings be held for decisions relating to FDA acceptance of test reports (full or abridged) from LAAF-accredited laboratories.

(Response 136) We decline to expand the availability of regulatory hearings to this situation. The mere acceptance of test reports from LAAF-accredited laboratories does not constitute regulatory action for which a hearing under part 16 is available or would be warranted. To the extent comments suggest a regulatory hearing should be available regarding whether a LAAF-accredited laboratory has met the criteria specified in § 1.1153 and thus may submit abridged analytical reports, as discussed in Response 124, we have revised the final rule based on the comments received to facilitate a more streamlined process for obtaining FDA permission to submit abridged analytical reports. In addition, under the final rule, if FDA identifies a deficiency in an abridged analytical report, such deficiencies are handled the same way

we would handle a deficiency in a full analytical report. Under § 1.1161 of the final rule, that means the laboratory generally has an opportunity to pursue corrective action before experiencing any negative consequences such as probation and loss of permission to submit abridged analytical reports. In our view, this process will be more productive and efficient than holding regulatory hearings in each case. Further, as discussed above in Response 57, permission to submit abridged analytical reports will not be included on the public registry described in § 1.1109. This decision mitigates any potential negative impact on a LAAF-accredited laboratory and obviates the need for a formal regulatory hearing.

1. How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement (§ 1.1171)?

Proposed § 1.1171 described the processes for an accreditation body to request that FDA reconsider its decision to deny an application either for recognition, renewal, or reinstatement. In paragraph (a), we proposed that an accreditation body must submit a reconsideration request within 10 business days after FDA issues the denial. In paragraph (b), we proposed that the reconsideration request must be signed and submitted in English, electronically, and in compliance with whatever procedures are described in the denial notice. In paragraph (c), we proposed that after reviewing and evaluating the reconsideration request, FDA would notify the accreditation body of our decision.

On our own initiative, we relocated the requirement that the reconsideration request be submitted to FDA electronically and in English in § 1.1171(b) of the proposed rule to § 1.1110 in the final rule. Additionally, we clarify in § 1.1171(b) that the request must include any supporting information. Comments regarding this section are discussed below.

(Comment 137) Some comments suggest that prior to denying an accreditation body's application for recognition, renewal, or reinstatement, FDA should provide the reason for the proposed denial and allow the accreditation body the opportunity to address FDA's concerns.

(Response 137) Procedures outlined in other sections of this final rule provide the notice and opportunity requested by these comments. With regard to an application for recognition or renewal, § 1.1115(a) provides that FDA will notify the applicant of any insufficiencies. FDA views the accreditation body application process as iterative; as stated in 1.1115(a), we will notify the applicant of any insufficiencies and provide an opportunity for the accreditation body to complete the application, before we evaluate it under § 1.1115(b).

With regard to reinstatement, under § 1.1117 an accreditation body seeks recognition by submitting a new application. The new application would be processed as described under § 1.1115. Note that an accreditation body that has had its recognition revoked by FDA is also required to submit evidence that the ground(s) for revocation have been resolved; for more information see the discussion of § 1.1117(a), above.

2. How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the accreditation body's recognition or disqualify a LAAF-accredited laboratory (§ 1.1173)?

Proposed § 1.1173 described the processes for a regulatory hearing concerning a decision by the Agency to revoke an accreditation body's recognition or disqualify a laboratory from the LAAF program.

In paragraph (a) we proposed that an entity must submit a request for a regulatory hearing within 10 business days after FDA issued a revocation of recognition or disqualification. We proposed that the hearing would be conducted under part 16 and that the revocation or disqualification notice would contain all necessary elements to constitute the notice of an opportunity for hearing under part 16 of this chapter. In brief, in paragraph (b) we proposed that the hearing request must be written and respond to the bases for FDA's determinations described in the notice.

Proposed paragraph (c) stated that the submission of a request for a hearing will not operate to delay or stay FDA's decision to revoke or disqualify, unless FDA determines that delay or a stay is in the public interest. Proposed paragraph (d) stated that the presiding officer would be designated after the hearing request is submitted to FDA and proposed paragraph (e) stated that the presiding officer may deny the hearing request under § 16.26(a). Proposed paragraph (f) addressed the conduct of the hearing.

In the proposed rule, we used the word, ''revocation'' in this section, to refer to FDA removing a laboratory from the program. We received comments expressing concern with that terminology and have revised our phrasing in light of such concerns, as discussed above at Response 10. On our own initiative, we relocated the requirement that the reconsideration request be submitted to FDA electronically and in English in § 1.1173(b) of the proposed rule to § 1.1110 in the final rule. We received no other comments solely related to this section and so have only made minor editorial and conforming changes (*e.g.,* FDA may ''disqualify'' a laboratory rather than ''revoke the laboratory's accreditation'') to the section, including the section title.

3. How does an owner or consignee request a regulatory hearing on a directed food laboratory order (§ 1.1174)?

Proposed § 1.1174 described the processes for a regulatory hearing concerning a directed food laboratory order. In paragraph (a) we proposed that an owner or consignee must submit a request for a regulatory hearing within 24 hours. We proposed that the hearing would be conducted under part 16 and that the directed food laboratory order would contain all necessary elements to constitute the notice of an opportunity for hearing under part 16 of this chapter.

In brief, in paragraph (b) we proposed that the hearing request must be written and respond to the bases for FDA's determinations described in the directed food laboratory order. Proposed paragraph (c) stated that the presiding officer would be designated after the hearing request is submitted to FDA and proposed paragraph (d) stated that the presiding officer may deny the hearing request under § 16.26(a). Proposed paragraph (e) addressed the conduct of the hearing.

On our own initiative, we relocated the requirement that the reconsideration request be submitted to FDA electronically and in English in § 1.1174(b) of the proposed rule to § 1.1110 in the final rule. We also revised the section to incorporate updated terminology and made minor editorial changes to improve the clarity and readability of the section. We discuss changes made in response to comments below.

(Comment 138) Several comments disagree with the proposed hearing process for a directed food laboratory order because they contend it would not afford sufficient due process protections to owners or consignees. Specifically, comments raise concerns that the hearing process under part 16 is discretionary and that an owner or consignee must request a hearing by filing an appeal within 24 hours. These comments state that the hearing should be guaranteed if requested. Further,

these comments argue that 24 hours is not enough time to request the hearing upon receipt of a directed food laboratory order, and that this timeframe is also not warranted from a public health standpoint. Instead, comments recommend more time, up to 10 days, as a reasonable timeframe in which to review the directed food laboratory order and prepare the request. Comments state the hearing should provide the opportunity to determine the appropriate scope of the directed food laboratory order and the ability to lift or vacate the directed food laboratory order. Comments suggest that the hearing process used for the facility registration suspension and mandatory recalls would be more appropriate.

(Response 138) After considering the comments, we agree that 24 hours may not be sufficient time to request a regulatory hearing on a directed food laboratory order. Part 16 of this chapter, which provides for regulatory hearings before the FDA, provides not less than 3 working days after receipt of the notice to request a hearing (see § 16.22(b)). We have therefore revised § 1.1174(a) to state that the hearing request under this subpart must be submitted within 3 business days, to align with the intent of part 16 of this chapter. We decline the request to establish a 10-day deadline because we consider the 3 business days applicable in other part 16 contexts to be sufficient in the directed food laboratory order context as well.

We also decline to adopt the hearing processes for facility registration suspension and mandatory recalls. The statute guarantees the opportunity for a hearing on the suspension of a food facility registration ''to be held as soon as possible, but not later than two business days after the issuance of the order . . .'' unless FDA and the registrant agree otherwise (section 415(b)(2) of the FD&C Act). Similarly, the statute guarantees the opportunity for an informal hearing regarding a mandatory recall order ''to be held as soon as possible, but not later than 2 days after the issuance of the order . . . . '' (section 423(c) of the FD&C Act). In contrast, section 422 of the FD&C Act does not provide for a guaranteed hearing process. Therefore we believe the discretionary hearing process proposed, which incorporates existing procedures in 21 CFR part 16, is appropriate with respect to directed food laboratory orders. Under § 16.26(a), a hearing request may be denied, in whole or in part, if ''no genuine and substantial issue of fact has been raised by the material submitted.''

With regard to the comments' contention that the hearing should provide the opportunity to determine the appropriate scope of the directed food laboratory order and the ability to lift or vacate the directed food laboratory order, we believe this is inherent in the procedure specified in § 16.60, which permits the presentation of any oral or written information relevant to the hearing, and which grants the presiding officer power to take any actions necessary or appropriate to conduct a fair, expeditious, and impartial hearing.

L. Comments Regarding Electronic Records and Public Disclosure Requirements

1. Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter (§ 1.1199)?

In § 1.1199 of the proposed rule, we proposed to exempt from the requirements of part 11 (21 CFR part 11) those records that meet the definition of electronic records in § 11.3(b)(6) and were established or maintained to satisfy the requirements of this subpart.

(Comment 139) Comments on this aspect of the proposed rule voice support for the proposed exemption. Comments contend that requiring such records to comply with the requirements in 21 CFR part 11 would be unnecessarily burdensome.

(Response 139) We appreciate support for this section and have finalized it without change.

2. Are the records obtained by FDA under this subpart subject to public disclosure (§ 1.1200)?

Proposed § 1.1200 stated that records obtained by FDA under this subpart are subject to the disclosure requirements under 21 CFR part 20. We received no comments on this section and have finalized the section without change.

M. Comments on Conforming and Technical Amendments and FDA Response

The proposed rule contained several conforming and technical amendments.

We proposed revising the requirements for certain analyses under the Accredited Third-Party Certification Program. Specifically, we proposed to revise § 1.651(b)(3) to require use of a laboratory that is accredited in accordance with ISO/IEC 17025:2017 to perform certain analyses for a regulatory audit. We also proposed to update the cross-reference in paragraph (c)(2) of the same section.

We received no comments on these proposed changes. Thus, we have finalized these changes as proposed, with one minor exception. In final § 1.651(c)(2), we changed, ''Federal Food, Drug, and Cosmetic Act,'' to ''FD&C Act'' to be consistent with references to the statute in the regulations for the Accredited Third-Party Certification Program in part 1, subpart M.

We proposed to amend § 11.1 regarding the scope of the electronic records and electronic signatures regulations to add paragraph (p) which states that part 11 does not apply to records required to be established or maintained by part 1, subpart R of this chapter (*i.e.,* the LAAF regulations). However, records that satisfy the requirements of subpart R of part 1 of this chapter (*i.e.,* the LAAF regulations), but that are also required under other applicable statutory provisions or regulations, remain subject to part 11.

We received no comments regarding this conforming amendment. Thus, we have finalized these changes as proposed.

We proposed conforming amendments to revise FDA's regulatory hearing regulations at § 16.1(b)(2) to include §§ 1.1173 and 1.1174 in the list of regulations covered by this part. We received no comments directly related to these conforming amendments. On our own initiative, we changed, ''revocation of accreditation'' to ''disqualification,'' consistent with the terminology changes discussed in Response 10, and ''food testing order'' to ''directed food laboratory order,'' consistent with the change in terminology discussed in the definitions section (§ 1.1102). In relation to the directed food laboratory order, we also replaced the reference to § 1.1107(a)(2) with a reference to § 1.1108, consistent with the reference we are providing in the definition of directed food laboratory order (see § 1.1102).

We proposed revising the bottled drinking water regulations in 21 CFR 129.35 to state that, ''the analysis of the five samples from the same sampling site that originally tested positive for *E. coli,* as required by paragraph (a)(3) of this section, must be conducted under part 1, subpart R of this chapter.'' We received a few comments on that proposal and are finalizing the revision without change; see comment and Response 87.

VI. Effective Date

This final rule will be effective 60 days after publication in the **Federal Register**. For information on implementation of the final rule, see the discussion under that subheading in section V.B. of this preamble.

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). We believe that this final rule is not a 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 the per-entity one-time costs of the rule may exceed one percent of revenues for accreditation bodies that choose to participate in the LAAF program, 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 proposing ''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 $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this rule. In table 13 we provide the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information System accounting information.

TABLE 13—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE [1]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$9.1	$6.6	$12.5	2020	7	10 years	Cost savings and avoided QALD losses.
	9.1	6.6	12.5	2020	3	10 years	Cost savings and avoided QALD losses.
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative	Reduced risk of food-related illness from improved test performance for covered tests. Cost savings from clarifying reporting requirements and from allowing abridged analytical reports. Reduced risk of food-related illness from unsafe food manufacturing practices.						
Costs:							
Annualized Monetized $millions/year	7.9	5.8	9.6	2020	7	10 years	
	7.9	5.9	9.7	2020	3	10 years	
Annualized Quantified	.....	.....	.....	.....	7		
					3		
Qualitative	.....	.....	.....	.....	.....		
Transfers							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7		
					3		
From/To	From:			To:			
Other	.....	.....	.....	.....	7		
Annualized Monetized $millions/year	.....	.....	.....	.....	3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None
Small Business: Potential impacts on laboratories currently not accredited to ISO/IEC 17025 that would participate in the LAAF program described by this rule
Wages: None
Growth: None

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

The full analysis of economic impacts is available in the docket for this final rule (Ref. 4) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the proposed rule (84 FR 59452 at 59496). 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 nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination (Ref. 22).

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). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. 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: Laboratory Accreditation for Analyses of Foods; OMB Control Number 0910–0898.

Description: As mandated by section 422 of the FD&C Act, we are establishing a program for the testing of food by accredited laboratories (LAAF program); establishing the standards and procedures for recognizing accredited laboratories and for recognized accreditation bodies that LAAF-accredit laboratories; establishing a publicly available registry of recognized accreditation bodies and LAAF-accredited laboratories; and establishing procedures for reporting any changes affecting the recognition of such accreditation bodies or LAAF-accreditation of such laboratories.

Description of Respondents: Respondents to the collection of information are accreditation bodies seeking recognition from FDA, recognized accreditation bodies, laboratories seeking LAAF-accreditation from recognized accreditation bodies, and LAAF-accredited laboratories.

We estimate the burden of the information collection as follows:

TABLE 14—ESTIMATED ANNUAL REPORTING BURDEN

Part 1, Subpart R Citation; Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§§ 1.1113 and 1.1114; Accreditation bodies (ABs) application for recognition (one-time submission).	4	1	4	20	80
§§ 1.1113 and 1.1114; ABs—application for renewal of recognition.	4	1	4	3.6	14.4
§ 1.1116(a) and (b); ABs—notices of intent to relinquish, records custodian.	0	3	0	3	0
§ 1.1123; ABs—reports, notifications, and documentation requirements.	4	42	168	1.75	294
§§ 1.1138 and 1.1139; laboratories—submission of application for LAAF-accreditation (one-time submission).	170	1	170	20	3,400
§ 1.1140(a); laboratories—notices of intent to relinquish, records custodian.	2	3	6	1	6
§§ 1.1149(a) and 1.1152(c)(1), (2); laboratories—submission of sampling plan, sample collection report, and sampler qualifications.	170	25	4,250	1.75	7,437.5
§§ 1.1152(d) and 1.1153(a); laboratories—qualification to submit abridged analytical reports (one-time submission).	170	10	1,700	2	3,400
§ 1.1153; laboratories—abridged analytical reports submissions.	170	25	4,250	1.16	4,930
§ 1.1152(c)(3), (4), and (5); laboratories—validation and verification studies submissions.	9	1	9	.25 (15 minutes)	2.25
§ 1.1149(c); laboratories—advance notice of sampling submissions.	170	1	170	1.5	255
§ 1.1152(f); laboratories—immediate notification.	170	1.5	255	.25 (15 minutes)	63.75
§§ 1.1142; 1.1171; 1.1173; and 1.1174—requests in response to FDA action.	1	1	1	1	1
Total					19,883.9

Reporting Burden: Consistent with estimates in our FRIA (see section II.F, Costs of this Rule (Ref. 4)), we estimate a total of 174 respondents. We estimate that 5 to 80 accreditation bodies could apply for FDA recognition under this final rule and assume that 4 accreditation bodies will apply for FDA recognition. We estimate 170 laboratories will participate in the program. The reporting burden includes a burden of 20,640 hours associated with one-time submissions. In this analysis, we annualize the one-time submission burden using a 3-year

period horizon and zero percent discount rate, for an annualized one-time reporting burden of 6,880 hours. Cumulatively, this results in a total annual reporting burden of 19,883.9 hours, as reflected in table 14.

Section 1.1114 requires an accreditation body seeking initial recognition to submit an application to FDA demonstrating it meets the eligibility requirements described in § 1.1113 of the final rule. The burden to prepare and submit an application is an initial burden and, once realized, would apply only to respondents new to the program. We estimate this process would take one analyst between 40 and 80 hours to compile all the relevant information, prepare for an assessment, complete the initial application process, and submit the application. For this analysis we assume a middle value of 60 hours. Also for this analysis, we use a 3-year period horizon and zero percent discount rate to convert the one-time submission burden to an annualized figure (*i.e.,* 60 hours ÷ by 3 = 20 hours). Annually this results in 80 hours of burden for initial applications submitted by 4 accreditation bodies (4 applications × 20 hours per application), as reflected in row 1.

Section 1.1114 requires a recognized accreditation body to apply for renewal of recognition at least every 5 years. We believe renewal would take less time than an initial application because much of the information will have already been compiled and therefore assume between 20 and 40 hours. For this analysis we use a middle value and calculate that each recognized accreditation body will spend 30 hours every 5 years to complete and submit an application for renewal of its recognition. This results in 6 hours per year (30 hours ÷ 5 years) for each accreditation body. Because we use a 3-year period horizon and zero percent discount rate for this analysis, we annualize that figure to three-fifths or 3.6. We multiply this figure by 4 accreditation bodies for a total of 14.4 hours annually for the submission of renewal of applications (4 applications × 3.6 hours per application), as reflected in row 2.

Section 1.1116 requires that if a recognized accreditation body voluntarily chooses to relinquish or not renew its recognition, it must notify FDA and the laboratories it LAAF-accredits of its intention to depart the program at least 60 days ahead of the departure. The recognized accreditation body must also provide FDA with the name and contact information of the custodian who will maintain and make available to FDA requisite program records. We estimate a 1 percent voluntary departure rate, which equates to the departure of 0.04 recognized accreditation body annually. We estimate it would take a recognized accreditation body one hour for each of the three required notices. Accordingly, with rounding, the estimate for the burden associated with § 1.1116 is zero (0.04 recognized accreditation body × 3 notices = .12 annual responses, which rounds to 0; 0 annual response × 3 hours = 0 total hours), as reflected in row 3.

Section 1.1123 requires a recognized accreditation body to submit certain reports, notifications, and documentation to FDA, including significant changes affecting its accreditation program or the accreditation status of laboratories it LAAF-accredits, and to ensure FDA has access to these and other records. We estimate recognized accreditation bodies would incur a burden of 3.5 hours per month, or 42 hours per year, complying with the reporting requirements of § 1.1123 and the recordkeeping requirements of § 1.1124. For this analysis, we identify recordkeeping and reporting burdens separately and assume 21 of the 42 hours (*i.e.,* 1.75 hours per month) would be spent meeting the reporting requirements of § 1.1123. Annually, this results in 294 hours (4 recognized accreditation bodies × 42 responses per accreditation body x 1.75 hours per response), as reflected in row 4.

Section 1.1139 requires a laboratory seeking LAAF-accreditation to submit an application to a recognized accreditation body, demonstrating that it meets the eligibility requirements specified in § 1.1138. We estimate 170 laboratories will apply and assume it would take one analyst an average of 60 hours to compile all the relevant information; however we regard the burden as a one-time burden and therefore have annualized it by 3 years (20 hours annually). This results in an annual reporting burden for initial applications by 170 laboratories being 3,400 hours (170 applications × 20 hours per application), as reflected in row 5.

Section 1.1140 provides that if a laboratory voluntarily chooses to relinquish or not renew its LAAF-accreditation, it must notify FDA and its recognized accreditation body of its intention to do so at least 60 days ahead of the departure. If the laboratory is voluntarily relinquishing or not renewing all methods within its scope, it must also provide FDA with the name and contact information of the custodian who will maintain and make available to FDA requisite program records. We estimate a 1 percent program departure rate, which equates to the departure of 1.70 LAAF-accredited laboratories each year, which we round to 2. We estimate it would take a laboratory one hour for each of the three required notices. Accordingly, we estimate a burden of 6 hours per year under § 1.1140 (2 laboratories × 3 notices = 6 annual responses; 6 annual responses × 1 hour = 6 total hours), as reflected in row 6.

Section 1.1152(a) through (e) requires a LAAF-accredited laboratory to submit results of testing required to be conducted under the LAAF program and include supporting documentation. As discussed in our supporting statement, only a percentage of that testing would be defined as information collection under the PRA. For this analysis we assume a mean figure of 4,065 test result and supporting documentation submissions (4,065.2 rounded to the nearest integer) as the basis for factoring a corresponding information collection burden. This figure is derived using lower and upper bound estimates of submissions we expect under the rule. To allow for adjustment and potential increase we have added 50 submissions for a total of 4,115.

Section 1.1152(c)(1) requires a LAAF-accredited laboratory to submit a sample collection plan and sample collection report (the contents of which are described in § 1.1149(a)) with each test result. Under § 1.1152(c)(2), a LAAF-accredited laboratory must include documentation of the sampler's qualifications the first time the sampler collects a sample. We assume that it would take 30 minutes to 1 hour to compile a sampling plan, 30 minutes to 1 hour to compile a sample collection report, and an average of 10 to 20 minutes to obtain the sampling plan, sample collection report, and sampler's qualifications. Using a middle value of 1.5 hours to generate the sampling plan and the sample collection report, and a middle value of 15 minutes (.25 hours) to obtain those two documents and documentation of the sampler's qualifications, we calculate a total time per test result of 1.75 hours (1.5 + .25). When multiplied together the total reporting burden for the submission of sampling plans, sample collection reports, and sampler qualification requirements (170 accredited laboratories × 25 sampling plans and sample collection reports × 1.75 hours) is 7,437.5 hours, as reflected in row 7.

Section 1.1153(a) allows a LAAF-accredited laboratory to qualify to submit abridged analytical reports in lieu of full analytical reports. We expect

this will be a one-time burden, but we may revisit this assumption in the future based on actual rates of revocation of permission to submit abridged analytical reports. We assume that each LAAF-accredited laboratory would submit 10 consecutive full analytical reports (for the middle value of 2 major food testing disciplines per laboratory) to qualify to submit abridged analytical reports. We also assume that a LAAF-accredited laboratory will spend 4 to 8 hours to compile and submit a full analytical report, and we use the middle value of 6 hours for this analysis. For initial or one-time burdens we use a 3-year period horizon and zero percent discount rate to convert the one-time burden to an annualized figure (2 hours). When multiplied together, this results in a total reporting burden for the LAAF-accredited laboratories to qualify to submit abridged analytical reports of 3,400 hours (170 laboratories × 10 full analytical reports each × 2 hours per analytical report), as reflected in row 8.

Once a LAAF-accredited laboratory qualifies to submit abridged analytical reports, we assume it will submit abridged analytical reports to us thereafter. We may revisit this assumption in the future based on actual rates of revocation of permission to submit abridged analytical reports. We estimate the burden to compile and submit an abridged analytical report to be between 25 percent and 33 percent of the burden of compiling and submitting a full analytical report, and we use a middle value of 29 percent here. Thus, using these figures we calculate it would take a LAAF-accredited laboratory 1.16 hours to compile and submit an abridged analytical report (29 percent × 4 hours). This results in an annual total reporting burden for the 170 LAAF-accredited laboratories to compile and submit abridged analytical reports of approximately 4,930 hours (170 laboratories × 25 abridged analytical reports × 1.16 hours per abridged analytical report), as reflected in row 9.

The final rule also requires a LAAF-accredited laboratory to submit verification and validation studies to FDA as part of an analytical report. The ISO/IEC 17025:2017 standard requires the use of validated and verified methods for food testing. However, the final rule requires additional verification studies over and above the requirements of ISO/IEC 17025:2017. Additional studies may include information to verify that a method previously validated for a specific food item is also valid for a different food item, in what is called a ''matrix extension.'' We estimate that the additional time burden of requiring a LAAF-accredited laboratory to submit verification studies such as matrix extensions under this final rule to be a middle value of approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025:2017 (the FRIA estimates a range of 1 percent to 5 percent). In the FRIA we also note that internal FDA experts suggest that between 5 percent and 30 percent of import food testing results require verification studies such as matrix extensions. We use a middle value of 17.5 percent for this analysis.

Regarding validation requirements, we assume that methods used to test shell eggs, sprouts, and bottled drinking water are either already validated or that the costs of doing so would be included in the costs to maintain ISO/IEC 17025:2017 accreditation. Consequently, we assume that shell eggs, sprouts, and bottled drinking water producers would incur no burden from this requirement beyond the burden of the final rule's requirement to meet the validation requirements of ISO/IEC 17025:2017.

We estimate the time required to perform a matrix extension is a middle value of 34 hours (the FRIA estimates a range of 22 to 46 hours). We do not distinguish between the burden of reporting the study and the burden of conducting the study. We assume 25 percent of the 34 hours (8.5 hours) is attributable to the associated reporting burden. Because we estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under this final rule would be approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025:2017, we multiply 8.5 hours by 3 percent to get the additional reporting burden of .255 hours (15.3 minutes, which we round to 15 minutes, which is .25 hours) per study imposed by the verification study submission requirements of the final rule. To estimate the number of test results that would require matrix extensions, we multiply the number of import testing results that would be submitted to us under this rule annually that are subject to PRA requirements (50) by the share of test results submitted to us for import food testing that require matrix extensions (17.5 percent), for a total of 8.75 matrix extensions per year. This equates to an average of .3241 matrix extensions per LAAF-accredited laboratory conducting food testing for imports (8.75 ÷ 27). Because the number of respondents and the annual responses per respondent in a PRA analysis must be whole numbers, we instead estimate that nine LAAF-accredited laboratories (27 × .3241, rounded to 9 from 8.75) will submit one full verification study to FDA annually. Therefore, the annual reporting burden of requiring the submission of validation and verification studies under this final rule is 2.25 hours (9 accredited laboratories × 1 verification studies × .25 hours per study), as reflected in row 10.

Under section 1.1149(c), FDA may require under certain circumstances, that a LAAF-accredited laboratory submit an advance notice of sampling to FDA before each of the next several occasions that the sampler will a collect a sample that the LAAF-accredited laboratory will analyze under the LAAF program. We assume that it would take a laboratory analyst between 1 and 2 hours to compile and submit the required information, and we assume that between one percent and five percent of all test results submitted annually under the LAAF program will be subject to the advance notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Thus, we estimate that 123.45 test results (4,115 × 3%) will require submission of advance notice of sampling under the final rule. For this analysis we assume that each of the estimated 170 LAAF-accredited laboratories will be required to submit three advance notices sampling annually under the final rule (123.45 ÷ 170 = 0.74; rounded to 1). Thus, the annual reporting burden on LAAF-accredited laboratories for the advance notice of sampling requirement would be 255 hours (170 laboratories × 1 advance notices of sampling × 1.5 hours), as reflected in row 11.

Section 1.1152(f) requires a LAAF-accredited laboratory to notify FDA and the recognized accreditation body of any changes that affect the laboratory's LAAF-accreditation. Note, however, that a LAAF-accredited laboratory is not required to notify FDA of changes that the recognized accreditation body must provide to FDA under § 1.1123(d). As a conservative estimate, we assume that each LAAF-accredited laboratory will have some change requiring notification of its recognized accreditation body, and for half of those changes the LAAF-accredited laboratory will also need to notify FDA. We estimate it will take a LAAF-accredited laboratory 15 minutes per notification. Thus, we estimate the burden associated with § 1.1152(f) would be 63.75 hours (170 accredited laboratories × 1.5 notifications × 0.25 hours per notification), as reflected in row 12.

Sections 1.1142, 1.1171, 1.1173, and 1.1174 provide for requests to FDA. Specifically, § 1.1142 provides for requests for reinstatement of LAAF accreditation; § 1.1171 provides for requests for reconsideration of denials; and §§ 1.1173 and 1.1174 provide for requests for hearings. Because this is a new collection, we estimate a cumulative total of 1 respondent and 1 burden hour, as reflected in row 13.

TABLE 15—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR part 1, subpart R; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
§ 1.1113; recordkeeping associated with ISO/IEC 17011:2017	4	1	4	1	4
§ 1.1124; ABs—additional recordkeeping requirements	4	1	4	21	84
§ 1.1138; laboratories—becoming accredited to ISO/IEC 17025:2017 (one-time)	9	1	9	91.06	819.54
§ 1.1138; laboratories—maintaining ISO/IEC 17025:2017 accreditation	170	1	170	889.53	151,220.10
§ 1.1154; laboratories—additional recordkeeping requirements	170	1	170	12	2,040
Total					154,167.64

Recordkeeping Burden: We estimate the annual recordkeeping requirements associated with the final rule to be 154,167.64 hours, as reflected in table 15.

Section 1.1113 requires a recognized accreditation body to meet the requirements of ISO/IEC 17011:2017. While ISO/IEC 17011:2017 includes recordkeeping requirements, as noted above we anticipate that all 4 of the accreditation bodies that we estimate will apply to become recognized currently adhere to ISO/IEC 17011:2017. We therefore regard these activities as usual and customary; however, we include a place holder of one response and one burden hour for each respondent, as reflected in row 1.

Section 1.1124 requires maintenance of certain records in addition to those required by ISO/IEC 17011:2017. We estimate that a recognized accreditation body will incur a burden of 12 hours per year to comply with both the recordkeeping requirements of § 1.1124 and the reporting requirements of § 1.1123. For this analysis, we identify the recordkeeping and reporting burdens separately, assuming 21 of those 42 annual hours would be spent complying with the recordkeeping requirements of § 1.1124. Thus, the annual recordkeeping burden for the 4 recognized accreditation bodies to meet the additional recordkeeping requirements of § 1.1124 would be 84 hours, as reflected in row 2.

Section 1.1138 requires a laboratory to be ISO/IEC 17025:2017-accredited, including meeting its recordkeeping requirements, to become LAAF-accredited under the rule. We estimate that 7 to 10 laboratories not currently accredited to ISO/IEC 17025:2017 would become so accredited to participate in the LAAF program. For this estimate, we assume the middle value of 8.5 laboratories, which we round up to 9, would become ISO/IEC 17025-accredited to participate in the LAAF program. The burden to become ISO/IEC 17025:2017-accredited is an initial burden and, once realized, would apply only to respondents becoming accredited to ISO/IEC 17025:2017 to participate in the LAAF program. We estimate that it would take a mean of 91.06 hours for the associated recordkeeping activities. In this analysis, we annualize this recordkeeping burden using a 3-year period horizon and zero percent discount rate, for an annualized recordkeeping burden of 819.54 hours, as reflected in row 3.

Section 1.1138 requires a LAAF-accredited laboratory to maintain conformance with ISO/IEC 17025:2017, including its recordkeeping requirements. As discussed in the proposed rule, we estimate a mean of 889.53 hours for this recordkeeping. This results in an annual burden of 151,220.10 hours, as reflected in row 4.

Section 1.1154 requires maintenance of certain records in addition to those required by ISO/IEC 17025:2017. We estimate that a LAAF-accredited laboratory will incur a burden of about 1 hour per month (12 hours per year) to comply with the recordkeeping requirements in § 1.1154. This results in an annual burden of 2,040 hours, as reflected in row 5.

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. We have 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.

* Ref. 1. Congressional Hearing, ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations.'' September 10, 1998. *https://www.gpo.gov/fdsys/pkg/CHRG-105shrg51562/pdf/CHRG-105shrg51562.pdf.* Accessed November 4, 2021.

Ref. 2. ISO/IEC 17011:2017(E), ''Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.'' ISO/IEC. November 2017. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/67198.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

Ref. 3. ISO/IEC 17025:2017(E), ''General Requirements for the Competence of Testing and Calibration Laboratories.'' ISO/IEC. November 2017. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/66912.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

* Ref. 4. FDA. LAAF: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2021. *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

* Ref. 5. Partnership for Food Protection, ''Human and Animal Food Testing Laboratories Best Practices Manual,'' December 2018, available at *https://www.pfp-ifss.org/ifss-resources/human-and-animal-food-testing-laboratories-best-practices-manual-december-2018/.* Accessed November 4, 2021.

* Ref. 6. Association for Public Health Laboratories, ''Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories,'' January 2019, available at *https://www.aphl.org/aboutAPHL/publications/Documents/FS-2019Jan-Best-Practices-Human-Animal-Food-Data.pdf.* Accessed November 4, 2021.

* Ref. 7. The Cambridge Dictionary, *https://dictionary.cambridge.org/us/dictionary/english/assess.* Accessed November 4, 2021.

* Ref. 8. ''OMB Circular A–119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.'' Office of Management and Budget. January 2016. *https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf.* Accessed November 4, 2021.

* Ref. 9. National Institute of Standards and Technology Special Publication 2000–02, ''Conformity Assessment Considerations for Federal Agencies,'' September 2018. *https://doi.org/10.6028/NIST.SP.2000-02.* Accessed November 4, 2021.

* Ref. 10. Codex Alimentarius Commission, ''General Guidelines on Sampling,'' CAC/GL–50–2004. *http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B50-2004%252FCXG_050e.pdf.* Accessed November 4, 2021.

* Ref. 11. FDA, ''Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry,'' Draft Guidance, January 2017. *https://www.fda.gov/media/102633/download.* Accessed November 4, 2021.

* Ref. 12. FDA, ''Outbreak Investigation of Scombrotoxin Fish Poisoning: Yellowfin/Ahi Tuna (November 2019).'' *https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-scombrotoxin-fish-poisoning-yellowfinahi-tuna-november-2019#:~:text=%2C%20WV%20(1)-,What%20is%20Scombrotoxin%20Fish%20Poisoning%3F,eating%20mishandled%20and%20decomposed%20fish.* Accessed November 4, 2021.

Ref. 13. AOAC International, ''Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2017.'' August 2018. Copies are available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, USA, or on the internet at *https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc/,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

Ref. 14. Association of American Feed Control Officials, ''2014 Quality Assurance/Quality Control Guidelines for Feed Laboratories, 2014.'' Copies are available from Association of American Feed Control Officials, 1800 South Oak St., Suite 100, Champaign, IL 61820 or on the internet at *https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

* Ref. 15. FDA Memorandum, ''Assessment of DWPE Sampling and Analysis Data to Determine what Portion of Sampling and Analysis of Food under DWPE is Conducted by Accredited Entities.'' Toni Morales and Tyler Scandalios, FDA. November 20, 2018.

Ref. 16. ISO/IEC 17043:2010, ''Conformity Assessment—General Requirements for Proficiency Testing.'' ISO/IEC. February 2010. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/29366.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

* Ref. 17. FDA, Investigations Operations Manual, 2021. *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual.* Accessed November 4, 2021.

* Ref. 18. University of Georgia Extension, Bulletin 1306, ''Biosecurity Basics for Poultry Growers,'' March 2020. *https://secure.caes.uga.edu/extension/publications/files/pdf/B%201306_6.PDF.* Accessed November 4, 2021.

* Ref. 19. Association of American Food Control Officials, ''GOODSamples: Guidance On Obtaining Defensible Samples,'' October 2015. *https://www.aafco.org/Portals/0/SiteContent/Publications/GOODSamples.pdf.* Accessed November 4, 2021.

* Ref. 20. Association of American Food Control Officials, ''GOOD Test Portions: Guidance On Obtaining Defensible Test Portions,'' June 2018. *http://www.aafco.org/Publications/GOODTestPortions.* Accessed November 4, 2021.

* Ref. 21. FDA, ''Methods, Method Verification and Validation,'' ORA Laboratory Manual, Vol. II, Section 2, document number ORA–LAB.5.4.5. June 30, 2020. *https://www.fda.gov/media/73920/download.* Accessed November 4, 2021.

* Ref. 22. FDA Memorandum, ''Categorical Exclusion—Final Rule Laboratory Accreditation for Analyses of Foods [Docket No. FDA–2019–N–3325].'' Mariellen Pfeil, FDA. July 21, 2021.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 129

Beverages, Bottled water, Food packaging, 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 parts 1, 11, 16, and 129 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues 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, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. In § 1.651, revise paragraphs (b)(3) and (c)(2) to read as follows:

§ 1.651 How must an accredited third-party certification body conduct a food safety audit of an eligible entity?

* * * * *

(b) * * *

(3) When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with ISO/IEC 17025:2017 to perform the analysis.

* * * * *

(c) * * *

(2) The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph (b)(3) of this section to conduct the analysis. The audit may include any other activities necessary to determine compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices.

* * * * *

■ 3. Add subpart R, consisting of §§ 1.1101 through 1.1201, to read as follows:

Subpart R—Laboratory Accreditation for Analyses of Foods

General Provisions

Sec.

General Requirements

FDA Recognition of Accreditation Bodies

Requirements for Recognized Accreditation Bodies

FDA Oversight of Recognized Accreditation Bodies

LAAF-Accreditation of Laboratories

Requirements for LAAF-Accredited Laboratories

FDA Oversight of LAAF-Accredited Laboratories

Requesting FDA Reconsideration or Regulatory Hearings of FDA Decisions Under This Subpart

Electronic Records and Public Disclosure Requirements

Subpart R—Laboratory Accreditation for Analyses of Foods

General Provisions

§ 1.1101 What documents are incorporated by reference in this subpart

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the source listed elsewhere in this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.*

(1) ISO/IEC 17011:2017(E), Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second edition, November 2017, IBR approved for §§ 1.1113(a) and (c), 1.1114(b), 1.1120(c), 1.1131(a).

(2) ISO/IEC 17025:2017(E), General requirements for the competence of testing and calibration laboratories, Third edition, November 2017, IBR approved for §§ 1.1120(c), 1.1121(a), 1.1138(a), 1.1139(b) and (c), 1.1141(a), 1.1152(a) and (d), 1.1153(c), and 1.1161(a).

§ 1.1102 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, unless otherwise specified. For the purposes of this subpart, the following definitions also apply:

Analyst means an individual who analyzes samples.

Corrective action means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.

Directed food laboratory order means an order issued by FDA under § 1.1108 requiring food testing to be conducted under this subpart by or on behalf of an owner or consignee.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food testing and *testing of food* means the analysis of food product samples or environmental samples.

Laboratory accreditation for analyses of foods (LAAF)-accreditation means a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this subpart to conduct food testing under this subpart using one or more methods of analysis.

LAAF-accredited laboratory means a laboratory that a recognized accreditation body has determined meets the applicable requirements of this subpart and has been LAAF-accredited to conduct food testing under this subpart using one or more methods of analysis.

Owner or consignee means any person with an ownership or consignment interest in the food product or environment that is the subject of food testing conducted under § 1.1107(a).

Recognition means a determination by FDA that an accreditation body meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

Representative sample means a sample that accurately, to a statistically acceptable degree, represents the characteristics and qualities of the food product or environment from which the sample was collected.

Sampler means an individual who collects samples.

Sampling firm means an entity that provides sampling services.

Scope of LAAF-accreditation refers to the methods of analysis for which the laboratory is LAAF-accredited.

Street address means the full physical address, including the country. For purposes of this rule, a post office box number alone is insufficient; however, a post office box number may be provided in addition to the street address.

§ 1.1103 Who is subject to this subpart?

(a) *Accreditation bodies.* An accreditation body is subject to this subpart if it has been or is seeking to be recognized by FDA to LAAF-accredit laboratories to conduct food testing under this subpart.

(b) *Laboratories.* A laboratory is subject to this subpart if it has been or is seeking to be LAAF-accredited by a recognized accreditation body to conduct food testing under this subpart.

(c) *Owners and consignees.* An owner or consignee is subject to this subpart if it is required to use a LAAF-accredited laboratory to conduct food testing under this subpart.

General Requirements

§ 1.1107 When must food testing be conducted under this subpart?

(a) Food testing must be conducted under this subpart whenever such testing is conducted by or on behalf of an owner or consignee:

(1) In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in the following provisions:

(i) *Sprouts.* Section 112.146(a), (c), and (d) of this chapter;

(ii) *Shell eggs.* Sections 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e) of this chapter; and

(iii) *Bottled drinking water.* Section 129.35(a)(3)(i) of this chapter (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli*);

(2) As required by FDA in a directed food laboratory order issued under § 1.1108;

(3) To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the Federal Food, Drug, and Cosmetic Act prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

(4) In support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act; and

(5) To support removal from an import alert through successful consecutive testing.

(b) When food testing is conducted under paragraph (a) of this section, analysis of samples must be conducted by a laboratory that is LAAF-accredited for the appropriate analytical method by a recognized accreditation body under this subpart.

(c) Food testing conducted on articles of food offered for import into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic

Act pursuant to paragraph (a)(4) or (a)(5) of this section may only be conducted after the articles offered for import have arrived in the United States unless the owner or consignee has written approval from FDA that a sample taken prior to arrival is or would be a representative sample of the article offered for import into the United States.

§ 1.1108 When and how will FDA issue a directed food laboratory order?

(a) FDA may require the owner or consignee to conduct food testing, or to have food testing conducted on their behalf, under this subpart to address an identified or suspected food safety problem, as FDA deems appropriate.

(b) The directed food laboratory order will specify the food product or environment to be tested; whether the food testing may be conducted using a LAAF-accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used.

(c) The directed food laboratory order will contain all the elements required by § 16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter. An affected owner or consignee may request a regulatory hearing on a directed food laboratory order pursuant to § 1.1174.

§ 1.1109 How will FDA make information about recognized accreditation bodies and LAAF-accredited laboratories available to the public?

FDA will place on its website a publicly available registry listing of:

(a) Recognized accreditation bodies, including for each: the name, contact information, and duration of recognition of the recognized accreditation body;

(b) Accreditation bodies that have a change in recognition, including for each: the name of the accreditation body, the specific change in recognition (*i.e.,* probation, revocation of recognition, denial of renewal of recognition, relinquishment of recognition, or expiration of recognition) and the effective date of the change;

(c) LAAF-accredited laboratories, including for each: the name, contact information, and scope of LAAF-accreditation, and the name and contact information of the recognized accreditation body that has LAAF-accredited the laboratory; and

(d) Laboratories that have a change in LAAF-accreditation, including for each: the name of the laboratory, the specific change in LAAF-accreditation (*i.e.,* suspension, reduction of scope, or withdrawal of LAAF-accreditation by the recognized accreditation body, probation or disqualification by FDA, or relinquishment of LAAF-accreditation), and the effective date of the change.

§ 1.1110 What are the general requirements for submitting information to FDA under this subpart?

(a) All applications, reports, notifications, and records submitted to FDA under this subpart must be submitted electronically and in English unless otherwise specified. If FDA requests inspection or submission of records that are maintained in any language other than English, the recognized accreditation body or LAAF-accredited laboratory must provide an English translation within a reasonable time.

(b) A program applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during any onsite assessments of the applicant by FDA.

FDA Recognition of Accreditation Bodies

§ 1.1113 What are the eligibility requirements for a recognized accreditation body?

A recognized accreditation body or an accreditation body seeking recognition must meet all of the following requirements:

(a) Demonstrates compliance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101).

(b) Demonstrates that it is a full member of the International Laboratory Accreditation Cooperative (ILAC).

(c) Demonstrates that it is a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017(E) with a scope of ''Testing: ISO/IEC 17025.''

(d) Will comply with all additional requirements for recognized accreditation bodies under this subpart while recognized.

§ 1.1114 How does an accreditation body apply to FDA for recognition or renewal of recognition?

(a) *Application for recognition or renewal of recognition.* An accreditation body seeking initial recognition or renewal of recognition must submit an application to FDA demonstrating that it meets the eligibility requirements in § 1.1113.

(b) *Documentation of conformance with requirements.* The accreditation body must submit documentation of conformance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101) and separate documentation of ILAC membership and ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017(E) with a scope of ''Testing: ISO/IEC 17025,'' in meeting the requirements of § 1.1113(a) through (c). The accreditation body also must submit documentation of its compliance with § 1.1113(d).

(c) *Signature.* An application for recognition or renewal of recognition must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.1115 How will FDA evaluate applications for recognition and renewal of recognition?

(a) *Review of application for recognition or renewal of recognition.* FDA will review an accreditation body's application for recognition or renewal of recognition for completeness and notify the applicant of any insufficiencies. FDA generally will review accreditation body applications for recognition or renewal of recognition in the order in which completed applications are received; however, FDA may prioritize the review of specific applications to meet program needs.

(b) *Evaluation of application for recognition or renewal of recognition.* FDA will evaluate a complete application for recognition or renewal of recognition to determine whether the applicant meets the requirements for recognition. Such evaluation may include an onsite evaluation of the accreditation body. If FDA does not reach a final decision on an application for renewal of recognition before an accreditation body's recognition expires, FDA may extend the existing term of recognition for a specified period of time or until FDA reaches a final decision on the application for renewal of recognition.

(c) *Grant of recognition.* FDA will notify the applicant that its application for recognition or renewal of recognition has been approved and will include any conditions associated with the recognition.

(d) *Duration of recognition.* FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition, except under the circumstances described in paragraph (b) of this section.

(e) *Denial of application for recognition or renewal of recognition.* FDA will notify the applicant that its

application for recognition or renewal of recognition has been denied and will state the basis for such denial and describe the procedures for requesting reconsideration of the application under § 1.1171.

(f) *Notice of records custodian after denial of an application for renewal of recognition.* Within 10 business days of the date of FDA's issuance of a denial of an application for renewal of recognition, the applicant must provide the name and contact information of the custodian who will maintain required records and make them available to FDA under § 1.1124. The contact information must include an email address for the records custodian and the street address where the records required under § 1.1124 will be located.

(g) *FDA notice to LAAF-accredited laboratories.* FDA will promptly notify all laboratories LAAF-accredited by the accreditation body whose application for renewal of recognition was denied, informing them of such denial.

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide public notice on the website described in § 1.1109 of the issuance of a denial of an application for renewal of recognition and will include the date of the issuance of such denial.

§ 1.1116 What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* At least 60 calendar days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal, a recognized accreditation body must notify FDA of its intention to leave the program, specifying the date on which the relinquishment or expiration will occur. The recognized accreditation body must provide the name and contact information of the custodian who will maintain and make available to FDA the records required by § 1.1124 after the date of relinquishment or the date recognition expires, as applicable. The contact information must include an email address for the records custodian and the street address where the records required under § 1.1124 will be located.

(b) *Notice to LAAF-accredited laboratories of intent to relinquish or not to renew recognition.* At least 60 calendar days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal, a recognized accreditation body must notify the laboratories it LAAF accredits of its intention to leave the program, specifying the date on which relinquishment or expiration will occur.

(c) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the website described in § 1.1109 of the voluntary relinquishment or expiration of recognition of an accreditation body.

§ 1.1117 How may an accreditation body request reinstatement of recognition?

(a) *Application following revocation of recognition.* An accreditation body that has had its recognition revoked by FDA (as described in § 1.1131) may seek reinstatement by submitting a new application for recognition under § 1.1114. The accreditation body must also submit evidence to FDA with its application to demonstrate that the issues resulting in revocation of recognition have been resolved, including evidence addressing the cause or condition of the grounds for revocation of recognition. The evidence also must identify measures that have been implemented to help ensure that such cause or condition is unlikely to recur.

(b) *Application following relinquishment or expiration of recognition.* An accreditation body that previously relinquished its recognition or allowed its recognition to expire (as described in § 1.1116) may seek reinstatement by submitting a new application for recognition under § 1.1114.

Requirements for Recognized Accreditation Bodies

§ 1.1119 What are the conflict of interest requirements for a recognized accreditation body?

(a) In addition to meeting the impartiality and conflict of interest requirements of § 1.1113(a), a recognized accreditation body must:

(1) Ensure that the recognized accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it LAAF-accredits, subject to the exceptions in paragraphs (c) and (d) of this section; and

(2) Prohibit, subject to the exceptions in paragraph (e) of this section, officers, employees, or other agents involved in LAAF-accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory the recognized accreditation body LAAF-accredits or assesses for LAAF-accreditation.

(b) The financial interests of any children younger than 18 years of age or a spouse of a recognized accreditation body's officers, employees, and other agents involved in LAAF-accreditation activities are considered the financial interests of such officers, employees, and other agents involved in LAAF-accreditation activities.

(c) An accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) may have an interest in a publicly traded or publicly available investment fund (*e.g.,* a mutual fund), or a widely held pension or similar fund if the accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(d) A recognized accreditation body's agent that is a contract assessor will be permitted to own or have a financial interest in, manage, or otherwise control a LAAF-accredited laboratory if all of the following circumstances apply:

(1) The contract assessor's primary occupation is owning or having a financial interest in, managing, or otherwise controlling a LAAF-accredited laboratory;

(2) The assessor contracts with the recognized accreditation body to provide assessment services on an intermittent or part-time basis;

(3) The contract assessor does not assess the LAAF-accredited laboratory that the assessor owns or has a financial interest in, manages, or otherwise controls; and

(4) The contract assessor and the recognized accreditation body inform any laboratory that the contract assessor may assess or reassess for LAAF-accreditation that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory. The laboratory seeking LAAF-accreditation assessment or reassessment must acknowledge that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory and be provided the option to be assessed by a different representative of the recognized accreditation body.

(e) The prohibited items of value specified in paragraph (a)(2) of this section do not include:

(1) Money representing payment of fees for LAAF-accreditation services or reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory; or

(2) Meal of de minimis value provided during the course of an assessment or reassessment and on the premises where

the assessment or reassessment is conducted, if necessary for the efficient conduct of the assessment or reassessment.

§ 1.1120 How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories?

(a) A recognized accreditation body must conduct an initial assessment of a laboratory seeking LAAF-accreditation in accordance with the requirements of this subpart, to determine whether the laboratory meets the requirements of § 1.1138.

(b) Subject to the exception in paragraph (c) of this section, the initial assessment must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(c) If, within the previous 2 years, the recognized accreditation body conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101) to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101), then the initial assessment under this section:

(1) May be conducted remotely, and

(2) Need only address whether the laboratory meets the requirements of § 1.1138(a)(2) and (3) and (b).

(d) A recognized accreditation body must oversee the performance of a laboratory it LAAF-accredits in accordance with the requirements of § 1.1113(a), except as otherwise provided by this subpart, to determine whether the LAAF-accredited laboratory continues to meet the applicable requirements of this subpart.

(e) A recognized accreditation body must conduct a reassessment of a LAAF-accredited laboratory in accordance with this subpart at least every 2 years. Such reassessment must be conducted onsite, although certain reassessment activities may be conducted remotely if it will not aid in the reassessment to conduct the activities onsite.

(f) If the recognized accreditation body conducted the initial assessment of the LAAF-accredited laboratory remotely in accordance with paragraph (c) of this section, the recognized accreditation body must conduct its first reassessment of the LAAF-accredited laboratory no later than 2 years after the recognized accreditation body last conducted an onsite assessment of the laboratory.

(g) The reassessment at the end of the LAAF-accredited laboratory's ISO/IEC 17025:2017-accreditation cycle, which the recognized accreditation body must conduct in accordance with this subpart, must be conducted onsite, although certain reassessment activities may be conducted remotely if it will not aid the reassessment to conduct them onsite.

(h) Any assessments or reassessments conducted by a recognized accreditation body in addition to the assessments or reassessments referred to in paragraphs (a), (e), and (g) of this section may be conducted remotely if it will not aid the assessment or reassessment to conduct it onsite.

§ 1.1121 When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, or reduce the scope of or withdraw the LAAF-accreditation of a laboratory?

(a) *Corrective action.* A recognized accreditation body may require corrective action using the procedures described by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) section 8.7 to address any deficiencies identified while assessing and overseeing a LAAF-accredited laboratory.

(1) The recognized accreditation body must notify the LAAF-accredited laboratory of all deficiencies requiring corrective action and will either specify a deadline to implement corrective action or will require the LAAF-accredited laboratory to submit a corrective action plan and timeframe for implementation to the recognized accreditation body for approval.

(2) The LAAF-accredited laboratory must implement appropriate corrective action under ISO/IEC 17025:2017(E) section 8.7, and submit the results of the corrective action to the recognized accreditation body.

(3) The recognized accreditation body will review the corrective action and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(b) *Suspension.* If a recognized accreditation body determines that a laboratory it LAAF-accredits has not effectively implemented corrective action or otherwise fails to address deficiencies identified, the recognized accreditation body may temporarily suspend the LAAF-accredited laboratory for one or more LAAF-accredited methods, and require corrective action under paragraph (a) of this section.

(1) The recognized accreditation body must notify the LAAF-accredited laboratory of the grounds for the suspension, the LAAF-accredited methods subject to the suspension, and all deficiencies that must be addressed via the process described in paragraph (a) of this section.

(2) The recognized accreditation body must notify FDA of the suspension under this section in accordance with the requirements of § 1.1123(d)(5). FDA will provide notice of the LAAF-accredited laboratory's suspension on the website described in § 1.1109.

(3) The recognized accreditation body will review the corrective action required under paragraph (b) of this section and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(4) A LAAF-accredited laboratory shall remain suspended until it demonstrates to the recognized accreditation body's satisfaction that the LAAF-accredited laboratory has successfully implemented appropriate corrective action.

(5) If the recognized accreditation body determines that a LAAF-accredited laboratory on suspension has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, the recognized accreditation body may reduce the scope of or withdraw the LAAF-accreditation of the laboratory under paragraph (c) of this section.

(c) *Reduction of scope or withdrawal of LAAF-accreditation.* A recognized accreditation body must reduce the scope of or withdraw the LAAF-accreditation of a laboratory it LAAF-accredits when the laboratory substantially fails to comply with this subpart. When only certain methods within the laboratory's scope of LAAF-accreditation are affected by the noncompliance, the recognized accreditation body may reduce the scope of the laboratory's LAAF-accreditation for only those affected methods. If all methods are affected, the recognized accreditation body must withdraw the laboratory's LAAF-accreditation.

(d) *Procedures for reduction of scope or withdrawal of LAAF-accreditation.* (1) The recognized accreditation body must notify the laboratory of any reduction of scope or withdrawal of LAAF-accreditation, including:

(i) The grounds for the reduction of scope or withdrawal of LAAF-accreditation;

(ii) The method(s) to which the reduction of scope applies;

(iii) The procedures for appealing the reduction of scope or withdrawal of LAAF-accreditation as described in § 1.1122; and

(iv) The date the reduction of scope or withdrawal of LAAF-accreditation is effective.

(2) The recognized accreditation body must notify FDA of the reduction of scope or withdrawal of LAAF-accreditation under this section in accordance with the requirements in § 1.1123(d)(4). FDA will provide notice of the reduction of scope or withdrawal of the laboratory's LAAF-accreditation on the website described in § 1.1109.

(e) *Records request associated with suspension, reduction of scope, or withdrawal of LAAF-accreditation.* To assist the recognized accreditation body in determining whether a suspension, reduction of scope, or withdrawal of LAAF-accreditation is warranted under this section, the recognized accreditation body may require the submission of records that the LAAF-accredited laboratory is required to maintain under § 1.1154.

(f) *Consequences of suspension, reduction of scope, or withdrawal of LAAF-accreditation.* (1) A LAAF-accredited laboratory may not conduct food testing under this subpart using suspended methods.

(2) If the recognized accreditation body withdraws the laboratory's LAAF-accreditation, the laboratory is immediately ineligible to conduct any food testing under this subpart. If the recognized accreditation body reduces the laboratory's scope of LAAF-accreditation, the laboratory is immediately ineligible to use the methods to which the reduction of scope applies to conduct food testing under this subpart.

§ 1.1122 What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation?

A recognized accreditation body must consider a laboratory's appeal regarding a decision to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation in accordance with the requirements of § 1.1113(a). Appeals must be reviewed and decided by a competent person(s) free from bias or prejudice who has not participated in the LAAF-accreditation decision and is not the subordinate of a person who participated in the LAAF-accreditation decision. For the purposes of appeals, the competent person(s) may be external to the recognized accreditation body.

§ 1.1123 What reports, notifications, and documentation must a recognized accreditation body submit to FDA?

(a) *General requirements.* All reports and notifications required by this section must include:

(1) The name, street address, telephone number, and email address of the recognized accreditation body associated with the report or notification, and the name of an appropriate point of contact for the recognized accreditation body, and

(2) If the report or notification concerns a LAAF-accredited laboratory, the name, street address, telephone number, and email address of the LAAF-accredited laboratory, and the name of an appropriate point of contact for the LAAF-accredited laboratory.

(b) *Internal audit reports.* A recognized accreditation body must submit to FDA a report of the results of the internal audit conducted pursuant to § 1.1125 within 45 calendar days of completing the audit. The audit report must include:

(1) A description of the internal audit conducted;

(2) A description of any identified deficiencies;

(3) A description of any corrective action taken or planned, including the timeline for such corrective action; and

(4) A statement disclosing the extent to which the internal audit was conducted by personnel different from those who perform the activity or activities that were audited.

(c) *Changes affecting recognition.* A recognized accreditation body must notify FDA within 48 hours when the recognized accreditation body is aware of a change that would affect the recognition of such accreditation body, and the notification must include:

(1) A description of the change, and

(2) If the change is one made by the recognized accreditation body, an explanation of the purpose of the change.

(d) *Changes in LAAF-accreditation.* A recognized accreditation body must notify FDA and submit a certificate reflecting the scope of accreditation within 48 hours when any of the following occur:

(1) The recognized accreditation body grants or extends LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation requested by the laboratory,

(ii) The scope of LAAF-accreditation granted, and

(iii) The effective date of the grant or extension;

(2) The recognized accreditation body denies LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation requested by the laboratory,

(ii) The scope of LAAF-accreditation denied, and

(iii) The grounds for the denial;

(3) The recognized accreditation body receives notice that a laboratory it LAAF-accredits intends to relinquish its LAAF-accreditation and the laboratory has not provided notice to FDA 60 calendar days prior to relinquishment as required under § 1.1140. The recognized accreditation body's notification must include:

(i) The scope of LAAF-accreditation to which the relinquishment applies, as applicable, and

(ii) The effective date of the relinquishment;

(4) The recognized accreditation body reduces the scope of or withdraws the LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation to which the reduction applies,

(ii) The grounds for the reduction of scope or withdrawal, and

(iii) The effective date of the reduction of scope or withdrawal;

(5) The recognized accreditation body suspends or lifts the suspension of a LAAF-accredited laboratory, and the notification must include:

(i) The scope of LAAF-accreditation to which the suspension applies,

(ii) The grounds for the suspension or for lifting the suspension, and

(iii) The effective date of the suspension or date the suspension is lifted.

(e) *Laboratory fraud.* A recognized accreditation body must notify FDA within 48 hours if the recognized accreditation body knows that a laboratory it LAAF-accredits has committed fraud or submitted material false statements to FDA, and the notification must include:

(1) A description of the basis for the recognized accreditation body's knowledge of the fraud or material false statements,

(2) A description of the fraud or material false statements, and

(3) The action(s) taken by the recognized accreditation body with respect to such LAAF-accredited laboratory.

§ 1.1124 What are the records requirements for a recognized accreditation body?

(a) In addition to meeting the requirements of § 1.1113(a) related to records, a recognized accreditation body must maintain, for 5 years after the date of creation of the records, records created while it is recognized demonstrating its compliance with this subpart, including records relating to:

(1) Applications for LAAF-accreditation;

(2) Assessments, reassessments, and decisions to grant, extend the scope of, renew, deny, reduce the scope of, or withdraw LAAF-accreditation or to

suspend or lift the suspension of a LAAF-accredited laboratory;

(3) Appeals of suspensions, denials, reductions of scope of, and withdrawals of LAAF-accreditation, final decisions on such appeals, and the bases for such final decisions;

(4) Its oversight of laboratories it has LAAF-accredited;

(5) Its oversight of its own performance, including all records related to internal audits, complaints, and corrective actions;

(6) Any reports or notifications required to be submitted to FDA under § 1.1123, including any supporting information;

(7) Records of fee payments and reimbursement of direct costs; and

(8) Any documents demonstrating compliance with the requirements for assessment activities by contract assessors with certain financial interests described in § 1.1119(d).

(b) A recognized accreditation body must make the records it is required to maintain by paragraph (a) of this section available for inspection and copying or for electronic submission upon written request of an authorized officer or employee of FDA. If FDA requests records for inspection and copying, the recognized accreditation body must make such records promptly available at the physical location of the recognized accreditation body or at another reasonably accessible location. If FDA requests electronic submission, the records must be submitted within 10 business days of the request.

(c) A recognized accreditation body must not prevent or interfere with FDA's access to the records the LAAF-accredited laboratories it LAAF-accredits are required to maintain under § 1.1154.

§ 1.1125 What are the internal audit requirements for a recognized accreditation body?

As part of the internal audit a recognized accreditation body is required to conduct pursuant to § 1.1113(a), the recognized accreditation body must audit its compliance with the requirements of § 1.1113(d).

FDA Oversight of Recognized of Accreditation Bodies

§ 1.1130 How will FDA oversee recognized accreditation bodies?

(a) FDA will evaluate each recognized accreditation body to determine its compliance with the applicable requirements of this subpart no later than:

(1) Year 4 of a 5-year recognition period; or

(2) The midpoint of a recognition period less than 5 years.

(b) An FDA evaluation of a recognized accreditation body may include review of records, an onsite evaluation of the accreditation body, and onsite reviews of one or more LAAF-accredited laboratories the recognized accreditation body LAAF-accredits, with or without the recognized accreditation body present. Certain evaluation activities may be conducted remotely if it will not aid in the evaluation to conduct them onsite.

(c) FDA may conduct additional evaluations of a recognized accreditation body at any time to determine whether the recognized accreditation body complies with the applicable requirements of this subpart.

§ 1.1131 When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?

(a) *Corrective action.* FDA may require corrective action to address any deficiencies identified while evaluating a recognized accreditation body under this subpart.

(1) FDA will notify the recognized accreditation body of all deficiencies requiring corrective action and will either specify a deadline to implement corrective action or will require the recognized accreditation body to submit a corrective action plan and timeframe for implementation to FDA for approval.

(2) The recognized accreditation body must handle FDA's notification as a complaint under ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101) section 7.12, implement appropriate corrective action under ISO/IEC 17011:2017 section 9.5, and submit both the results of the complaint investigation and subsequent corrective action to FDA.

(3) FDA will review the corrective action and will notify the recognized accreditation body whether the corrective action is acceptable.

(b) *Probation.* If FDA determines that a recognized accreditation body has not effectively implemented corrective action or otherwise fails to address deficiencies identified, FDA may put the recognized accreditation body on probation and require corrective action under paragraph (a) of this section.

(1) FDA will notify the recognized accreditation body of the grounds for the probation and all deficiencies requiring corrective action via the process described in paragraph (a) of this section.

(2) FDA will notify all laboratories LAAF-accredited by the recognized accreditation body that the recognized accreditation body is on probation and will provide notice of the probation on the website described in § 1.1109.

(3) FDA will review the corrective action and will notify the recognized accreditation body whether the corrective action is acceptable.

(4) A recognized accreditation body shall remain on probation until the recognized accreditation body demonstrates to FDA's satisfaction that it has successfully implemented appropriate corrective action.

(5) If FDA determines that a recognized accreditation body on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, FDA may revoke recognition of the recognized accreditation body under paragraph (c) of this section.

(c) *Revocation of recognition.* FDA will revoke the recognition of an accreditation body if it fails to meet the requirements of this subpart, if FDA determines the accreditation body has committed fraud or submitted material false statements to FDA, or if FDA determines that a recognized accreditation body on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified.

(d) *Revocation of recognition procedures.* (1) FDA will issue a notice of revocation of recognition to the recognized accreditation body that will include the grounds for revocation, the date on which revocation is effective, the procedures for requesting a regulatory hearing on the revocation under § 1.1173, and the procedures for requesting reinstatement of recognition under § 1.1117.

(2) FDA will notify all laboratories LAAF-accredited by the recognized accreditation body that recognition has been revoked and will provide notice of the revocation of recognition of an accreditation body on the website described in § 1.1109.

(3) Within 10 business days of the date of issuance of revocation, the accreditation body must provide the name and contact information of the custodian who will maintain records and make them available to FDA as required by § 1.1124. The contact information must include an email address for the records custodian and the street address where the records required by § 1.1124 will be located.

(e) *Effect of probation or revocation of recognition on the accreditation body.* (1) A recognized accreditation body that is put on probation by FDA must continue to oversee laboratories that it has LAAF-accredited under this subpart

and may continue to LAAF-accredit laboratories under § 1.1120.

(2) An accreditation body that has had its recognition revoked by FDA may not LAAF-accredit laboratories under this subpart or continue to oversee the laboratories it has previously LAAF-accredited while the accreditation body is not recognized.

LAAF-Accreditation of Laboratories

§ 1.1138 What are the eligibility requirements for a LAAF-accredited laboratory?

(a) A laboratory that is LAAF-accredited or seeking LAAF-accreditation must demonstrate it is capable of conducting each method of food testing for which it is or will be LAAF-accredited by meeting all of the following requirements:

(1) For each method, the laboratory is accredited by a recognized accreditation body to ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101).

(2)(i) Except as provided in paragraph (a)(2)(ii) of this section, the laboratory has successfully passed a proficiency test provided by a competent proficiency testing organization within the last 12 months for each method within the scope of LAAF-accreditation.

(ii) If the laboratory determines there is no proficiency testing program available or practicable for a method, it may use a comparison program. A laboratory must request approval from the recognized accreditation body regarding the determination prior to using a comparison program in lieu of an annual proficiency test. The laboratory is required to demonstrate competency through participation in the comparison program.

(iii) A laboratory must submit all proficiency test and comparison program results, regardless of outcome, to the recognized accreditation body within 30 calendar days of receipt.

(3) The laboratory ensures that its procedures for monitoring the validity of the results of testing it conducts under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.

(b) Will comply with all additional requirements for LAAF-accredited laboratories under this subpart while LAAF-accredited.

§ 1.1139 How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation?

(a) *Application for LAAF-accreditation.* A laboratory seeking LAAF-accreditation or extension of its scope of LAAF-accreditation must submit its application for LAAF-accreditation to a recognized accreditation body identified on the website described in § 1.1109. The recognized accreditation body will review and assess the application in accordance with the requirements of this subpart. If the laboratory seeking LAAF-accreditation had its LAAF-accreditation withdrawn or one or more methods within its scope of LAAF-accreditation reduced by a recognized accreditation body or has been previously disqualified by FDA, the laboratory must meet the additional requirements specified by § 1.1142(a).

(b) *Documentation of conformance with ISO/IEC 17025:2017(E).* The laboratory may use documentation of conformance with ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101), as applicable and supplemented as necessary, in meeting the applicable requirements of this subpart.

(c) *Duration of accreditation.* If a LAAF-accredited laboratory maintains compliance with all requirements of this subpart, including accreditation to ISO/IEC 17025:2017(E), the laboratory's LAAF-accreditation will not end until reduced in scope, withdrawn, relinquished, or the laboratory is disqualified, under this subpart.

§ 1.1140 What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation?

(a) *Notice to FDA and the recognized accreditation body of intent to relinquish.* A LAAF-accredited laboratory must notify FDA and its recognized accreditation body at least 60 calendar days before voluntarily relinquishing LAAF-accreditation or any method within the scope of LAAF-accreditation. The notice must include the date on which relinquishment will occur. If the laboratory will relinquish all methods within its scope of LAAF-accreditation, the notification must also include the name and contact information of the custodian who will maintain the records required by § 1.1154 after the date of relinquishment. The contact information for the records custodian must include an email address and the street address where the records required by § 1.1154 will be located.

(b) *Public notice of voluntary relinquishment of accreditation.* FDA will provide notice on the website described in § 1.1109 of the voluntary relinquishment of LAAF-accreditation of a laboratory.

§ 1.1141 What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA?

If a recognized accreditation body has its application for renewal of recognition denied, relinquishes its recognition or allows its recognition to expire, or has its recognition revoked, any laboratory LAAF-accredited by the accreditation body must take either the actions in paragraph (a) of this section or the action in paragraph (b) of this section no later than 30 calendar days after receiving the notice to the LAAF-accredited laboratory required under § 1.1115(g), § 1.1116(b), or § 1.1131(d)(2):

(a)(1) The LAAF-accredited laboratory must submit to FDA documentation of the LAAF-accredited laboratory's most recent internal audit, required under § 1.1154(a)(5), documentation showing compliance with the conflict of interest requirements in § 1.1147, and documentation of the most recent proficiency test or comparison program result for each test method within the laboratory's scope of LAAF-accreditation, to show compliance with § 1.1138(a)(2); and

(2) The laboratory must become LAAF-accredited by another recognized accreditation body before the laboratory's ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) accreditation lapses or not later than 1 year after the LAAF-accredited laboratory receives the applicable notice under § 1.1115(g), § 1.1116(b), or § 1.1131(d)(2), whichever is sooner.

(b) The LAAF-accredited laboratory initiates relinquishment of its LAAF-accreditation under § 1.1140, with the relinquishment to occur within 90 calendar days.

§ 1.1142 How does a laboratory request reinstatement of LAAF-accreditation?

(a) *Application following reduction of scope or withdrawal of LAAF-accreditation by a recognized accreditation body or disqualification by FDA.* A laboratory that has had any methods within its scope of LAAF-accreditation reduced or has had its LAAF-accreditation withdrawn by a recognized accreditation body or that has been disqualified by FDA may seek reinstatement of LAAF-accreditation by submitting a new application for LAAF-accreditation to a recognized accreditation body under § 1.1139. The laboratory must also:

(1) Notify FDA prior to submitting a new application for LAAF-accreditation to the recognized accreditation body, including in the notification the name of the laboratory, contact information for

the laboratory, the name of the recognized accreditation body to which the laboratory will be submitting the application, and the date that the laboratory expects to submit the new application for LAAF-accreditation; and

(2) Demonstrate, to the satisfaction of the recognized accreditation body to which it is submitting the new application, that the grounds for the reduction of scope or withdrawal of LAAF-accreditation or disqualification have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring.

(b) *Application following voluntary relinquishment of LAAF-accreditation.* A laboratory that voluntarily relinquished any methods within the scope of its LAAF-accreditation pursuant to § 1.1140, may seek reaccreditation by submitting a new application for LAAF-accreditation to a recognized accreditation body under § 1.1139.

Requirements for LAAF-Accredited Laboratories

§ 1.1147 What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?

(a) In addition to the impartiality and conflict of interest requirements in § 1.1138(a)(1), a LAAF-accredited laboratory must, subject to the exceptions in paragraph (b) of this section, prohibit the LAAF-accredited laboratory's employees, contractors, and agents involved in food testing under this subpart and related activities from accepting any money, gift, gratuity, or other item of value from the owner or consignee of the food that is being tested or will be tested by the LAAF-accredited laboratory.

(b) The prohibited items of value in paragraph (a) of this section do not include:

(1) Payment of fees for food testing under this subpart and related services;

(2) Reimbursement of direct costs associated with the food testing by the LAAF-accredited laboratory; and

(3) With respect to a LAAF-accredited laboratory that is owned by the owner or consignee of the food that is or will be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

(c) The LAAF-accredited laboratory must require the owner's or consignee's payment to the LAAF-accredited laboratory of fees for food testing services and reimbursement of direct costs associated with food testing to be independent of the outcome of the test results.

§ 1.1149 What oversight standards apply to sampling?

(a) *Documents.* Before analyzing a sample, the LAAF-accredited laboratory must develop (if it collected the sample) or obtain (if another firm collected the sample) the following information to be submitted with test results (see § 1.1152(c)):

(1) Written documentation of the sampler's applicable qualifications by training and experience. A LAAF-accredited laboratory only needs to develop or obtain documentation of a sampler's qualifications the first time that sampler collects a sample for the LAAF-accredited laboratory under this subpart. If a LAAF-accredited laboratory has previously submitted the sampler's qualifications to FDA under § 1.1152(c), the LAAF-accredited laboratory may refer to its previously submitted qualifications.

(2) The written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler and sampling firm and must list factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample; and

(3) A written sample collection report for each sample collected. The written sample collection report must include:

(i) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled);

(ii) The date of the sampling;

(iii) The lot number, size, identity, and quantity of the sample;

(iv) Documentation of sample collection procedures and any sample preparation techniques; and

(v) Documentation of the chain of custody of the sample and of measures taken to ensure the validity of the subsequent analytical testing, including controlling for the representational nature of the sample.

(b) *Potential consequences.* If any of the requirements in paragraph (a) of this section is not met, FDA may consider the analysis of the sample to be invalid.

(c) *Advance notice of sampling.* (1) If FDA determines that sampling conducted may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if FDA determines that the sampling otherwise may have been improper, FDA may require the LAAF-accredited laboratory that analyzed the associated sample, and other LAAF-accredited laboratories that have analyzed samples previously collected by the sampling firm, to obtain from the sampling firm, and submit, or require the sampling firm to submit, an advance notice of sampling. The advance notice of sampling must be submitted to FDA at least 48 hours before each of the next 10 occasions that the sampling firm will collect a sample that the LAAF-accredited laboratory will analyze under this subpart.

(2) FDA may, as appropriate:

(i) Specify that the requirement applies to samples collected by a particular sampler;

(ii) Specify the type of food product or environment that requires advance notice of sampling under this subpart;

(iii) Determine that an amount of time other than 48 hours in advance is required, from a minimum of 24 hours up to 7 business days in advance;

(iv) Determine that a number of occasions other than 10 is required, from a minimum of 1 occasion to a maximum of 20 occasions;

(v) Notify affected LAAF-accredited laboratories that submission of additional notices of sampling are not required; and

(vi) Notify the owner or consignee that the advance notice applies to sampling for food testing being conducted on their behalf.

(3) The advance notice of sampling must contain:

(i) A unique identification for the advance notice of sampling;

(ii) The name of the LAAF-accredited laboratory that will conduct analysis of the sample;

(iii) The name and street address of the sampling firm that will conduct the sampling;

(iv) A primary contact (name and phone number) for the sampling firm;

(v) The reason why the food product or environment will be sampled;

(vi) The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled;

(vii) As applicable, the U.S. Customs and Border Protection entry and line number;

(viii) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled); and

(ix) The date and approximate time the sampling will begin.

§ 1.1150 What are the requirements for analysis of samples by a LAAF-accredited laboratory?

In addition to the sample analysis requirements of § 1.1138(a):

(a) The analysis must be conducted on either the sample received from the

sampling firm or, if appropriate, on a representative sample of the sample received from the sampling firm.

(b) The analyst must:

(1) Be qualified by appropriate education, training, and/or experience to conduct the analysis;

(2) Have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and

(3) Be in compliance with the conflict of interest requirements of §§ 1.1138(a) and 1.1147.

(c) The method used to conduct the food testing must meet the requirements of § 1.1151.

(d) The LAAF-accredited laboratory must document the testing information and test results to the extent necessary to account for all information that is required to be included in a full analytical report (*see* § 1.1152(d)).

§ 1.1151 What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart?

In addition to the requirements of § 1.1138(a), a LAAF-accredited laboratory must meet the following requirements:

(a) The method of analysis used to conduct food testing under this subpart must be:

(1) Fit for purpose;

(2) Within the laboratory's scope of LAAF-accreditation;

(3) Appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and

(4) Appropriately verified by the LAAF-accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.

(b) Food testing must be conducted using the specified method:

(1) Under § 1.1107(a)(1), if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribe a test method.

(2) Under § 1.1107(a)(2), if the directed food laboratory order prescribes a test method.

(c)(1) A LAAF-accredited laboratory must validate methods in accordance with the requirements of § 1.1138(a).

(2) A LAAF-accredited laboratory performing validation of a method under this subpart must record the information required by § 1.1138(a) and the supporting analytical data.

(d)(1) Before a LAAF-accredited laboratory conducts food testing under this subpart using a method for a specific intended use for which the method has been validated, but for which the LAAF-accredited laboratory has not previously applied the method under this subpart, the LAAF-accredited laboratory must have verified it can properly perform the method for the specific intended use.

(2) A LAAF-accredited laboratory performing verification of a method under this subpart must record the method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the LAAF-accredited laboratory is able to properly perform the method.

(e) A LAAF-accredited laboratory may submit a written request to FDA requesting permission to use a method outside of its scope of LAAF-accreditation for food testing. FDA may approve the request if both following conditions are satisfied:

(1) A new method or methodology has been developed and validated but no reasonably available laboratory has been LAAF-accredited to perform such method or methodology, and

(2) The use of such method is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

§ 1.1152 What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA?

(a) *General requirements.* (1) All notifications, results, reports, and studies required to be submitted to FDA by a LAAF-accredited laboratory under this subpart must:

(i) Include the name and street address of the LAAF-accredited laboratory;

(ii) Identify a point of contact for the LAAF-accredited laboratory, including email and telephone number, whom FDA may contact with questions or comments;

(iii) Display an identification unique to the test results, report, notification, or study; and

(iv) Be true, accurate, unambiguous, and objective.

(2) The LAAF-accredited laboratory that conducts the analysis of the sample under this subpart is responsible for the submission of all notifications, results, reports, and studies to FDA as required by this section.

(3) If the LAAF-accredited laboratory becomes aware that any aspect of the submitted material is inaccurate, the LAAF-accredited laboratory must immediately inform FDA and submit a corrected version. Such corrections must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) section 7.8.8.

(4) Any opinions and interpretations in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements in ISO/IEC 17025:2017(E) section 7.8.7 and any statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements of ISO/IEC 17025:2017(E) section 7.8.6.

(b) *Test results.* (1) The LAAF-accredited laboratory must submit the results of all testing required to be conducted under this subpart directly to FDA via the location specified by the website described in § 1.1109, unless another location is specified by FDA regarding testing conducted under § 1.1107(a)(2) or (3).

(2) The test results must be clear and identify:

(i) The name and street address of the owner or consignee for which the testing was conducted,

(ii) As appropriate, the U.S. Customs and Border Protection entry and line number(s), and

(iii) The associated notifications, reports, and studies required to be submitted with the test results under this subpart.

(c) *Documentation required to be submitted with test results.* The following documentation must be included with each full analytical report (see paragraph (d) of this section) and each abridged analytical report (see § 1.1153) submitted to FDA under this subpart:

(1) All sampling plans and sample collection reports related to the food testing conducted as developed or obtained by the LAAF-accredited laboratory in accordance with § 1.1149;

(2) Written documentation of the sampler's qualifications or an indication that the sampler's qualifications have been submitted previously, in accordance with § 1.1149(a)(1);

(3) For any validation studies required by § 1.1151(c)(1), the documentation required by § 1.1151(c)(2);

(4) For any verification studies required by § 1.1151(d)(1), the documentation required by § 1.1151(d)(2);

(5) The justification for any modification to or deviation from the method(s) of analysis used and documentation of the LAAF-accredited laboratory's authorization for the modification or deviation; and

(6) A certification from one or more members of the LAAF-accredited laboratory's management certifying that the test results, notifications, reports, and studies are true and accurate; and that the documentation includes the results of all tests conducted under this subpart. The certification must include

the name, title, and signature of any certifiers.

(d) *Full analytical report contents.* In addition to the documentation required to be submitted with all test results (see paragraph (c) of this section), a full analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d);

(2) Documentation of references for the method of analysis used;

(3) Name and signature of the analyst who conducted each analytical step, including any applicable validation and verification steps, and the date each step was performed;

(4) Calculations, presented in a legible and logical manner;

(5) As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and presented in a clear order;

(6) Identification of the source and purity of reference standards used, and, as applicable: Certified reference materials, certified reference cultures traceable to a nationally or internationally recognized type culture collection (including concentration, units, preparation, and storage conditions), and reference standard preparation information (including who prepared the reference standard, date of preparation, expiration date, chemical balance, and solvent used);

(7) A copy of the label from any immediate container sampled, if available, and any additional labeling needed to evaluate the product;

(8) All original compilations of raw data secured in the course of the analysis, including discarded, unused, or re-worked data, with the justification for discarding or re-working such data, corresponding supporting data, and quality control results (including the expected result and whether it is acceptable), all identified with unique sample identification, date, and time, associated with the test;

(9) Any other relevant additional supporting information such as the storage location of analyzed samples, appropriate attachments such as instrument printouts, computer generated charts and data sheets, and photocopies or original labels for the product analyzed;

(10) Identification of any software used;

(11) Any certificate of analysis for standards and software; and

(12) The following information about the qualifications of each analyst involved in the analysis conducted under this subpart, if the LAAF-accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly changed since the LAAF-accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

(i) The analyst's curriculum vitae;

(ii) Training records for the applicable methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider; and

(iii) Any other documentation of the analyst's ability to perform the method properly in the context of the food testing to be conducted, pursuant to § 1.1150(b).

(e) *Additional information about non-standard methods.* If the LAAF-accredited laboratory conducts the analysis using a method that is not published in a reputable international or national standard or that is otherwise not publicly and readily available, upon request by FDA the LAAF-accredited laboratory must submit documentation of the method to FDA.

(f) *Immediate notification of significant changes.* The LAAF-accredited laboratory must notify FDA and the recognized accreditation body that LAAF-accredited the laboratory of changes that affect the LAAF-accreditation of the laboratory within 48 hours, including a detailed description of such changes, and an explanation of how such changes affect the LAAF-accreditation of the laboratory. LAAF-accredited laboratories are not required to notify FDA of changes that a recognized accreditation body must provide to FDA under § 1.1123(d).

(g) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA under this section, FDA may consider the related food testing to be invalid.

§ 1.1153 What are the requirements for submitting abridged analytical reports?

(a) *Requesting permission.* A LAAF-accredited laboratory may request permission to submit abridged analytical reports for each major food testing discipline: Biological, chemical, and physical.

(1) FDA will grant permission to submit abridged analytical reports for a single major food testing discipline if all of the following conditions are met:

(i) The LAAF-accredited laboratory is not on suspension or probation for any method within the major food testing discipline that is the subject of its request (see § 1.1121(b) or § 1.1161(b));

(ii) The LAAF-accredited laboratory has successfully implemented any required corrective action under § 1.1121(a) or § 1.1161(a); and

(iii) The last five full analytical reports for the major food testing discipline contain no shortcomings that call into question the validity of the test results or repeated administrative errors.

(2) FDA will notify the LAAF-accredited laboratory if permission is granted or denied.

(b) *FDA review of abridged analytical reports.* (1) FDA will review all abridged analytical reports submitted.

(2) FDA will notify the LAAF-accredited laboratory if FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors, will require corrective action under § 1.1161(a), and may revoke permission to submit abridged analytical reports for the specific major food testing discipline.

(3) If FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors in abridged analytical reports from a LAAF-accredited laboratory that has previously had its permission to submit abridged analytical reports revoked for any major food testing discipline, FDA may put the LAAF-accredited laboratory on probation for one or more methods under § 1.1161(b). Under § 1.1162(a), a laboratory on probation for one or more methods may not submit abridged analytical reports for the major food testing disciplines of which the probationary methods are a part.

(4) A LAAF-accredited laboratory that has had permission to submit abridged analytical reports revoked for one or more major food testing disciplines may request permission to submit abridged analytical reports as described in paragraph (a) of this section for each major food testing discipline.

(c) *Contents of abridged analytical reports.* In addition to the documentation required to be submitted with all test results (see § 1.1152(c)), an abridged analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d); and

(2) Quality control results (including the expected result and whether it is acceptable).

(d) *Exceptions.* FDA may require additional documentation or a full analytical report from a LAAF-accredited laboratory permitted to submit abridged analytical reports in the following circumstances:

(1) FDA may require a full analytical report related to an FDA investigation or FDA enforcement proceeding.

(2) Occasionally, for the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program, FDA will require additional documentation or a full analytical report within 72 hours of FDA's request.

(e) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA under paragraph (c) of this section, FDA may consider the related food testing to be invalid.

§ 1.1154 What other records requirements must a LAAF-accredited laboratory meet?

(a) In addition to the records requirements of § 1.1138(a), a LAAF-accredited laboratory must maintain, for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart, including:

(1) Documents related to the LAAF-accredited laboratory's grant of LAAF-accreditation (and, if applicable, extensions and reductions of scope of LAAF-accreditation) from its recognized accreditation body, including all required proficiency test and comparison program records for each method within the scope of LAAF-accreditation under § 1.1138(a)(2);

(2) Documentation of food testing the LAAF-accredited laboratory conducted under this subpart sufficient to account for all information required by § 1.1152(d), in accordance with § 1.1150(d);

(3) All documents that the LAAF-accredited laboratory was required to submit to FDA under §§ 1.1152 and 1.1153, and associated correspondence between the LAAF-accredited laboratory (and its officers, employees, and other agents) and the owner or consignee (and its officers, employees, and other agents) regarding food testing under this subpart;

(4) All requests for food testing from an owner or consignee that would be conducted under this subpart;

(5) Documentation of any internal investigations, internal audits, and corrective action taken to address any problems or deficiencies related to activities under this subpart;

(6) All documentation related to suspension, probation, reduction of scope, or withdrawal of LAAF-accreditation, or laboratory disqualification under this subpart; and

(7) Documentation of changes to its management system or food testing activities that may affect its compliance with this subpart.

(b) Make the records required by paragraph (a) of this section available for inspection and copying or for electronic submission upon written request of an authorized officer or employee of FDA. If FDA requests records for inspection and copying, the laboratory must make such records promptly available at the physical location of the laboratory or at another reasonably accessible location. If the authorized officer or employee of FDA requests electronic submission, the records must be submitted within 10 business days of the request.

(c) Ensure that significant amendments to records described by this section can be tracked to previous and original versions. If such a significant amendment is made, both the original document and amended document must be maintained by the LAAF-accredited laboratory during the time period for which the amended document must be maintained under this subpart. The laboratory must also document the date of amendment, the personnel responsible for the amendment, and a conspicuous indication on the original document stating that the document has been altered and that a more recent version of the document exists.

FDA Oversight of LAAF-Accredited Laboratories

§ 1.1159 How will FDA oversee LAAF-accredited laboratories?

(a) FDA may review the performance of LAAF-accredited laboratories at any time to determine whether the LAAF-accredited laboratory continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the LAAF-accredited laboratory that, if not corrected, would warrant corrective action, probation, or disqualification under § 1.1161.

(b) In evaluating the performance of a LAAF-accredited laboratory, FDA may review any of the following:

(1) Records the LAAF-accredited laboratory is required to maintain under this subpart;

(2) Records the recognized accreditation body that LAAF-accredited the laboratory is required to maintain under this subpart;

(3) Information obtained by FDA during a review of the LAAF-accredited laboratory conducted pursuant to paragraph (c) of this section;

(4) Information obtained by FDA during an evaluation of the recognized accreditation body that LAAF-accredits the laboratory;

(5) Analytical reports and test results submitted to FDA; and

(6) Any other information obtained by FDA, including during FDA's inspections or investigations of one or more owners or consignees.

(c) FDA may conduct an onsite review of a LAAF-accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to review the performance of a LAAF-accredited laboratory under this subpart. Certain review activities may be conducted remotely if it will not aid in the review to conduct them onsite.

(d) FDA may report any observations and deficiencies identified during its review of LAAF-accredited laboratory performance under this subpart to the recognized accreditation body.

§ 1.1160 How will FDA review test results and analytical reports?

(a) If FDA finds that any test result, analytical report, related documents, or the associated analysis contains deficiencies or otherwise indicates that any aspect of the food testing is not being conducted in compliance with this subpart, FDA will notify the LAAF-accredited laboratory that submitted the analytical report of any deficiency and may:

(1) Require the laboratory to correct the test result, analytical report, related documents, or the associated analysis;

(2) Revoke permission to submit abridged reports for that major food testing discipline under § 1.1153(b);

(3) Require a corrective action under § 1.1161(a);

(4) Consider the analysis to be invalid; and/or

(5) Notify the owner or consignee of the deficiency.

(b) FDA may report any deficiencies identified during its review of any test results, reports, and related documents under this subpart to the recognized accreditation body that LAAF-accredits the laboratory.

(c) Nothing in this subpart shall be construed to limit the ability of FDA to review and act on information received about food testing, including determining the sufficiency of such information and testing.

§ 1.1161 When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?

(a) *Corrective action.* FDA may require corrective action to address any deficiencies identified while reviewing a LAAF-accredited laboratory's performance under this subpart.

(1) FDA will notify the LAAF-accredited laboratory of all deficiencies requiring corrective action and will

either specify a deadline to implement corrective action or will require the LAAF-accredited laboratory to submit a corrective action plan and timeframe for implementation to FDA for approval.

(2) The LAAF-accredited laboratory must handle FDA's notification as a complaint under ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) section 7.9, implement appropriate corrective action under ISO/IEC 17025:2017(E) section 8.7, and submit both the results of the complaint investigation and subsequent corrective action to FDA.

(3) FDA will review the corrective action and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(b) *Probation.* If FDA determines that a LAAF-accredited laboratory has not effectively implemented corrective action or otherwise fails to address deficiencies identified, FDA may put the LAAF-accredited laboratory on probation for one or more methods and require corrective action under paragraph (a) of this section.

(1) FDA will notify the LAAF-accredited laboratory and its recognized accreditation body of the grounds for the probation, the method(s) covered by the probation, and all deficiencies requiring corrective action via the process described in paragraph (a) of this section.

(2) FDA will provide notice of a LAAF-accredited laboratory's probation on the website described in § 1.1109.

(3) FDA will review the corrective action and will notify the LAAF-accredited laboratory and its recognized accreditation body whether the corrective action is acceptable.

(4) A LAAF-accredited laboratory will remain on probation until the LAAF-accredited laboratory demonstrates to FDA's satisfaction that it has successfully implemented appropriate corrective action.

(5) If FDA determines that a LAAF-accredited laboratory on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, FDA may disqualify the LAAF-accredited laboratory under paragraph (c) of this section.

(c) *Disqualification.* FDA may disqualify a LAAF-accredited laboratory from submitting analytical reports under this subpart for one or more methods for good cause, which may include any of the following reasons:

(1) Deliberate falsification of analytical reports, testing results, or other records submitted to FDA.

(2) Failure of a LAAF-accredited laboratory on probation to effectively implement corrective action or otherwise address identified deficiencies.

(3) Other failure to substantially comply with this subpart where the laboratory's recognized accreditation body has not reduced the scope of or withdrawn LAAF-accreditation of the laboratory.

(d) *Disqualification procedures.* (1) FDA will issue a notice of disqualification to a LAAF-accredited laboratory and its recognized accreditation body, which will include:

(i) The grounds for disqualification;

(ii) The method or methods to which the disqualification applies;

(iii) The date the disqualification will be effective;

(iv) The procedures for requesting a regulatory hearing on the disqualification under § 1.1173; and

(v) The procedures for requesting reinstatement after disqualification under § 1.1142.

(2) FDA will provide notice of a LAAF-accredited laboratory's disqualification on the website described in § 1.1109.

§ 1.1162 What are the consequences if FDA puts a LAAF-accredited laboratory on probation or disqualifies a LAAF-accredited laboratory?

(a) A LAAF-accredited laboratory that FDA has put on probation for one or more methods is permitted to continue to conduct food testing under this subpart; however, a LAAF-accredited laboratory that is on probation for one or more methods is not permitted to submit abridged analytical reports for the major food testing discipline of which the probationary methods are part.

(b) If FDA disqualifies a LAAF-accredited laboratory for all methods within its scope of LAAF-accreditation, the laboratory is immediately ineligible to conduct food testing under this subpart. If FDA disqualifies a LAAF-accredited laboratory for specific methods within the scope of LAAF-accreditation, the laboratory is immediately ineligible to use the methods for which the laboratory has been disqualified to conduct food testing under this subpart.

(c) With respect to food testing conducted by the laboratory prior to its disqualification, FDA may refuse to consider results and associated reports of food testing conducted under this subpart if the basis for the disqualification of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

(d) Within 10 business days of the date of issuance of disqualification, the laboratory must provide the name and email address of the custodian who will maintain and make available to FDA the records required by § 1.1154, and the street address where the records will be located.

(e) Within 10 business days of the date of issuance of a notice of probation or disqualification, the laboratory must notify any owners or consignees for which it is conducting food testing using methods for which it is being placed on probation or disqualified under this subpart, that it is on probation or has been disqualified.

Requesting FDA Reconsideration or Regulatory Hearings of FDA Decisions Under This Subpart

§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?

(a) *Timing of request.* An accreditation body may seek reconsideration of FDA's decision to deny its application for recognition or renewal of recognition under § 1.1114, or reinstatement of recognition under § 1.1117, no later than 10 business days after the date of the issuance of such denial.

(b) *Submission of request.* The request to reconsider an application under paragraph (a) of this section must be signed by the accreditation body, as appropriate, or by an individual authorized to act on its behalf. The accreditation body must submit the request, together with any supporting information, to FDA in accordance with the procedures described in the notice of denial.

(c) *Notification of FDA's decision.* After completing its review and evaluation of the request for reconsideration and any supporting information submitted pursuant to paragraph (b) of this section, FDA will notify the accreditation body of its decision to grant or deny recognition upon reconsideration.

§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the accreditation body's recognition or disqualify a LAAF-accredited laboratory?

(a) *Request for hearing.* No later than 10 business days after the date FDA issued a revocation of recognition of an accreditation body pursuant to § 1.1131 or disqualification of a LAAF-accredited laboratory under § 1.1161, the accreditation body, laboratory, or an individual authorized to act on the accreditation body's or laboratory's behalf, may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the revocation or disqualification. The notice of revocation issued under § 1.1131 or notice of disqualification issued under § 1.1161, as applicable, will contain all the elements required by § 16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing under this subpart must be submitted with a written appeal that responds to the bases for the FDA decision described in the written notice of revocation or disqualification, together with any supporting information. The request, appeal, and supporting information must be submitted to FDA in accordance with the procedures described in the notice of revocation or disqualification.

(c) *Effect of submitting a request for a regulatory hearing on an FDA decision.* The submission of a request for a regulatory hearing under this subpart will not operate to delay or stay the effect of a decision by FDA to revoke the recognition of an accreditation body or disqualify the LAAF-accredited laboratory unless FDA determines that delay or a stay is in the public interest.

(d) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(e) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to § 16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(f) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the accreditation body or laboratory, and the presiding officer and FDA.

(2) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to § 16.5(b) of this chapter, the procedures for a regulatory hearing apply only to the extent that such procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: The requirements of § 16.22 (Initiation of regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or laboratory disqualification is considered a final agency action under 5 U.S.C. 702.

§ 1.1174 How does an owner or consignee request a regulatory hearing on a directed food laboratory order?

(a) *Request for hearing.* No later than 3 business days after FDA has issued the directed food laboratory order, an owner or consignee may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the directed food laboratory order. The directed food laboratory order will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing must be submitted with a written appeal that responds to the bases, as appropriate, for FDA's determinations described in the directed food laboratory order, together with any supporting information. The request, appeal, and supporting information must be submitted in accordance with the procedures described in the directed food laboratory order.

(c) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(d) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to § 16.26(a) of this chapter.

(e) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, such hearing will be held within 2 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the requestor and the presiding officer and FDA.

(2) The presiding officer may require that a hearing conducted under this subpart be completed within 1 business day, as appropriate.

(3) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to § 16.5(b) of this chapter, the procedures for a regulatory hearing described in part 16 of this chapter apply only to the extent that such procedures are supplementary and not in conflict with the procedures specified for the conduct of regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: § 16.22 (Initiation of regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(4) A decision by the presiding officer to affirm the directed food laboratory order is considered a final agency action under 5 U.S.C. 702.

Electronic Records and Public Disclosure Requirements

§ 1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

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.

§ 1.1200 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 4. The authority citation for part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 5. In § 11.1, add paragraph (p) to read as follows:

§ 11.1 Scope.

* * * * *

(p) This part does not apply to records required to be established or maintained by subpart R of part 1 of this chapter. Records that satisfy the requirements of subpart R of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 6. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C.141–149, 321–394, 467f, 679, 821, 1034, 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 7. In § 16.1, add entries for §§ 1.1173 and 1.1174 in numerical order to paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1.1173, relating to the revocation of recognition of an accreditation body, and the disqualification of a laboratory, with respect to food testing conducted under part 1, subpart R of this chapter.

§ 1.1174, relating to the issuance of a directed food laboratory order by FDA pursuant to § 1.1108.

* * * * *

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

■ 8. The authority citation for part 129 is revised to read as follows:

Authority: 21 U.S.C. 342, 348, 350k, 371, 374, 42 U.S.C. 264.

■ 9. Amend § 129.35 by revising paragraph (a)(3)(iii) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (*e.g.,* Environmental Protection Agency (EPA) and State-certified laboratories), except that the analysis of the five samples from the same sampling site that originally tested positive for *E. coli,* as required by paragraph (a)(3) of this section, must be conducted under part 1, subpart R of this chapter.

* * * * *

Dated: November 15, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–25716 Filed 12–1–21; 11:15 am]

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Part III

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 92, 93, 94, et al.
Importation of Sheep, Goats, and Certain Other Ruminants; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 92, 93, 94, 95, 96, and 98

[Docket No. APHIS–2009–0095]

RIN 0579–AD10

Importation of Sheep, Goats, and Certain Other Ruminants

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of animals and animal products to revise conditions for the importation of live sheep, goats, and certain other non-bovine ruminants, and products derived from sheep and goats, with regard to transmissible spongiform encephalopathies such as bovine spongiform encephalopathy (BSE) and scrapie. We are removing BSE-related import restrictions on sheep and goats and most of their products, and adding import restrictions related to transmissible spongiform encephalopathies for certain wild, zoological, or other non-bovine ruminant species. The conditions we are adopting for the importation of specified commodities are based on internationally accepted scientific literature and will generally align our regulations with guidelines established in the World Organization for Animal Health's Terrestrial Animal Health Code.

DATES: Effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Alexandra MacKenzie, Veterinary Medical Officer, Strategy & Policy, VS, APHIS, 4700 River Road, Unit 39, Riverdale, MD 20737–1231; (301) 851–3300, option 2.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Need for the Regulatory Action

The current bovine spongiform encephalopathy (BSE)-related import regulations prohibit the importation of most live sheep and goats, and most sheep and goat products, from countries considered a risk for BSE. The current regulations allow only the importation of non-pregnant slaughter or feeder sheep under 12 months old from Canada, certain products from sheep and goats, and sheep and goat semen. We are amending the regulations to remove BSE-related import restrictions on sheep and goats and most of their products because they are no longer warranted, and to add import restrictions related to transmissible spongiform encephalopathies (TSEs) for certain wild, zoological, or other non-bovine ruminant species because those animals pose a risk of introducing or spreading BSE or other TSEs.

The conditions we are adopting for the importation of sheep and goats and their products are based on internationally accepted scientific literature and are generally consistent with World Organization for Animal Health (OIE) guidelines. We are taking this action after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues [1] and concluding that the changes to the regulations will continue to guard against the introduction of transmissible spongiform encephalopathies such as BSE and scrapie into the United States, while allowing the importation of additional animals and animal products into this country.

Legal Authority for the Regulatory Action

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to issue orders and promulgate regulations to prevent the introduction into the United States and the dissemination within the United States of any pest or disease of livestock. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or Department) administers regulations in title 9, chapter I, subchapter D that govern the exportation and importation of animals (including poultry) and animal products.

Summary of the Major Provisions of the Regulatory Action

We are removing BSE-related import restrictions on sheep and goats and the products derived from them. We are also adding import restrictions related to TSEs for certain wild, zoological, or other non-bovine ruminant species. The existing BSE-related import restrictions also function as protection against the introduction of other TSEs, such as scrapie. While the BSE-related restrictions are no longer warranted for non-bovine ruminant products, it is necessary for us to add appropriate safeguards against the introduction of other TSEs for non-bovine ruminants.

Costs and Benefits

This final rule's impact would stem from its effect on U.S. imports of the affected commodities. Assuming an increase in imports of 3,165 metric tons (MT) in a net trade welfare model, we project 1.5 percent decrease in wholesale prices and a fall in domestic production of 878 MT. We estimate consumption would increase by 2,287 MT. As a result, producer welfare decline by about $8.7 million and U.S. consumer welfare would increase by about $23.7 million, yielding an annual net welfare benefit of about $15.1 million.

The rule has the potential to expand the U.S. export market, to the extent that it influences changes in our trading partners' import policies. Because predicting if and when other countries will make changes to their trade policies is highly speculative, our analysis assumes no trade policy changes by foreign countries as a result of the rule and therefore no impact on U.S. exports.

II. Background

In order to guard against the introduction and spread of livestock pests and diseases, APHIS regulates the importation of animals and animal products into the United States. The regulations in 9 CFR parts 92, 93, 94, 95, 96, and 98 (referred to below as the regulations) govern the importation of certain animals, meat, other animal products and byproducts, hay and straw, embryos, and semen into the United States in order to prevent the introduction of various livestock pests and diseases.

Two of the diseases addressed by the current regulations regarding sheep and goats are scrapie and BSE. Scrapie and BSE belong to the family of diseases known as TSEs. In addition to scrapie and BSE, TSEs include, among other diseases, chronic wasting disease in deer and elk, and variant Creutzfeldt-Jakob disease in humans.

The current BSE-related import regulations restrict the importation of most live ruminants and ruminant-derived products and byproducts. The exceptions are cervids and camelids, and their products, which are not subject to BSE-related restrictions. The regulations in § 94.18 provide for the importation of meat, meat products, and other edible products derived from bovines (*Bos indicus, Bos taurus,* and *Bison bison*). The current regulations in § 93.419 allow only the importation of sheep and goats for immediate slaughter or restricted feeding for slaughter from

[1] To view the supporting scientific documentation, other supporting documents, the proposed rule, and the comments we received, go to *https://www.regulations.gov* and enter APHIS–2009–0095 in the Search field. In the supporting scientific documentation, the list of scientific literature referenced begins on page 17.

Canada, provided that the sheep and goats are under 12 months of age and are not pregnant.

APHIS has had import restrictions related to BSE since 1991 for live ruminants and most ruminant products. In a final rule published in the **Federal Register** on December 4, 2013 (78 FR 72980–73008, Docket No. APHIS–2008–0010), we amended the BSE-related import requirements for *B. indicus, B. taurus, B. bison,* and removed the BSE-related import restrictions on camelids and cervids from any region. However, that rule did not address BSE-related restrictions on domesticated sheep and goats. We therefore believe that further refinement of the regulations is in order given the latest scientific information regarding BSE transmission in sheep and goats.

Scientific Basis

The protective measures APHIS has taken against BSE have evolved over the years, as scientific understanding of the disease has changed. When the BSE regulations were codified on April 30, 1991 (56 FR 19794–19796, Docket No. 90–252), they applied to all ruminants.

Over the past three decades, however, extensive research has been conducted regarding BSE transmissibility for various ruminant species. Based on the information available, it does not appear to be necessary to continue to prohibit or restrict the importation of sheep and goats and their products with regard to BSE, except in certain limited situations.

This scientific information is as follows: Experiments dating back to shortly after the issuance of the regulations have demonstrated the ability of BSE to be transmitted to domestic sheep and goats via oral challenge and other routes of inoculation, and, in one study, for inoculated sheep to transmit BSE laterally (Foster, Hope et al. 1993; Foster, Parnham et al. 2001; Foster, Parnham et al. 2001; Jeffrey, Ryder et al. 2001; Bellworthy, Hawkins et al. 2005; Andreoletti, Morel et al. 2006; Bellworthy, Dexter et al. 2008; Konold, Bone et al. 2008). However, naturally occurring BSE has not been identified in sheep, and has only been documented in two goats, as a result of retrospective surveillance studies. Both goats were born prior to our initiation of extended ruminant feed bans, and ongoing surveillance has not shown evidence that BSE is circulating within domestic sheep and goat populations. Therefore, the science suggests that import restrictions for sheep and goats based on BSE, other than general prohibition on processed ruminant proteins and products containing them for use as ruminant feed, are not warranted to address BSE risk.[2] (We discuss the scientific background for removing or revising particular restrictions below in the context of specific changes to the regulations.) APHIS has continued to monitor the scientific literature regarding BSE transmissibility in sheep and goats under conditions other than experimental inoculation and no contravening literature has been published. Additionally, no evidence has emerged to indicate that BSE is circulating in domesticated sheep and goats.

Based on the evidence cited above, which was described at greater length in the proposed rule and the supporting scientific documentation that accompanied it, we believe it is not warranted to continue to prohibit or restrict trade of live sheep and goats and the products of sheep and goats due to BSE, other than processed animal protein.[3] Conversely, small ruminants can transmit another TSE, scrapie, and scrapie-specific restrictions are warranted.[4]

Therefore, on July 18, 2016, we published in the **Federal Register** (81 FR 46619–46639, Docket No. APHIS–2009–0095) a proposal [5] to amend the regulations regarding BSE and scrapie as they apply to the importation of sheep and goats and products derived from sheep and goats, as well as to other ruminant species that are not bovines, cervids, and camelids. We proposed to remove BSE-specific prohibitions and restrictions, and, in their place, establish a framework for evaluating foreign regions and, as warranted, foreign flocks for scrapie status.

We solicited comments concerning our proposal for 60 days ending September 16, 2016. We received 53 comments by that date. They were from sheep and goat producers, importers, private citizens, and representatives of State and foreign governments. Most of the commenters were generally supportive of the proposed rule, but some asked questions or expressed concerns about some of the provisions.

We describe the changes we proposed below, and whether we received any comments regarding them. We then discuss the comments that we did receive, by topic.

Before going through the changes that we proposed, however, we believe that it is important to note that the primary regulations that we proposed revisions to were those governing the importation of animals, meat, and other animal products into the United States, which are set forth in 9 CFR parts 93, 94, 95, and 96.

Section 93.401 prohibits the importation of any non-bovine ruminant that has been in a region listed in § 94.24(a). Section 93.405 contains BSE-specific requirements for health certificates for sheep and goats intended for importation. Section 94.24 restricts the importation of meat and edible products from ovines and caprines due to BSE. Section 94.25 restricts the importation from Canada of meat and edible products other than gelatin from sheep and goats, and § 94.26 provides for the importation of gelatin derived from horses or swine, or from sheep and goats that have not been in a region restricted because of BSE. Section 94.27 provides for the transit shipment of meat, meat products, and other edible products derived from bovines, ovines, or caprines that are otherwise prohibited importation into the United States in accordance with §§ 94.18 through 94.26. Section 95.4 contains restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy. Section 96.2 prohibits the importation of casings, except stomach casings, from ovines or caprines that originated in or were processed in any region listed in § 95.4(a)(4) as having BSE, unless certain conditions are met.

While these regulatory provisions, which contain BSE-specific restrictions and prohibitions on the importation of small ruminants and their products, were those primarily addressed by the proposed rule, the changes that we proposed to these sections necessitated proposing a number of smaller, harmonizing changes throughout the regulations. Therefore, for the sake of completeness, we now discuss all of the changes that we proposed. We present these sequentially, except when the various provisions work in consort and a thematic discussion is therefore warranted.

[2] A fuller discussion of the scientific information in support of the proposed rule is found in the supporting scientific documentation that accompanied that rule. See footnote 1.

[3] We continue to consider processed animal protein-containing materials derived from sheep and goats to be a BSE risk due to the possibility that such material has been commingled with bovine materials, and because one significant use of these materials is in animal feed, the consumption of which can result in BSE transmission. For these reasons, we continue to restrict the importation of these commodities.

[4] An extensive discussion of the transmissibility of scrapie is found in our prior proposed and final rules to revise our domestic scrapie regulations, and their supporting documents. To view these documents, go to *https://www.regulations.gov/docket/APHIS-2007-0127.*

[5] See footnote 1.

§ 93.400, Definitions

We proposed to revise definitions for *designated feedlot* and *flock.* We proposed to change the definition of *designated feedlot* to reference scrapie-related restrictions rather than BSE-related restrictions. We proposed to expand the definition of *flock* to include goats as well as sheep. We also proposed to remove the definition of *suspect for a transmissible spongiform encephalopathy* because that term would no longer appear in the regulations. We received no comments on these changes and they will not be discussed further in this document.

We also proposed to add definitions for terms that are currently not defined in the regulations. Specifically, we proposed to define *certified status, classical scrapie, flock of birth, flock of residence, killed and completely destroyed, non-classical scrapie, transmissible spongiform encephalopathies (TSEs),* and *TSE-affected sheep or goat.* We received no comments on these changes and they will not be discussed further in this document.

We proposed to define *country mark* to distinguish this mark from other forms of identification, such as eartags or backtags, that might be used on an animal. We also proposed to require the use of country marks for sheep and goats because this permanent identification allows APHIS to trace an animal back to the country of origin in the event that the animal shows symptoms of a TSE. We received no comments on the definition itself, but did receive comments on the proposed use of country marks for imported sheep and goats. The comments are discussed below.

We proposed to define *goat* as ''any animal of the genus *Capra*'' and *sheep* as ''any animal of the genus *Ovis*'' to clarify that the requirements for sheep and goats apply not only to domesticated sheep and goats, but also to wild animals of those genera which are also susceptible to scrapie. We received comments on these definitions and discuss them below.

§ 93.401, General Prohibitions; Exceptions

As noted above, § 93.401 of the regulations contains general prohibitions on the importation of ruminants. We proposed to amend this section by revising the second sentence, which prohibits the importation of non-bovine ruminants that have been in regions listed in § 94.24(a). (Section 94.24(a) currently contains a list of regions in which BSE is known to exist, but is being removed because this blanket prohibition was no longer needed since we were proposing to allow the importation of small ruminants from BSE-affected regions of the world.) We also proposed to amend the second sentence of § 93.401 to read ''Notwithstanding any other provision of this subpart, the importation of any ruminant that is not a bovine, camelid, cervid, sheep, or goat is prohibited.'' This change would remove BSE restrictions on the importation of many non-bovine ruminants, but would continue to protect against the introduction of TSEs into the United States.

Currently § 93.401(a) also provides that the Administrator may, upon request in specific cases, allow ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States. Providing for the importation of specific animals in individual cases has great value for conservation efforts. In order to maintain genetic diversity in species with very small populations, animals must be moved between zoological collections, both domestically and internationally.

We received comments on these changes to § 93.401 and discuss them below.

§ 93.404, Import Permits for Ruminants

We proposed to specify additional information that an importer would have to submit with the application for an import permit for sheep and goats for immediate slaughter or restricted feeding for slaughter. We need this information to validate that the animals are slaughtered and to rapidly locate the animals should the country of origin report a disease outbreak. It also is needed to clarify that these animals are in, and are not to be removed from, slaughter channels. We also proposed to require additional information for sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter. We need this information to ensure that a continuous previous health history is available for animals that may be considered for importation into the United States. We received some questions about these requirements. We respond to them below.

We also proposed to add a new paragraph to this section to address mitigation measures to allow the importation of zoological ruminants. This change, and the scientific basis for it, are discussed at greater length below under the heading ''Zoological Ruminants.'' We received comments on this change and will discuss them below.

Last, we proposed to provide for permits to be issued by the Administrator for sheep of certain classical scrapie-resistant genotypes, as determined by testing at the National Veterinary Services Laboratories (NVSL) or another laboratory approved by the Administrator. This would reduce import restrictions on animals found to be genetically resistant to scrapie. We received several questions about this provision. We respond to them below.

§ 93.405, Health Certificate for Ruminants

We proposed to revise the requirements for health certificates for sheep and goats to remove BSE-specific requirements. The requirements that we proposed included some information that was previously required; however, that information is relevant to animal diseases other than BSE and could not be removed. We also proposed to remove certain additional requirements for health certificates for sheep. We received no comments on these changes and will not discuss them further in this document.

§ 93.406, Diagnostic Tests

We proposed a minor harmonizing change to this section due to our proposed removal of § 93.419, which we discuss immediately below. We received no comments on this change and will not discuss it further in this document.

§ 93.419, Sheep and Goats From Canada

We proposed to remove and reserve this section, and move provisions for the importation of sheep and goats from Canada to § 93.435. We received no comments on this change and will not discuss it further in this document.

§ 93.420, Ruminants From Canada for Immediate Slaughter Other Than Sheep and Goats

Paragraph (a) of this section referred to the provisions regarding sheep and goats for immediate slaughter in § 93.419. We proposed to update the reference because we proposed to move these provisions to § 93.435. We received no comments on this change and will not discuss it further in this document.

§ 93.424, Import Permits and Applications for Inspection of Ruminants (From Mexico)

The regulations in this section provide that wethers (castrated male sheep or goats) do not need to be accompanied by an import permit if they enter the United States from Mexico through land border ports, even if they are not being imported for immediate slaughter. We proposed to revise the requirements in this section to state that sheep and goats for immediate slaughter do not need to be accompanied by an import permit if entering the United States through a port on the United States/Mexico border. We proposed to remove this exemption for small ruminants not intended for immediate slaughter because we need the information from the import permit to conduct a traceback investigation in the event of a disease outbreak. We received no comments on these proposed changes and will not discuss them further in this document.

§ 93.428, Sheep and Goats and Wild Ruminants From Mexico

We proposed to revise this section to refer to the scrapie provisions in § 93.435, which would apply to sheep and goats from anywhere in the world, including Mexico. We received no comments on this change and will not discuss it further in this document.

§ 93.435, Sheep and Goats

We proposed to revise this section to contain provisions for importing sheep and goats from anywhere in the world. We proposed provisions for sheep and goats imported for immediate slaughter or restricted feeding for slaughter, and provisions for other intended purposes.

The provisions for sheep and goats imported for immediate slaughter and restricted feeding for slaughter that we proposed are similar to the requirements for sheep and goats imported for those purposes from Canada, which had been contained in § 93.419. In other words, we proposed to make the provisions, which had been Canada-specific, broadly applicable to ruminants from anywhere in the world.

We also proposed to update the requirements for importing sheep and goats for other purposes, which had been contained in § 93.435. Because we proposed to remove the general prohibition on importing small ruminants from BSE-affected regions in § 93.401, we proposed to make the requirements here in general consistent with international standards by limiting imports for these purposes to animals from classical scrapie-free countries or flocks, except as permitted by the Administrator under paragraph (a)(5) of § 93.404. This change was intended to work in tandem with the proposed revision to § 93.401 to allow for the importation of animals that are very low risk for scrapie due to their genotype or other factors, in the absence of a general BSE-specific prohibition. We received some comments on these changes and discuss them below.

We also proposed to revise this section to establish a notice-based approach for recognizing regions as free of classical scrapie. The regulations would provide the web address and a contact for requesting copies of the list of classical scrapie-free regions by mail, fax, or email. The regulations also would explain APHIS' process for adding or removing a region to or from the list. This approach is similar to the method we use to recognize disease status for other diseases. It would also allow more timely changes to the list than if we had to do it through rulemaking, as we do now. We received several comments on the implementation of this approach and discuss them below.

Transit Shipment of Articles

The regulations in §§ 94.15, 94.27, and 95.15 currently provide requirements for the transit shipment of animal products and materials. Section 94.15 provides general requirements for the movement and handling of animal products and materials through the United States for immediate export. Section 94.27 provides requirements for transit shipment of meat, meat products, and other edible products derived from bovines, ovines, or caprines through air or ocean ports or by overland transport. Section 95.15 provides requirements for transit shipment of animal byproducts through air or ocean ports or by overland transport.

We proposed to revise § 94.15 to consolidate the requirements for transit shipment of all these products into one section and to eliminate some BSE-related restrictions that are no longer warranted. The new requirements that we proposed are similar to those that already exist in § 94.15.

We proposed that the specific requirements for meat, meat products, and other edible products derived from bovines, ovines, or caprines in § 94.27 would be removed because they are no longer warranted. We also proposed that § 95.15 would be removed. Finally, we proposed to remove references in parts 94 and 95 to §§ 94.27 and 95.15.

We received no comments on these changes and will not discuss them further in this document.

Sheep and Goat Products

The regulations in parts 94, 95, and 96 prohibit or restrict the importation of certain animals and animal products, byproducts, and foreign animal casings into the United States to prevent the introduction of communicable diseases of livestock and poultry. We proposed to amend parts 94, 95, and 96 of the regulations to remove the current BSE provisions regarding sheep and goats. In the following sections, we identify those sections and paragraphs from which regulatory text relating to BSE and sheep and goats would be removed.

As we mentioned previously in this document, § 94.24 restricts the importation of meat and edible products from ovines and caprines due to BSE. Section 94.25 restricts the importation from Canada of meat and edible products other than gelatin from sheep and goats, and § 94.26 provides for the importation of gelatin derived from horses or swine, or from sheep and goats that have not been in a region restricted because of BSE.

We proposed to remove §§ 94.24 and 94.25. We also proposed to amend § 94.26 by removing the references to ovines and caprines that have not been in a region restricted because of BSE from the section heading and the regulatory text. In place of those references we would add a reference to non-bovine ruminants. Gelatin derived from non-bovine ruminants, like gelatin derived from horses and swine, does not present a risk for BSE since there is no scientific evidence that BSE is circulating in sheep or goats.

We received no comments on these changes and will not be discussing them further in this document.

Restrictions on Importation of Byproducts Derived From Ruminants Due to BSE

Part 95 of the regulations prohibits or restricts the importation of products other than meat and other edible products to prevent the introduction of certain animal diseases.

Section 95.1 contains definitions of terms used in the part. We proposed to amend § 95.1 by removing the definitions for *positive for a transmissible spongiform encephalopathy* and *suspect for a transmissible spongiform encephalopathy* because those terms would no longer appear in the regulations. We received no comments on these changes and will not be

discussing them further in this document.

Section 95.4 contains restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy. We proposed amending this section first by revising the section heading to remove the exception for certain tallow derivatives. We are also revising paragraph (b)(1) to remove the exception for tallow derivatives from that paragraph. We proposed making these changes in order to be consistent with our requirements for bovine-derived tallow derivatives, which are subject to restrictions set out in § 95.9. We received no comments on these changes and will not be discussing them further in this document.

In paragraph (c) of § 95.4, we proposed to remove the reference to paragraph (a)(4) from paragraph (c)(1)(iv), and to remove paragraphs (c)(2) and (3) entirely. These revisions would collectively remove BSE-related restrictions from these products when derived from sheep and goats.

We also proposed to amend paragraphs (c)(1)(ii) and (iv) to clarify that the material that is imported must not be ineligible for importation under the conditions of § 95.5 of the regulations. Section 95.5 contains our restrictions on the importation of processed animal protein to address possible BSE risk; as we mentioned previously in this document, consumption of processed animal protein is a viable pathway for the transmission of BSE.

This was a clarification rather than a new requirement; the regulations in § 95.5 have always applied to products derived from all ruminant species, due to concerns about commingling or cross-contamination. However, this change would clarify that the restrictions in that section continue to apply to products derived from cervids, camelids, ovines, and caprines. We also proposed to redesignate paragraphs (c)(4) through (8) as paragraphs (c)(2) through (6), respectively. We received no comments on these changes and will not be discussing them further in this document.

In newly redesignated paragraph (c)(3), we proposed amending the first sentence to remove the requirement that facilities that process or handle any material derived from mammals be inspected at least annually for compliance with the provisions of this section, either by a representative of the government agency responsible for animal health in the region, or by APHIS. Instead, we would require only facilities that process or handle processed animal protein be inspected at least annually. The rendering process used to make processed animal protein creates a material that cannot be differentiated by species without a polymerase chain reaction test, and much rendering is performed involving multiple species. As a result, there is a risk of cross-contamination with processed animal protein that does not exist with the other products. For this reason, we continue to require inspections for facilities that process or handle processed animal proteins.

We received no comments on this change and will not be discussing it further in this document.

Paragraphs (d) and (e) in § 95.4 contain restrictions on serum, serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines and caprines due to BSE. We proposed to remove both of these paragraphs because BSE-related restrictions on these products are no longer warranted. These products present a risk of introducing other diseases, however, and would continue to be prohibited importation into the United States, except for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of animal diseases into the United States.

We received no comments on these changes and will not be discussing them further in this document.

Paragraph (g) contains restrictions on offal derived from ovines and caprines. These restrictions are no longer warranted and paragraph (g) would be removed. We received no comments on this change and will not be discussing it further in this document.

Section 95.40 contains additional certification requirements for certain materials derived from sheep and goats, including processed animal protein, tankage, offal, glands and unprocessed fat tissue, and derivatives of those products. These additional certification requirements were established due to BSE concerns and are no longer warranted; therefore, we proposed to remove § 95.40. We received no comments on this change and will not be discussing it further in this document.

Restrictions on the Importation of Foreign Animal Casings

Part 96 of the current regulations includes provisions regarding the importation of animal casings into the United States. The regulations in § 96.2 prohibit the importation of ruminant casings into the United States to prevent the introduction of BSE. We proposed to remove the restrictions on casings derived from sheep and goats by removing paragraph (b)(1), which pertains to casings derived from sheep slaughtered in Canada.

We received no comments on this change and will not be discussing it further in this document.

Sheep and Goat Germplasm

The regulations in part 98 govern the importation into the United States of germplasm (embryos and semen), including germplasm from sheep and goats.

Subpart A sets forth requirements for ruminant and swine embryos from regions free of foot-and-mouth disease (FMD), and for embryos of horses and asses.[6] Subpart B sets forth requirements for ruminant and swine embryos from regions where FMD exists. Subpart C sets forth the requirements for the importation of animal semen from species regulated by APHIS.

The regulations in § 98.10a require that embryos from sheep in regions other than Australia, Canada, and New Zealand may be imported only under certain conditions that serve to protect against the introduction of TSEs into the United States. Because sheep and goat embryos and oocytes present similar disease risks, those risks can be addressed by the same mitigations, and also because we anticipate that use of oocytes will increase as reproductive technology continues to improve, we proposed to add provisions for goat embryos and both sheep and goat oocytes to the regulations in § 98.10a. Specifically, we proposed to revise the section heading to read ''Sheep and goat embryos and oocytes.'' We also proposed to add a definition of *oocyte* consistent with international standards. We received no comments on these changes and will not be discussing them further in this document; however, we did receive other comments on the requirements for imported embryos and oocytes and discuss them below.

We proposed to allow the importation of in vivo-derived sheep and goat

[6] At the time the 2016 proposed rule was published, these regulations also governed the importation of ruminant and swine embryos from regions where rinderpest exists. Since then, rinderpest was removed from the regulations in a final rule published on April 11, 2018 (83 FR 15491–15495) because the disease has been eradicated worldwide. Therefore, we will not be referring to rinderpest in this document. To view the rule removing rinderpest from the regulations, go to *https://www.regulations.gov/document/APHIS-2017-0070-0001.*

embryos and oocytes with the requirement that, if these embryos and oocytes are collected from donors in, or originating from, regions not free of classical scrapie, the health certificate required under § 98.5 must include additional declarations stating that the embryos or oocytes were collected, processed, and stored in accordance with the requirements in § 98.3, and, for in vivo-derived sheep embryos only, that the embryo is of either of the scrapie-resistant genotypes, AARR or AAQR, based on official testing of the parents or the embryo. The testing may be performed at the NVSL or at another laboratory approved by the Administrator. We received some comments on these changes and will discuss them below.

We proposed that the certificate that would accompany sheep embryos that are not of either of these genotypes, sheep embryos that are in vitro-derived or processed, and all goat embryos, would also have to include statements that in the region where the embryos originate:

- TSEs of sheep and goats are compulsorily notifiable;
- A classical scrapie awareness, surveillance, monitoring, and control system is in place;
- TSE-affected sheep and goats are killed and completely destroyed; and
- The feeding of meat-and-bone meal of ruminant origin has been banned and effectively enforced in the whole country.

The certificate would also have to state that the donor animals:

- Have been kept since birth in flocks in which no case of classical scrapie had been confirmed during their residency;
- Are permanently identified to enable traceback to their flock of birth or herd of origin, and the identification is recorded on the certificate accompanying the embryos and linked to the embryo container identification;
- Showed no clinical sign of classical scrapie at the time of embryo or oocyte collection; and
- Have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy.

We proposed adding these certification requirements for embryo genotypes that are not scrapie resistant, but which originate from regions not considered by APHIS as free of classical scrapie, to ensure that mitigations are in place to detect classical scrapie if it is present in sheep or goat populations. We received comments on these changes and will discuss them below.

We also proposed to remove the existing requirement that sheep embryos from regions other than Australia, New Zealand, or Canada be transferred only to flocks in the Voluntary Scrapie Flock Certification program (SFCP). Enrollment in this program requires an annual inspection with inventory reconciliation and submission of tissues from certain animals for scrapie testing. We proposed making this change because the scientific literature demonstrates that embryos are low risk for scrapie transmission. APHIS has determined that requiring all first-generation offspring to be maintained in an SFCP flock is unnecessary as well as overly burdensome on importers.

Instead, we proposed to require that sheep and goat embryos or oocytes from regions that are not free of classical scrapie be imported only for transfer to females in flocks listed in the National Scrapie Database, or to an APHIS-approved storage facility where they may be kept and later transferred to recipient females in a flock that is listed in the National Scrapie Database. We also proposed to allow imported embryos or oocytes that are not otherwise restricted by the conditions of an import permit to be transferred from a listed flock to any other listed flock with written notification to the responsible APHIS Veterinary Services (VS) Service Center. To be listed in the National Scrapie Database, a flock owner must contact the local VS Field Operations (FiOps) office for the receiving State or a cooperating State Veterinarian's office and request to be listed; and provide the location of the flock and the owner's contact information. The VS FiOps office or State Veterinarian's Office will enter the information in the database, and will issue the flock identification and the premises identification number that are required to be submitted on the permit application. To find the nearest VS FiOps office, contact the State or Territory Point of Contact (POC). A list of POCs can be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/contact-us.*

We received no comments on these changes and will not be discussing them further in this document.

Finally, we proposed to require the importer, owner of a recipient flock, or the owner of an APHIS-approved embryo or oocyte storage facility to maintain records of the disposition (including destruction) of imported or stored embryos or oocytes for 5 years after the embryo or oocyte is transferred or destroyed. These records would have to be made available during normal business hours to APHIS representatives on request for review and copying. This recordkeeping requirement is consistent with the recordkeeping requirements for imported semen that already exist, and would allow us to conduct traceback investigations in the event of a disease introduction. We received no comments on this change and will not be discussing it further in this document.

The regulations in § 98.3(h) currently require that ruminant and swine embryos have an intact zona pellucida, which effectively prohibits the importation of in vitro-derived and micromanipulated embryos except as provided under § 98.10. We stated that we intended to continue to allow such importations on a case-by-case basis, if the Administrator determines that any disease risk posed by the embryos can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures.

We received no comments on this explanation of the interaction between the two sections and will not be discussing it further in this document.

The regulations in § 98.13 provide requirements for import permits for ruminant and swine embryos from regions where FMD exists. We proposed to add a new paragraph (c) to this section specifying that applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included. We proposed this change to ensure that the permit requirements for sheep and goat embryos and oocytes from regions where FMD exists are consistent with the requirements for sheep and goat embryos and oocytes from regions that are free of the disease. We received no comments on this change and will not be discussing it further in this document.

The regulations in § 98.15 set forth the requirements for ruminant and swine embryos from regions where foot-and-mouth disease exists. Currently, § 98.15(a)(1) and (2) require that, for ruminants, no case of BSE (among other diseases) occurred (1) during the year before collection in the embryo collection unit or in any herd in which the donor dam was present, or (2) in or within 5 kilometers of the embryo collection unit, or in any herd in which the donor dam was present. We proposed to remove these requirements because we believe the proposed requirements for sheep and goat embryos in § 98.10a will provide

adequate protection against a TSE introduction via embryo or oocyte transfer. We received no comments on this provision and will not be discussing it further in this document.

Section 98.15(a)(7)(i)(A) currently requires that, for ruminants, not less than 30 days, nor more than 120 days after embryo collection, the donor dam must be examined and found free of BSE (among other diseases). We proposed to remove the requirement that sheep and goats be found free of clinical signs of BSE because sheep and goat embryos do not present a risk for transmitting BSE since BSE is not circulating in the sheep and goat populations. We received no comments on this provision and will not be discussing it further in this document.

Currently § 98.15(a)(8)(i)(A) requires that, for ruminants, between the time of embryo collection and all required examinations and tests are completed, no animals in the embryo collection unit with the donor dam, or in the donor dam's herd of origin, exhibited clinical evidence of BSE (among other diseases). We proposed to remove BSE from the list of diseases in this paragraph because we believe the proposed requirements for sheep and goat embryos in § 98.10a will provide adequate protection against a TSE introduction through embryo or oocyte transfer. We received no comments on this provision and will not be discussing it further in this document.

Currently, the regulations in § 98.35(e) require that, for sheep and goat semen from any part of the world to be imported into the United States:

- The donor animals must be permanently identified to enable traceback to their establishment of origin;
- They have been kept since birth in establishments in which no case of scrapie has been confirmed during their residency;
- They neither showed clinical signs of scrapie at the time of semen collection nor developed scrapie between the time of semen collection and the export of semen to the United States; and
- The dam of the semen donor is not, or was not, affected with scrapie.

The regulations also require that in the region where the semen originates, scrapie is a compulsorily notifiable disease, an effective surveillance and monitoring program for scrapie is in place, affected sheep and goats are slaughtered and completely destroyed, and the feeding of meat and bone meal or greaves derived from ruminants has been banned and the ban effectively enforced for the whole region.

At the time the regulations were established, they were consistent with the then-current scientific understanding of scrapie and existing international standards. However, advances in scientific understanding of the disease now allow us to relieve some restrictions on the importation of sheep and goat semen. Epidemiological evidence from natural cases in the field suggests that classical scrapie is unlikely to be transmitted via semen (Wrathall 1997). In addition, studies to date have failed to detect PrPSc proteins in components of semen (Gatti, Meyer et al. 2002).

As part of a study to investigate transmission of classical scrapie through embryo transfer, Wang, et al., used a classical scrapie-positive ram to mate with two donor ewes, one scrapie positive, the other negative (Wang, Foote et al. 2001). None of the lambs resulting from embryos of either ewe developed classical scrapie, nor did the uninfected ewe that was bred to the infected ram. The study did not provide information about the scrapie strain or the genotypes of the rams, donor ewes, and recipient ewes.

A more recent study evaluated the infectivity of semen from infected rams by injecting it via intracerebral inoculation into classical scrapie-susceptible transgenic mice overexpressing the VRQ allele. Semen from three classical scrapie-positive VRQ homozygous sheep was injected into a total of 40 transgenic mice, with none subsequently developing classical scrapie. One of the infected sheep was exhibiting clinical signs of classical scrapie and the other two were asymptomatic at the time of collection. In comparison, the injection of brain homogenate from 4 scrapie-infected sheep intracerebrally into 23 transgenic mice resulted in infection of 100 percent of the mice (Sarradin, Melo et al. 2008).

More recently, 8 ewes in a historically scrapie-negative sentinel flock of 24 sheep were discovered to be scrapie-positive 4 months after having been bred to scrapie-positive rams from an adjacent highly infected flock. The flock had also been bred in previous years by other rams from the infected flock and had fence line contact with rams from the infected flock. The ewes had been bred to these rams in order to increase the scrapie-susceptibility of the sentinel flock to the 'Caine' strain of scrapie (*i.e.,* to increase the proportion of sheep with at least one valine insertion at codon 136). This strain has a relatively short incubation period, particularly in sheep that are homozygous for valine at codon 136. The discovery of the infected ewes led to an investigation by Rubenstein et al. (2012) to determine whether it was possible that scrapie could have been transmitted to the ewes through exposure to the semen of infected rams (Rubenstein, Bulgin et al. 2012).

Using newly developed detection techniques such as serial protein misfolding cyclic amplification, combined with an optical fiber immunoassay, the investigators detected prion disease-associated-seeding activity, which is assumed to imply the presence of PrPSc in semen samples from the rams in the affected flock described above. In addition, intracerebral inoculation of a newly-generated sheep scrapie-susceptible transgenic mouse line with semen from both infected and uninfected rams from the flock resulted in the detection of PrPSc in all of the mice inoculated with semen from scrapie-positive rams, but in none of the mice inoculated with semen from scrapie-negative rams.

These experiments suggest that semen from scrapie-infected rams could harbor infectious PrPSc; however, additional studies are necessary to determine whether the level of infectivity in semen is sufficient to transmit scrapie laterally to ewes or to embryos resulting from the use of scrapie-infected semen donors.

To date, there has been no direct evidence to support the transmission of TSE infectivity through semen of sheep and goats to other sheep or goats; however, the studies conducted have been somewhat limited.

Based on the findings of these studies, we proposed to amend § 98.35 to eliminate the requirement that donor animals have been kept since birth in establishments in which no case of scrapie has been confirmed during their residency, and to redesignate the subsequent paragraphs. We also proposed to require that the donor animals were not, and are not, restricted in the country of origin or destroyed due to exposure to a TSE, and proposed to add a new paragraph to allow APHIS to establish testing requirements for semen and/or semen donors. We received no comments on these changes and will not be discussing them further in this document.

We also proposed to revise paragraph (e)(3) to include semen from all countries, and to allow semen to be imported to an APHIS-approved semen storage facility prior to being transferred to females in a flock listed in the National Scrapie Database. This change will provide an additional option for producers and importers. Further, we proposed to add new paragraphs to describe recordkeeping requirements for APHIS-approved semen storage facilities, including a requirement that

progeny of imported semen be officially identified and records maintained of their disposition in order to allow these animals to be traced if a need arises. We received no comments on these provisions and will not be discussing them further in this document.

We now discuss the comments that we did receive, by topic.

Importation of Live Ruminants

We proposed to amend § 93.404 to specify additional information that an importer would have to submit with the application for an import permit for sheep and goats. For sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter, we proposed to require that, if the sheep and goats originate in regions not free of classical scrapie, the importer would have to provide documentation showing that the animals have reached and maintained certified status in a scrapie flock certification program that has been evaluated and approved by the Administrator. The documentation would have to specify the address, or other means of identification, of the premises and flock of birth, and any other flocks in which the animal has resided. We also proposed to add a new paragraph (a)(6) which would provide for permits to be issued by the Administrator for sheep of certain classical scrapie-resistant genotypes, as determined by testing at the NVSL or another laboratory approved by the Administrator.

One commenter stated that sheep entering the United States from other countries should be held to the same set of rules and regulations as flocks at the Export Certified level in the U.S. SFCP (described in the regulations in 9 CFR part 54) in the United States. The commenter also stated that sheep should not be allowed to enter the country based solely on codon test results.

We agree with the commenter that the same level of risk mitigation should be required for imported sheep and goats as required by the Export Category of the U.S. SFCP. However, we disagree that genotype should not be used to mitigate risk associated with imported sheep. As we explained in the supporting scientific documentation that accompanied the proposed rule, resistance to classical scrapie is consistently associated with the presence of alanine (A) at codon 136, arginine (R) at codon 154, and R at codon 171. Sheep homozygous for this combination appear almost completely resistant to classical scrapie under natural conditions. Female sheep with RR at codon 171, or male sheep either with RR at codon 171 or with AA at codon 136 and QR at codon 171, are no more likely to transmit classical scrapie than sheep meeting the requirements of the Export Category of the U.S. SFCP.

We proposed to remove BSE-related restrictions from goats as well as sheep. Four commenters stated that there is neither sufficient published literature nor large enough surveillance sampling to draw the conclusion that there is no BSE risk in goats. The commenters stated that surveillance for goats needs to be expanded in the national scrapie eradication program and APHIS should recommend that trading partners expand their TSE surveillance for goats so good decisions may be made regarding safe trade. The commenters further stated that APHIS should publish another proposed rule regarding goats specifically when APHIS is able to demonstrate and cite evidence documenting BSE restrictions on goats should be removed.

As we explained in the supporting scientific documentation accompanying the proposed rule, naturally occurring BSE has only been documented in two goats, as a result of retrospective surveillance studies. Both goats were born prior to the initiation of extended ruminant feed bans, and ongoing surveillance has not shown evidence of BSE circulating within domestic sheep and goat populations. Experience internationally in countries with BSE has demonstrated that feed bans are effective control measures and the incidence of BSE worldwide continues to decline because of these measures. Furthermore, we will require that any goat imported into the United States either comes from a region recognized by APHIS as free of classical scrapie or has reached and maintained certified status in a SFCP determined by APHIS to provide equivalent risk reduction as the USDA APHIS Export Category of the SFCP. The requirements for APHIS to determine classical scrapie-free status and for equivalent status for scrapie flock certification programs in an exporting region are set out in the APHIS guidance document accompanying the proposed rule,[7] and includes the flock meeting the requirements equivalent to the Export Certified status of the U.S. SFCP while participating in a program under the supervision of the national veterinary authority of the region of origin. This equivalency must be determined by APHIS evaluation. We also require that the feeding of meat and bone meal, greaves, or similar materials of ruminant origin to sheep and goats is banned and has been effectively enforced in the region for at least 7 years.

As discussed previously in this document, we proposed a requirement for additional information that an importer would have to submit with the application for an import permit for sheep and goats. One commenter stated the proposed rule seemed to require an import permit, but currently, all other livestock exports from Canada to the United States are completed with only an export certificate or a less complex requirement, if the animals are entering the United States via a land port. The commenter asked for Canada and the United States to enter into a bilateral agreement to remove the requirement for an import permit for live sheep and goats and replace it with an export certification.

In § 93.417, paragraph (a) specifies that for ruminants imported from Canada, the importer must apply for and obtain an import permit as provided in § 93.404. An exception to the permit requirement is provided for certain ruminants, including wethers and sheep or goats imported for immediate slaughter, if those ruminants are offered for entry at a land border port, and provided certain other conditions are met. We did not propose to amend this section. A permit ensures collection of the additional information needed to determine the initial eligibility of animals for importation.

One commenter stated that it appears in cases of export of small ruminants for any purpose other than slaughter or feeding for slaughter, the export certificate required in § 93.405(b) will require an extensive amount of information including transport route, port of entry, and, most notably, all premises on which the animal has resided throughout its life. The commenter asked us to explain the need for this documentation.

The documentation is needed to ensure animals have been kept in holdings complying with § 93.405(b) and (c), equivalent to the Export Category of the U.S. Scrapie Flock Certification Program. This certification requirement is incorporated to address the potential risks of other premises where the donor animals resided which were not of equivalent status.

We proposed to define *country mark* as ''a permanent mark approved by the Administrator for identifying a sheep or goat to its country of origin.'' We proposed this definition to distinguish this mark from other forms of identification, such as eartags or backtags, that might be used on an

[7] See *https://www.regulations.gov/document/APHIS-2009-0095-0005.*

animal. We also proposed to require the use of country marks for sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter because these other purposes are not terminal, and this permanent identification allows APHIS to trace an animal back to the country of origin in the event that the animal shows symptoms of a TSE.

One commenter stated that the proposed changes do not address the requirement for animal branding. The commenter claimed that current requirements for cattle branding are not enforced consistently at different border ports, creating trade barriers and expressed concern that branding requirements for sheep and goats exported for feeding prior to slaughter may present similar trade barriers. The same commenter and four other commenters also noted the proposed rule required a permanent country mark for all imported live sheep and goats. The commenters stated branding is not common practice in the sheep and goat industries and has been raised as a significant issue for the humane treatment of these animals. The commenters asked APHIS to provide an alternative option to branding, where possible.

APHIS notes that we proposed in § 93.435(a)(3) to require imported sheep and goats to be permanently identified with a country mark using a means and in a location on the animal approved by the Administrator, but we did not specify any particular method of identification. We may approve methods other than hot iron branding to permanently identify animals; however, no consistently effective alternative methods exist currently. The revisions that we proposed were simply to allow for their development, should it occur.

This requirement is similar to the requirements for bovines from Canada, which must be permanently identified with a brand, ear tattoo, or other means deemed acceptable by the Administrator. This permanent identification allows APHIS to trace an animal back to the country of origin in the event the animal shows symptoms of a TSE. Because many forms of eartags are not tamper-evident and may be lost or removed and reused, we generally do not consider eartags a permanent form of identification. We are not aware of these requirements resulting in barriers to trade.

We proposed to require that health certificates for imported sheep and goats include the official individual sheep or goat identification applied to the animals. One commenter asked what would be required as official identification, particularly for goats. The commenter noted that in Canada, all sheep are currently required to be tagged with an official Canadian government radio frequency identification (RFID) device when they leave the farm of origin, but goats are not required to be tagged. However, for the voluntary scrapie flock certification program, animals must only carry two unique forms of identification while on farm, but neither of those identification methods is required to be the Canadian official RFID. The commenter asked if APHIS would recognize this as acceptable identification.

APHIS will require official Canadian RFID eartags for goats and sheep imported from Canada and this will be specified in guidance published on APHIS' website. Sheep and goats imported for purposes other than immediate slaughter will also require a permanent mark unless maintained as a segregated group in a designated feedlot.

One commenter noted that under proposed § 93.435(b), officials of the country of origin would be required to seal conveyances at the point of departure for animals going directly to slaughter or feeding for slaughter. The commenter asked why this is different from the requirements for cattle, where seals are placed at the port of entry by U.S. inspection staff.

The commenter is correct in identifying a discrepancy between the treatment of cattle going directly to slaughter or restricted feeding for slaughter and our proposed requirements for sheep and goats going directly to slaughter or restricted feeding for slaughter. This was an oversight in the proposed rule and there is no technical basis for such a discrepancy. The requirement that conveyances carrying sheep and goats for immediate slaughter be sealed at the point of departure is a BSE-related restriction and is no longer warranted. We have amended § 93.435(b) to remove this restriction.

One commenter stated that while the proposed § 93.435(e) addresses provisions for transit through the United States, it does not seem to address the possibility of a rest stop should the duration of travel be excessive.

Under the 28-Hour Law (49 U.S.C. 80502), rest stops are required for animals being transported in the United States. Section 93.401(b) of the regulations sets out the conditions under which rest stops for ruminants may occur. We did not propose any changes to those provisions.

In proposed § 93.435(f), we set out the process by which we would recognize regions as free of classical scrapie. One commenter asked what criteria would be used to determine whether a region is free of classical scrapie and if those criteria were consistent with World Organization for Animal Health (OIE) guidelines. The commenter noted three European Union (EU) Member States have met EU criteria to be considered negligible risk for classical scrapie, and asked whether, given the EU criteria were the same as the OIE, EU Member States could be recognized (or receive an expedited review) as free of classical scrapie by the United States.

The criteria for classical scrapie-free country status were described in the guidance document published with the proposed rule. The criteria are consistent with OIE guidelines and include the existence of a system of effective official veterinary control and oversight within the region for at least 7 years, a program of targeted surveillance and monitoring for classical scrapie in place for at least 10 years, and a ban on feeding to sheep and goats of meat and bone meal, greaves, or similar materials of ruminant origin that has been effectively enforced in the region for at least 7 years, among other requirements. EU Member States will be reviewed in accordance with § 92.2 of the regulations using the criteria in the guidance document in the order in which complete submissions are received.

One commenter asked why, for imports based on the scrapie status of the flock of origin, the certification program of the country must be approved by APHIS. The commenter asked APHIS to consider, as recommended by OIE, including in its import health certificate requirements criteria that are equivalent to the OIE's criteria for ''scrapie free establishments'' and accept imports based on the certification that these criteria have been met.

We cannot accept imports solely on certification that OIE requirements have been met. The United States needs to ensure that proper oversights by the competent authority exist in the region of origin and that the program has been effectively implemented. Further, because the OIE guidelines do not specify a minimum number of animals that must be tested before a flock is certified, we believe that testing levels specified by OIE may not be sufficient to detect scrapie in a flock before it is certified as free.

One commenter asked whether APHIS could approve the EU scrapie status flock certification program as a whole, instead of requesting applications from each Member State. The commenter stated that the EU flock certification

program respects harmonized rules, laid down in Annex VIII to Regulation (EC) No 999/2001,[8] which follow OIE criteria for establishments free from scrapie, and require the Member State to maintain lists of holdings with negligible risk of classical scrapie based on those criteria. The commenter also stated that EU holdings listed as having a negligible risk of classical scrapie would be considered equivalent to 'Export Certified Flocks' in the United States and also meet the recommendations at Article 14.8.5 of the OIE Code. The commenter stated that, once APHIS considers and confirms this to be the case, documentation detailing all the holdings of residence or provenance since birth of sheep and goats intended for export to the United States should not be necessary or required.

We will review the EU scrapie status flock certification program when the first EU Member State applies. If the implementation by that Member State of the EU scrapie flock certification program requirements are determined to be equivalent to the United States' program requirements, subsequent Member State certification program reviews may be limited to an evaluation of the Member State's implementation of the EU scrapie status flock certification program and may take into consideration the prior APHIS determination of the EU scrapie flock certification program. We will not prejudge the results of any EU Member State's program evaluation in this final rule.

In the proposed rule, we proposed to define *certified status* as a flock that has met the requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program while participating in a program under the supervision of the national veterinary authority of the region of origin as determined by an evaluation conducted by APHIS of the program.

One commenter asked if the program in Canada, which is administered by Scrapie Canada but is overseen by the Canadian Food Inspection Agency (CFIA), and for which all inspections are performed by federally accredited veterinarians, would meet the requirements. The commenter noted that in the U.S. SFCP, Export Certified flocks receive a high level of monitoring, including annual inspections and inspection of all cull animals. The commenter stated that in Canada, cull animals are not inspected although records of sales are reviewed. On-farm adult mortalities are tested for scrapie by accredited laboratories. The commenter asked if this level of surveillance would be acceptable.

Countries should request evaluation of their certification program to have it officially recognized by APHIS as equivalent. We will not prejudge the results of any country's program evaluation in this final rule.

We proposed to allow sheep and goats for breeding to be imported in two ways. One way is for the animal to originate in a region recognized by APHIS as free of classical scrapie. The other is for the animal to reach and maintain certified status in a scrapie flock certification program determined to provide the same risk reduction as the Export Category of the U.S. SFCP. One commenter stated that Canada's voluntary scrapie free flock certification program has been designed based on OIE guidelines, with some exceptions based on equivalent risk outcomes. Canada's program differs in allowing flocks or herds to achieve certified status after 5 years of monitoring, whereas the OIE guidelines and the U.S. program require 7 years of monitoring. The commenter stated that the rule only considers a country's flock certification program guidelines and does not consider the impact of a country's national scrapie prevalence, or the presence of a national scrapie eradication program. The commenter stated that the very low national prevalence for scrapie and the CFIA's ongoing and robust national scrapie eradication program, in combination with strict flock certification program requirements, provide the confidence needed to certify flocks or herds as negligible risk after 5 years on the program.

Countries should request evaluation of their certification program to have it officially recognized by APHIS as equivalent. In recognizing equivalence, we will consider the possibilities that countries could apply additional or different mitigations to provide equivalent risk status as the U.S. program. We will not prejudge the results of any country's program evaluation in this final rule.

We proposed to allow for permits to be issued by the Administrator for sheep of certain classical scrapie-resistant genotypes, as determined by testing at the NVSL or another laboratory approved by the Administrator. One commenter expressed confusion about what will be expected for sheep tested for genetic markers of scrapie resistance. The commenter noted that the proposed rule states such sheep must meet all requirements for import other than the requirement that they originate in a flock or region free of classical scrapie. The commenter asked if this means sheep confirmed to carry the specified genes for scrapie resistance will not be required to be from a flock that is certified under the CFIA's Voluntary Scrapie Flock Certification Program (VSFCP). The commenter asked if this would apply uniformly to both males and females. The commenter also asked if importation of these genetically low-risk sheep would be at the discretion of the Administrator, *i.e.* on a case-by-case basis.

The provisions for the importation of genetically resistant sheep are in § 93.404(a)(6). Sheep permitted entry under these provisions are not required to come from a flock certified under a scrapie free certification program. However, as we explained in the proposed rule, only females that are genotype AARR, or males that are genotype AARR or AAQR, may be imported under this provision on a case-by-case basis at the discretion of the Administrator.

One commenter noted that in § 93.404(a)(6), we proposed to require that genetic testing be completed at the National Veterinary Services Laboratories or another laboratory approved by the Administrator. The commenter asked whether we would require these tests to be completed at a laboratory in the United States. The commenter also asked if a laboratory recognized by the CFIA for the VSFCP in Canada would be recognized, and if we would make a list of acceptable laboratories available.

APHIS will consider approval of foreign laboratories with the required expertise and where there are appropriate quality assurance procedures in place. In general, APHIS will consider approving laboratories that are approved by the competent veterinary authority of the national government of the exporting region, provided that region has a scientifically sound approval and oversight process in place for laboratories. Review of the degree of laboratory oversight in the country will occur in our overall evaluation of the country's scrapie program. If we approve foreign laboratories, this will be detailed in the import protocols designed for the importation of sheep/goats for specific countries/regions and the negotiated export health certificates. APHIS will need the approved laboratory results before import permit issuance, and the information will accompany export health certificates.

One commenter stated that the EU recognizes sheep with genotype ARR/

[8] The EU regulations can be viewed online at *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001R0999&from=EN.*

ARR as genetically resistant. The commenter asked APHIS to take this into consideration for all sheep, not just those for research and diagnostics, when a permit is requested.

As we explained in the proposed rule, only females with genotype AARR or males with genotype AARR or AAQR may be imported under this provision. The reason for this restriction is that the OIE does not recognize the ARR/ARR genotype as genetically resistant to scrapie. Permits will still be required for animals with known genotypes which may be allowed if they meet other import requirements. The genotyping requirements are not specific to sheep for research/diagnostics.

We proposed to amend § 93.405(b)(2)(i) to require that the health certificate accompanying imported sheep and goats state that the sheep or goats originated from a region recognized as free of classical scrapie by APHIS, or that the animals had reached and maintained certified status in a scrapie flock certification program approved by APHIS. One commenter suggested that we amend this requirement to read ''or the animals have reached and maintained certified status in a scrapie flock certification program approved by APHIS or equivalent status.'' The same commenter also suggested amending § 93.435(d) in a similar fashion. The commenter stated these changes would accommodate holdings in the EU designated as negligible risk for classical scrapie.

Our intent is to recognize equivalent status in an equivalent program regardless of the name given to the status or to the program. For clarity, we will revise both paragraphs, paragraph (b)(2)(i) of § 93.405 and paragraph (d) of § 93.435, to read ''certified status or equivalent status in a scrapie flock certification program approved by APHIS.''

We proposed that sheep and goats entering ''terminal feedlots'' be required to be permanently identified. One commenter stated that while there is no scrapie transmission risk associated with lambs being fed for slaughter, on occasion ewe lambs do move out of feedlots and enter breeding flocks. The commenter stated that this poses an enforcement problem and an unnecessary risk since records and inspection are the only practical tools for assuring all animals in a terminal feedlot are either processed or terminated and are properly disposed of. The commenter stated that APHIS should require all imported sexually intact sheep and goats be permanently identified in a tamper-proof manner regardless of their age or intended use.

Since all imported animals require official identification, we presume the commenter is referring to the country marks exemption for animals kept segregated in feedlots as provided in § 93.435(a)(3). While there are circumstances where the Administrator may determine that a country mark is required for animals imported to terminal feedlots, we disagree that there is significant risk associated with animals properly handled within these terminal feedlots under APHIS oversight and restrictions that would necessitate all such animals having country marks as well as official identification.

One commenter recommended that APHIS place additional requirements on designated feedlots receiving imported animals from regions not free of classical scrapie for restricted feeding and eventual slaughter to include that there be no fence-line contact with other sheep or goats. The commenter stated that this could be accomplished by requiring at least a 30-foot fence separation or a solid-wall perimeter designed to prevent fluid transfer between animals in the designated feedlot and sheep or goats outside the feedlot. The commenter also stated that APHIS should also inspect and approve the designated feedlot's biosecurity provisions and practices to minimize the risk of TSE transmission between animals in and outside the designated feedlot.

We agree with the commenter. A designated feedlot may be a specified area within a larger facility that contains animals intended for subsequent movement from the facility. Additionally, scrapie may be spread through contact with bodily fluids such as nasal mucus, urine, saliva, and feces and therefore fence-line contact between imported animals in designated feedlots and other sheep or goats that could subsequently move from the facility could pose a risk of scrapie transmission. We have amended § 93.435 to include a new paragraph (c)(11)(viii) requiring the operator of the feedlot to prevent fence-line contact by a method acceptable to the Administrator. We will work with individual operators to determine the best means of preventing such contact in their feedlots.

One commenter asked that, in addition to recognizing the negligible risk that genotype AARR females pose in transmitting scrapie, APHIS also allow the import of genotype AAQR females under the same conditions. The commenter cited the limited risk genotype AAQR females pose, given the additional requirement that these animals must come from a flock known to be free of classical scrapie.

APHIS disagrees. In general, a glutamine (Q) at codon 171 of the PrP allele is associated with susceptibility to scrapie. AAQR scrapie-positive animals occur with some frequency.[9] AARR sheep imported under this provision of the proposed rule do not have to originate in scrapie-free flocks, only in flocks having no known risk for scrapie.

One commenter noted that for ruminant species that are not bovines, cervids, sheep, goats or camelids, the rule indicates a case-by-case approach will be used to mitigate TSE risk for zoological or wild ruminants considered for import. The commenter stated this approach works well in these unique situations but may be too burdensome for certain farmed alternative livestock (*e.g.,* water buffalo and yaks) posing an extremely low risk based on both reported susceptibility to TSEs and known feeding practices.

Farmed alternative bovid livestock (domestic water buffalo, *Bubalus bubalis* or domestic yak, *Bos grunniens*) that are not sheep or goats are recognized as very low risk for BSE, but unknown risk for other TSEs. An unknown risk should not be presumed to be a negligible risk, particularly when the diseases in question are degenerative and fatal. Accordingly, these species may be evaluated under a similar process as zoological ruminants on a case-by-case basis, or through protocols with detailed mitigations for import of these domestic bovid species.

Zoological Ruminants

Currently, non-bovine ruminants other than sheep and goats from regions not listed in § 94.24(a) are not subject to any import restrictions with regard to BSE. We believe, however, that there is a certain category of ruminants that present enough of a potential risk of spreading TSEs that their importation should be prohibited unless certain risk mitigation measures are in place. This category of ruminants includes certain ruminants held in zoological facilities and certain wild ruminants. For the purposes of discussion, we will refer to such animals as zoological ruminants to distinguish them from domesticated sheep, goats, and bovines.

Scientific literature indicates that at least certain zoological ruminants are

[9] The genetics of scrapie resistance were discussed extensively in a rulemaking that amended the domestic scrapie regulations in 2019. To view the proposed and final rules, supporting materials, and comments we received, go to *https://www.regulations.gov* and enter APHIS–2007–0127 in the Search field.

susceptible to TSEs caused by the BSE agent. In association with the BSE epidemic in domestic cattle in Europe, TSEs have been diagnosed in several species of zoo animals, all from the families Bovidae and Felidae. Sixteen cases of TSEs have been recorded from antelope in U.K. zoos including one nyala (*Tragelaphus angasi*), six eland (*Taurotragus oryx*), six greater kudu (*Tragelaphus strepsiceros*), one gemsbok (*Oryx gazelle*), one Arabian oryx (*Oryx leucoryx*), and one scimitar-horned oryx (*Oryx dammah*) (Travis and Miller 2003). The first recorded case was a nyala euthanized at a wildlife park in England in 1986, the same year that the first BSE cases in cattle were recognized (Wells, Scott et al. 1987; Jeffrey and Wells 1988). Reported cases of TSEs in zoo bovids peaked around 1991, and no additional cases in zoo antelope have been reported since 1996 (Kirkwood 2000).

Several lines of evidence support the hypothesis that at least some, if not all, of the spongiform encephalopathy cases diagnosed in zoo bovids were caused by the BSE agent. First, the cases in zoos coincide geographically and temporally with the BSE epidemic in Great Britain. Second, epidemiologic investigations indicated that all affected animals, or the herds into which they were born or moved, could have been exposed to feeds containing ruminant- derived protein or other potentially contaminated material (Kirkwood and Cunningham 1994). Finally, comparable patterns of incubation periods and pathologic effects were seen in mice inoculated with brain tissue homogenate from the affected nyala, an affected kudu, and BSE-affected cattle (Jeffrey, Scott et al. 1992).

The greater kudu, a non-domestic African antelope, appears to be particularly susceptible to BSE. Six of eight kudu that died in a small herd at the London Zoo from 1989 through 1992 were diagnosed with spongiform encephalopathy (Kirkwood and Cunningham 1994). The disease is presumed to have been introduced to the kudu herd through feeds containing ruminant-derived protein around the time of the BSE epidemic in U.K cattle. However, some of the affected kudu were born after the elimination of the potentially contaminated feed from the premises, and one case occurred in a kudu born at another zoo and introduced to the affected herd (Kirkwood, Cunningham et al. 1994). Because most of the affected kudu did not consume feed containing ruminant-derived protein, it was postulated that the disease may have spread naturally in the herd, either by transmission between individuals or through contamination of the environment (Kirkwood, Cunningham et al. 1993).

The epidemiology of the TSE cases in kudu contrasts with BSE in cattle in several respects. The attack rate in the London Zoo kudu herd is notably higher than the attack rate seen in BSE affected cattle herds. The pattern of disease in antelope also differs from cattle affected with BSE, characterized by a younger average age of onset and a shortened clinical course (Kirkwood and Cunningham 1999). Additionally, infectivity in greater kudu with TSE is distributed in a wider range of tissues than in cattle with BSE (Cunningham, Kirkwood et al. 2004).

A wide range of species in zoological collections were probably exposed to BSE-contaminated feed; new cases in other captive zoological species may emerge, or it is possible that some species may carry and transmit the disease without showing clinical signs. The possibility of transmission of BSE-related encephalopathy between members, or from mother to offspring, within herds of zoological ruminants, as suspected with the London Zoo kudus, cannot be ruled out. Although there is currently no evidence that TSEs exist in free-living zoological ruminants (veterinary authorities in southern African countries conducting passive surveillance in wildlife have not encountered any clinical cases or histopathological lesions compatible with TSEs (Horn, Bobrow et al.), active surveillance has not been implemented in any region of the world for TSEs in antelope or free-living Caprinae.

Many of the non-domestic ruminants are endangered species. The scimitar-horned oryx, for example, is listed as ''Extinct in the Wild'' on the International Union for Conservation of Nature Red List (*https://www.iucnredlist.org/*), and 13 species of the Caprinae subfamily are listed as threatened on the Red List. In order to maintain genetic diversity in these very small populations, animals must be moved between zoological collections, both domestically and internationally (Shackleton 1997). Movement of animals may also be a goal of conservation programs seeking to reintroduce captive-bred endangered species into the wild. Both types of movement carry the risk of inadvertent introduction of infectious diseases that may have serious consequences for conservation efforts. The management of animal genetic resources must include a consideration of the potential risk of importing undetected prion diseases with rare breeding stock.

Although each of the cases to date of ruminant TSEs possibly connected to BSE in zoo animals was diagnosed in a region known to be affected with BSE, we believe that even zoological ruminants in regions not categorized as BSE-affected or as posing undue risk of BSE could be at risk for BSE-related TSEs, due to possible origin in a BSE-affected region or feeding with BSE-contaminated protein. Even in countries that have enforced a ban on the feeding of ruminant protein to domestic ruminants for an identifiable period of time, it can be difficult in some cases to determine when and if a country ceased feeding ruminant protein to zoo ruminants.

Because of the potential variety of practices in the feeding of zoo ruminants, as well as the potential that certain zoo ruminants may have originated in BSE-affected countries, we believe it is necessary to consider on a case-by-case basis the potential spongiform encephalopathy risk of zoological ruminants. As noted above, a ruminant may not be imported into the United States unless the importer has first applied for and obtained a permit from APHIS for such importation. In the case of zoological ruminants, the Administrator will consider the disease risk of each animal and the ability of the receiving zoo to manage the risks before deciding whether to issue an import permit.

Paragraph (a)(3) of § 93.404 currently provides that an application for a permit to import ruminants may be denied due to, among other reasons, the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry of the United States.

Even with zoological ruminants that would otherwise be denied importation into the United States, however, we believe that, in most cases, adequate mitigation measures with respect to potential TSE risks can be taken to allow the animal to be safely imported into the United States. The precise measures APHIS considers necessary could vary on a case-by-case basis.

As noted above, the current regulations contain broad prohibitions and restrictions regarding the importation of non-bovine ruminants other than sheep and goats from regions listed in § 94.24(a). The prohibitions apply to zoological ruminants as well as to domesticated ruminants. However, the regionally-based prohibitions do not address individual situations where a ruminant that would otherwise be denied entry from a region listed in § 94.24(a) could be safely entered into

the United States, provided certain risk mitigation measures are taken.

Therefore, we proposed to add a new paragraph (a)(5) to the import permit provisions in § 93.404 to address such situations. The new paragraph provides that, in specific cases, a permit may be issued for ruminants that would otherwise be prohibited importation due to TSEs pursuant to part 93, subpart D, if the Administrator determines that the disease risk posed by the animals can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures. Such measures would be specified in the permit. If it is determined prior to or after importation that any pre-entry or post-entry requirements were not met, or that the ruminants are affected with or have been exposed to TSEs, the ruminants, their progeny, and any other ruminants that have been housed with or exposed to the ruminants will be disposed of or otherwise handled as directed by the Administrator.

We also proposed to require that importers seeking a permit pursuant to the paragraph must send their request by postal mail to the Administrator, c/o Strategy and Policy, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, or make their request online via APHIS' electronic permitting system, by email or by fax. Information about using these methods to request a permit can be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits.*

Several commenters raised concerns about the conditions for importation of zoological ruminants.

Four commenters stated that for true (traditional) zoo animals, the originally imported animals should stay in zoo confinement—that is, essentially quarantined—for life and only their progeny could move, provided there was the observed and/or tested absence of TSEs in the imported animals and the progeny.

APHIS generally agrees with the commenters, and it is our intent that the animals would remain under quarantine within a zoo for life. If an animal had to be transferred between zoos, the receiving zoo would need APHIS approval as a quarantine facility and would need to operate under a compliance agreement with APHIS. As we explained in the proposed rule, importation of zoological ruminants will be considered on a case-by-case basis. This includes a compliance agreement between APHIS and the zoo regarding how the animal will be maintained, including with cohorts and offspring, APHIS approval of any post-importation movement of the animal, proper notification upon death of the animal, post-mortem examination, and proper carcass disposal.

The same commenters stated, with regard to importing any zoological or wild animals into the United States other than to traditional zoos, that APHIS should consider this only after a whole country or region risk assessment has been done with a finding of negligible risk for TSEs and a proposal for public notice and comment be published.

We do not consider that a TSE risk assessment of the country or region of origin is warranted. As we explained above, the pathology and spread of TSEs associated with zoological ruminants vary from the pathologies of BSE in cattle and scrapie in domesticated sheep and goats, and there is not yet any evidence for TSEs in free-living zoological ruminants. The evaluations will be case-specific, and will focus on the TSE risk associated with each specific importation. We will evaluate herd and individual health histories for the animals, necropsy records maintained by the zoos and in large databases maintained by zoo organizations (such as the International Species Information System) and the ability of the zoo to quarantine the animals. We would have to reach a determination that it is possible to mitigate any TSE risk through post-export quarantine and movement regulation.

We proposed to define *goat* as ''any animal of the genus *Capra*'' and *sheep* as ''any animal of the genus *Ovis*.'' One commenter stated that classifying all species in the genus *Ovis* as sheep and all species in the genus *Capra* as goats for the purposes of importation and with regards to TSE requirements is overly cautious and puts unwarranted restrictions on wild members of the genera. The commenter stated that bighorn sheep (*O. canadensis*) from wild populations present a limited risk for the introduction of TSEs. The mitigation measures provided as examples would be impossible to apply to a free-ranging population. The commenter recommended factors such as the history of exposure to domestic sheep as well as other criteria be considered in the evaluation of requests for importation of bighorn sheep by wildlife management agencies.

The rule provides the flexibility necessary to assess each importation in light of the science known at the time, the risk factors associated with the area from which the animals are to be imported, and the risk factors associated with the animals themselves, including for imports of wild and free-ranging species, such as bighorn sheep.

One commenter stated that non-bovine ruminants, other than domestic sheep and goats, should be subject to import restrictions and concurred with APHIS that at least some animals in this category present enough of a potential risk of spreading TSEs that their importation should be prohibited, unless certain risk mitigation measures are in place. The commenter stated it is inappropriate to propose regulatory changes for zoological and wild ruminants in this rulemaking and that APHIS should withdraw the sections dealing with these animals and propose them in a separate rulemaking, if warranted.

APHIS disagrees that making changes to the regulations governing the importation of zoological and wild ruminants is inappropriate in this rulemaking. As we explained in the proposed rule, APHIS will consider the potential TSE risk for each proposed importation on a case-by-case basis and may deny entry if the risk presented is too great.

Sheep and Goat Germplasm

One commenter stated that sheep with genotype AARR are considered genetically resistant and the EU accepts semen of such sheep. Under EU regulations, if the donor is not genetically resistant, then the donor must belong to a holding listed as presenting at least a controlled risk of classical scrapie. The commenter asked that APHIS take this into consideration when a permit is requested.

We agree that semen from genotype AARR rams is genetically resistant to scrapie and should be accepted with minimal additional requirements; we have amended § 98.35(e) accordingly.

Five commenters stated that the risk of scrapie transmission via semen or embryos is very low and the genetic profile of rams for scrapie resistance may be even more important than country status. The commenters therefore asked APHIS to grant permit exemptions for semen collected from rams testing AARR and AAQR. The commenters stated that this change would result in the sheep semen import requirements being generally equivalent to the embryo importation requirements.

APHIS agrees with the commenters concerning the low risk of scrapie transmission from AARR and AAQR semen donors and we have amended § 98.35(e) accordingly.

One commenter stated that there should be no restrictions pertaining to scrapie for ovine in vivo-derived

embryos to be consistent with Article 4.7.14 of the OIE Code.

APHIS disagrees. As we explained in the supporting scientific documentation accompanying the proposed rule, although the scientific literature has supported classifying embryos collected in accordance with International Embryo Transfer Society guidelines as low risk with respect to scrapie transmission, the limited number of animals studied, and the lack of diversity of scrapie strains evaluated, make it appropriate to apply additional mitigations in order to reduce the likelihood embryos selected for export will be infected. These concerns also extend to the use of in vivo-derived sheep embryos, which the OIE classifies as unrestricted. Therefore, APHIS will also apply the OIE criteria for in vivo-derived goat embryos to in vivo-derived sheep embryos unless the embryo is of genotype AA at codon 136 and either RR or QR at codon 171. APHIS may also require additional testing for sheep and goat-derived oocytes and embryos (and their donor animals) originating from countries or regions not considered scrapie-free by APHIS.

One commenter noted that the proposed rule mentioned possible additional certification or testing requirements as established by APHIS for semen and embryos. The commenter stated that if this is to allow for flexibility as science progresses, they supported the provisions, but they would also appreciate further details and clarification if APHIS intends to add further certification and testing requirements immediately.

The commenter's interpretation is correct. The provisions in § 98.10a(c) are intended to address any new developments in scrapie testing, our understanding of embryo risk, or unforeseen situations. We have no plans to implement additional certification or testing requirements for semen and embryos at this time.

One commenter stated that in the EU, ARR/ARR homozygote or ARR heterozygote embryos are considered genetically resistant and may be traded regardless of the scrapie status of the donor flock. The commenter noted that the provisions in § 98.10a(b)(1)(ii) appear to allow this possibility. The commenter asked for clarification about what would be required under § 98.10a(c), which provides that any additional certifications or testing requirements will be specified on the import permit.

The commenter's understanding of § 98.10a(b)(1)(ii) is correct. We note that the requirements for additional certification and testing in § 98.10a(c) are the same as those in § 98.35; that is, these requirements are the same for both semen and embryos. APHIS notes most conditions are waived for genetically resistant embryos, but the statement that the donors were not affected by, or exposed to, a TSE is required for all embryos, even those that are genetically resistant.

One commenter stated that if embryos are not genetically resistant, then the EU requires that the donors belong to a holding designated as at least ''controlled risk'' for classical scrapie. The commenter noted § 98.10a(a) requires that the holding has a certified status equating to 'negligible risk' under EU TSE legislation. However, § 98.10a(b)(1)(iii) provides another option provided the country requirements and donor requirements can be met. The commenter asked for clarification that this arrangement would be considered acceptable by APHIS.

The commenter is correct; the provisions in § 98.10a(b)(1)(iii) allow for the importation of genetically susceptible embryos with additional certifications.

Issues Outside the Scope of the Rule

Two commenters were opposed to the importation of live animals because of concerns about humane treatment of the animals.

The humane treatment of regulated animals is outside the scope of this rulemaking.

One commenter stated that APHIS should also harmonize its other import regulations, especially those for FMD, with OIE standards to remove impediments to trade.

Amending our other import regulations, including those governing imports from regions where FMD exists, is outside the scope of this rulemaking.

One commenter asked for requirements for importation of cervids in regard to the presence or absence of TSEs to be included in the rules. The commenter noted that chronic wasting disease has been detected in moose and reindeer in Norway, a country that has conducted a low level of surveillance for a number of years. The commenter further stated that it is clear that the full-range of susceptible species has not yet been identified for this disease, in spite of more than 20 years of research.

Amending our import regulations regarding cervids is outside the scope of this rulemaking. We removed BSE-related restrictions from cervids in a final rule published in the **Federal Register** on December 4, 2013 (78 FR 72980–73008, Docket No. APHIS–2008–0010).[10]

Five commenters noted that we did not propose to prohibit the feeding of sheep and goat milk or milk products to ruminants in the United States. The commenters stated that this is a mistake because of the risk of scrapie transmission through these products. The commenters also stated that the importation of sheep and goat milk or milk products into the United States from scrapie-infected countries for sheep and/or goat feeding should be prohibited as recommended by the OIE and supported by the scientific literature. The same five commenters stated that the importation and feeding of blood and blood products from sheep and goats to sheep and goats from countries not free of scrapie and not at least negligible risk for BSE is a risk and should not be allowed. This is because blood and blood products are not covered under the U.S. Food and Drug Administration's (FDA) ruminant feed rule and therefore not covered under the processed animal protein restrictions as discussed in the proposed rule.

Provisions governing the importation of most milk and milk products are contained in §§ 94.2 and 94.16 of the regulations. We note that animal feed is within the purview of the FDA and that prohibiting the use of any products in animal feed is outside the scope of APHIS' regulatory authority.

Miscellaneous

In part 92, we are revising the Office of Management and Budget statement at the end of § 92.2 to add reference to the paperwork burden requirements associated with this final rule, which were filed under 0579–0453.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a not a 'major rule', as defined by 5 U.S.C. 804(2).

We have prepared an economic analysis for this rule. The economic

[10] To view the rule, the supporting documents, and the comments we received, go to *https://www.regulations.gov* and enter APHIS–2008–0010 in the Search field.

analysis provides a cost-benefit analysis, as required by Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act.

This analysis examines impacts on U.S. entities of a rule that will remove BSE restrictions on the importation of live sheep and goats and most of their products. We are amending the import regulations for certain wild, zoological, or other non-bovine ruminant species by adding safeguards related to transmissible spongiform encephalopathies. The rule aligns our scrapie regulations in general with OIE guidelines and establish a notice-based approach for recognizing regions as free of scrapie. This action is part of a continuing program to allow the importation of agricultural products that APHIS has determined are without significant risk of introducing exotic animal diseases.

This rule's impact will stem from its effect on U.S. imports of the affected commodities. Consumer welfare gains from the increase in imports are expected to exceed producer welfare losses. While the rule will affect U.S. imports of a wide range of commodities, we focus our attention on the production and trade of live sheep and goats and their meat. This rule may affect imports of other ruminants such as non-bovine ruminant species received by zoos, but APHIS does not have information that would allow us to evaluate such impacts. Estimated net benefits of the rule are quantified in terms of increased imports of sheep meat and goat meat.

Over the past 5 years, 2016–2020, annual live sheep and goat imports averaged about 12,167 head, valued at a little over $800,000, and all of which came from Canada (see table 2). We do not anticipate a significant increase because of this rule in the number of sheep and goats imported.

U.S. imports of sheep and goat meat come almost entirely from Australia and New Zealand (see table 5), with chilled or frozen lamb the main product. To evaluate potential effects of the rule, we estimate impacts for U.S. production, consumption, and prices of sheep and goat meat imports using a net trade welfare model. The increase in import quantities attributable to this rule is expected to be small in comparison to existing imports. We model three levels of additional sheep and goat meat imports: 1,582 metric tons (MT), 3,165 MT, and 4,747 MT. These quantities are equal to approximately 5, 10, and 15 percent of the sum of (i) average EU–27 sheep and goat meat exports to non EU–27 markets, 2016–2019 (*i.e.,* 26,251 MT, see table 8), and (ii) average sheep and goat meat exports to EU–27 countries by other eligible countries, 2016–2019, excluding Australia and New Zealand (see table 9) of 5,396 MT. In sum, this is the EU–27's external volume of trade of the above-mentioned commodities. The largest assumed quantity (*i.e.,* 4,747 MT) is equivalent to less than 2 percent of average annual U.S. sheep and goat meat consumption (*i.e.,* 193,839 MT) during this same time period (see table 4).

The medium level of assumed additional imports, 3,165 MT, would cause a decrease in wholesale prices of less than 1.5 percent and a fall in domestic production of 878 MT, whereas U.S. consumption would increase by 2,287 MT. U.S. producer welfare would decline by about $8.7 million and U.S. consumer welfare would increase by about $23.7 million, yielding an annual net welfare benefit of about $15.1 million (see table 10). Similarly, the other two assumed import levels yield positive net benefits. To the extent that sheep and goat meat imported as a result of this rule may displace U.S. imports from existing sources, the price and welfare effects would be smaller than indicated; we note that over one-half of the U.S. market for sheep and goat meat is imported.[11]

The majority of establishments that may be affected by the rule are small entities, and economic impacts are likely to be small as well. If an additional 3,165 MT of sheep and goat meat were to be imported by the United States because of this rule, the annual decrease in producer welfare per small entity would be about $67, or the equivalent of about 1 percent of average annual sales by small entities.

Introduction

This economic analysis examines impacts on U.S. entities for a rule that will change BSE and scrapie import and transit restrictions for sheep, goats, and non-bovine wild ruminants, their embryos, semen, and products. The rule will amend most of the BSE restrictions on the importation of live sheep and goats and their products; align our scrapie regulations in general with OIE guidelines and establish a notice-based approach for recognizing regions as free of scrapie; and amend the BSE and scrapie regulations as they apply to other ruminant species that are not bovines, cervids, camelids, sheep or goats. The rule is part of a continuing program to allow the importation of agricultural products that APHIS has determined are without significant risk of introducing exotic animal diseases into the United States.

This document provides a benefit-cost analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize potential net economic benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This document also examines the potential economic effects of the rule on small entities, as required by the Regulatory Flexibility Act, and possible cost savings.

When the BSE regulations were codified in 1991, they applied to all ruminants. Over the past two decades, however, extensive research on BSE has been conducted. Based on the information now available, it is not warranted to continue to prohibit or restrict the importation of sheep and goats and their products with regard to BSE, other than processed animal protein.

The revisions for scrapie will set restrictions for live animal importation that are generally consistent with those recommended by the OIE. For embryos of sheep and goats, APHIS will require the donor to be eligible for importation, genetically resistant, or tested and found negative for scrapie, and the sire to not be a suspect, scrapie-positive, or high-risk animal. The revisions will also allow importation of most sheep- and goat-derived material in imported feed or feed ingredients from countries that are scrapie-free.

This rule's expected impact stems from its potential effect on U.S. imports of the affected commodities. We begin the analysis with an overview of production and trade in sheep and goats and their meat by the United States and other countries. While the rule will allow imports of sheep and goats and their products without regard to a country's BSE status, we restrict the analysis to countries of negligible or

[11] USDA, National Agricultural Statistics Service (NASS), Sheep and Goats; Commodity Trade, United Nations Trade Data Base (HTS–0104): *https://comtrade.un.org.*

controlled BSE risk. Regions of unknown risk for BSE are likely as well to be of unknown risk for scrapie. Scenarios are modeled to evaluate the significance of potential changes in sheep and goat meat imports.

This rule may affect imports of other ruminants such as animals received by zoos, but APHIS does not have information that would allow us to evaluate such impacts. Potential net benefits of the rule are quantified in terms of increased availability of sheep and goat meat to U.S. consumers at competitive prices.

Overview of the Action and Affected Entities

U.S. Production and Trade of Sheep, Goats, and Their Products

The United States is not a major producer of sheep, and the sector has been in long-term decline for decades. The Nation's sheep inventory fell by 7 percent between 2010 and 2019 (from 5.62 million to 5.23 million head).

Over half of the U.S. produced sheep are raised primarily in western, southwestern and midwestern States, such as: California, Idaho, Montana, Wyoming, Texas, and South Dakota; and in the east, mainly in Vermont.

The U.S. meat goat industry is small, with the national inventory averaging, between 2016 and 2020, at 2.1 million head. The number of goats raised for meat production increased between 2016 and 2020 on average by about 13 percent. On average between 2016 and 2020 the U.S. goat inventory was around 2.1 million animals.

Goats are raised in many States, with major holdings in 10 States: Alabama, California, Georgia, Kentucky, Missouri, North Carolina, Oklahoma, South Dakota, Tennessee, and Texas, which account for 70 percent of the total.

TABLE 1—U.S. INVENTORY (IN 1,000 HEAD) OF LIVE GOATS BY CLASS

U.S. goat inventory by class	January 1, 2017	January 1, 2018	January 1, 2019	January 1, 2020	January 1, 2021	5-yr average
All Goat and kids	1,706	1,675	1,646	2,655	2,582	2,053
Market	409	400	409	478	465	432
Breeding	1,305	1,275	1,270	2,177	2,117	1,629

Source: USDA, NASS, Sheep and Goats (February 2021).

Between 2016 and 2020, Canada was the only foreign supplier of sheep and goats into the United States. Over these 5 years, the annual average U.S. imports of sheep and goats was 12,167 animals, valued on average at $801,383 (tables 2 and 3). In 2016, there was a notable increase in the number of imported sheep and goats. However, after that year, their numbers decreased substantially.

TABLE 2—U.S. NUMBER (HEAD) OF IMPORTED LIVE SHEEP (HS 010410) AND GOATS (HS 010420) BY COUNTRY

Country	2016	2017	2018	2019	2020	5-yr average
Canada	21,223	8,829	7,338	13,341	10,102	12,167
World	21,223	8,829	7,338	13,341	10,102	12,167

Source: Commodity Trade, United Nations Trade Data Base (HTS–0104) (*https://comtrade.un.org*)/.

TABLE 3—U.S. VALUE (US $) OF IMPORTS OF LIVE SHEEP (HS 010410) AND GOATS (010420) BY COUNTRY

Country	2016	2017	2018	2019	2020	5-yr average
Canada	1,641,000	497,437	402,884	817,565	648,029	801,383

Source: Commodity Trade, United Nations Trade Data Base (HTS–0104) (*https://comtrade.un.org/*).

In order for sheep and goats to be eligible to be imported into the United States, they have to be from scrapie-free flocks. Under the rule, sheep and goats from flocks having certified status (meeting requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program) would be eligible for U.S. importation. Only two countries are recognized by the United States as being wholly free of scrapie: Australia and New Zealand.

With this rule, we do not anticipate a significant increase in the number of sheep and goats imported. The fact that Australia and New Zealand have ceased exporting sheep and goats to the United States in recent years supports this expectation. A major reason is the cost of transporting live animals.

Over the 5-year period, 2016–2020, the year average value of sheep and goats imported by the United States was around $801,000, as shown in table 3, was small in comparison to the value of $548 million per year in imported lamb, mutton, and goat meat. The quantity of U.S. imported lamb, mutton and goat meat supplies was over one-half of the U.S. consumption for these meats. Over the 2016–2020 period, lamb, mutton, and goat meat consumption grew from around 179,000 MT to over 195,000 MT, a 9 percent increase (table 4).

The amount of U.S. exports of lamb and mutton during this period when compared to U.S. imports of the same product accounts for only 5 percent. In terms of value, the difference is even greater since U.S. imports of lamb and goat meat consist of higher quality lamb cuts such as legs and loins, whereas it exports primarily lower quality cuts. Over one-half of U.S. lamb, mutton, and goat meat exports, 2016–2020, were to Mexico (40 percent), the Netherlands (10 percent), and Canada (7 percent).

TABLE 4—U.S. LAMB, MUTTON, AND GOAT PRODUCTION, IMPORTS, EXPORTS, AND CONSUMPTION

[2016–2020]

Year	U.S. production (MT)	U.S. imports (MT)	U.S. imports ($1,000)	U.S. exports (MT)	U.S. exports ($1,000)	U.S. consumption (MT)
2016	78,729	103,893	$785,801	3,381	$17,222	179,241
2017	74,491	122,078	978,335	3,849	20,377	192,720
2018	79,926	124,874	1,032,717	3,867	19,732	200,933
2019	77,316	127,150	1,149,380	4,104	19,448	200,362
2020	72,596	132,966	1,010,793	9,625	16,644	195,937
Average	76,595	122,192	991,405	4,965	19,448	193,839

Source: UN Commercial Trade Data (*https://comtrade.un.org*), USDA/ERS/Red Meat Production, and Consumption Statistics by meat categories, 2019; *https://www.ers.usda.gov/data-products/* Lamb, Mutton and Goat Meat Domestic Historical and Recent data, 2020.

Roughly 99 percent of U.S. imports of sheep and goat meat have been supplied by Australia (*i.e.,* 77 percent) and New Zealand (*i.e.,* 22 percent) during 2016 and 2020 (table 5).

TABLE 5—U.S. IMPORTS OF LAMB, MUTTON, AND GOAT MEAT BY COUNTRY OF ORIGIN IN MT

2014–2018

Country	2016	2017	2018	2019	2020	Average (2016–2020)
Australia	80,949	92,514	97,448	101,031	107,516	95,892
New Zealand	22,222	28,034	26,011	24,465	23,380	24,822
Rest of the World	723	1,530	1,415	1,654	2,070	1,478
TOTAL	103,894	122,078	124,874	127,150	132,966	122,192

Source: USDA/Foreign Agricultural Service (FAS), United Nations Commercial Trade Data (*https://comtrade.UN.ORG/*). *https://www.ers.usda.gov/data-products/* Lamb, Mutton, and Goat Meat Domestic Historical and Recent data, 2020.

The increasing U.S. demand for meats of goat as well as lamb is reflected in the increasing import levels. The volume of imported meats of goat, lamb, and mutton between 2016 and 2020 increased by 28 percent from 103,894 to 132,966 metric tons.

Production and Trade by Countries of Negligible-Risk or Controlled-Risk for BSE

This section presents information on sheep and goat inventories; lamb, mutton, and goat meat production; and trade of these animals and products by countries listed by OIE as having negligible- or controlled-risk for BSE. Tables 6 and 7 show the countries classified, as of September 2021, as having negligible BSE risk or controlled BSE risk. The lists include Australia, New Zealand, and Canada, the principal sources of U.S. imports of these commodities. Also included are EU–27 members and other countries that are potential sources of additional imports. (Source: *https://www.oie.int/en/disease/bovine-spongiform-encephalopathy/#uiid-2*).

TABLE 6—MEMBER COUNTRIES RECOGNIZED AS HAVING A NEGLIGIBLE BSE RISK *

Argentina	Hungary	Panama
Australia	Iceland	Paraguay
Austria	India	Peru
Belgium	Ireland	Poland
Bolivia	Israel	Portugal [7]
Brazil	Italy	Romania
Bulgaria	Japan	Serbia [8]
Canada	Korea (Rep. of)	Singapore
Chile	Latvia	Slovakia
Colombia	Liechtenstein	Slovenia
Costa Rica	Lithuania	Spain [9]
Croatia	Luxembourg	Sweden
Cyprus	Malta	Switzerland
Czech Republic	Mexico	The Netherlands
Denmark	Namibia	United States of America
Estonia	New Zealand	Uruguay
Finland [10]	Nicaragua	
Germany	Norway	

* In accordance with Chapter 11.4 of the *Terrestrial Code* OIE (September 2021) *https://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/.*

[7] Includes Azores and Madeira.

[8] Includes Excluding Kosovo administered under the United Nations.
[9] Includes Balearic Islands and Canary Islands.
[10] Includes Asland Island.

TABLE 7—OIE-MEMBER COUNTRIES RECOGNIZED AS HAVING A CONTROLLED BSE RISK**

Chinese Taipei. Ecuador.	France. Greece.	Ireland.

** In accordance with Chapter 11.4 of the Terrestrial Code of OIE (September 2021).

China (with the exclusion of Hong Kong and Macau) as of November 2013 is recognized as a country having one zone with negligible BSE risk. United Kingdom as of September 2016 is recognized as a country with two negligible BSE risk zones: England and Wales, and Scotland, according to Chapter 11.4 of the *Terrestrial Code*. For this analysis, we categorize potential sources into two groups: Countries that belong to the EU and all others. Trade information for the two groups of countries is presented in tables 8 and 9.

The EU–27 had on average between 2016 and 2020 annual inventories of 90 million sheep and 13 million goats.[12] Five countries (France, Greece, Italy, Romania, and Spain) accounted for 85 percent of the goat inventory and 80 percent of the sheep inventory.[13] Combined sheep and goat meat production in the EU–27 averaged about 926,000 MT during the same period.

As can be seen in table 8, between 2016 and 2019, live sheep and goats imported by EU–27 countries averaged around 716 animals. Almost all of these imports were sourced within the EU–27. Four countries (Italy, France, Greece, and Spain) accounted for over 70 percent of imports. Exports of live sheep and goats totaled over 2.67 million head. Three EU–27 countries (Romania, Spain, and France) accounted for 75 percent of the EU–27's sheep and goat exports.

TABLE 8—EXTERNAL TRADE FLOWS OF LIVE SHEEP AND GOATS (HS: 0104) AND THEIR MEAT (HS: 0204) BETWEEN THE EU–27 GROUP COUNTRIES WITH NEGLIGIBLE-BSE RISK OR CONTROLLED-BSE RISK AND THE NON EU–27 GROUP COUNTRIES

Year	Sheep and goats (numbers)		Meat of sheep and goat (metric tons)	
	Export	Import	Export	Import
2016	2,650,680	133	16,462	161,418
2017	2,496,323	714	29,873	140,283
2018	2,432,082	953	25,408	141,472
2019	3,117,174	1,065	33,261	112,070
Average	2,674,065	716	26,251	138,811

Data Source: *https://comtrade.un.org/*.

Table 8 shows that EU–27 countries as a group were net importers of sheep meat and goat meat with annual imports averaging between 2016 and 2020 around 139,000 MT, compared to their annual exports of 26.3 thousand metric tons. The yearly average number of EU–27 exports of live sheep and goats between 2016 and 2020 was approximately 2.7 million. EU–27 countries are net exporters of these animals, even though exporting live animals costs more than exporting their animal products (*i.e.,* due to higher transportation costs which include the cost of veterinarians accompanying animals in long distances to ensure their good health.)

New Zealand is the largest exporter of sheep and goats to the EU–27 countries followed by Australia and the South American countries of Chile and Argentina. Other non EU–27 countries that supply this group are Canada, Norway, Iceland, Switzerland, and Singapore (table 9).

New Zealand and Australia with about 90 percent of sheep and goat meat exports in their group are the dominant exporters. Excluding these two countries, because they are already the principal U.S. suppliers, the remaining countries in this group exported on average between 2016 and 2020 annually about 5,396 MT of goat and sheep meat and 58 live animals.

Excluding Australia and New Zealand (*i.e.,* 96 percent of this group's exports to EU–27), seven other countries (*i.e.,* Argentina, Canada, Chile, Iceland, Norway, Singapore, and Uruguay) supplied the EU–27 group with less than 4 percent (or 5,640 MT) of sheep and goat meat on average between 2014 and 2018.

Several of the non-EU group countries are not free of FMD. For live sheep and goats and their products to be eligible to be imported by the United States, they have to come from regions that are free of this disease. The rule would revise import restrictions related to BSE and scrapie only; other animal health restrictions would still apply, so imports from those non-EU group countries with FMD would still be prohibited and are not considered in this analysis.

Altogether, the North and South American countries of Canada, Argentina, Uruguay, Chile; the Asian country of Singapore; and the European countries of Norway, Switzerland, and Iceland exported to the EU–27 an annual average of 5,396 MT of sheep and goat meat between 2016 and 2020. We combine this quantity of sheep and goat meat with the average amount

[12] European Commission Agriculture and Rural Development, EU agriculture- statistical & economic information. Sheep meat & goat meat. *https://ec.europa.eu/agriculture/statistics/agricultural/20162011/pdf/d17-0-417_en.pdf*

[13] Although Romania is the fourth largest producer of sheep & goats in the EU & about 88 percent of its exports goes to EU countries, it is not classified as negligible- or controlled-risk for BSE by the OIE.

shipped by EU–27 countries to non EU–27 markets, 26,251 MT (table 8) and from table 9 the amount of sheep meat countries that are allowed to ship to EU–27 (*i.e.,* 5,396 MT), to arrive at a base value for examining possible impacts of the rule for U.S. entities (26,251 + 5,396 = 31,647 MT). Particularly in the case of Argentina, Canada, Chile, and Uruguay, lower transportation costs could provide an incentive for exporters to divert a share of their sheep and goat meat EU–27 shipments to the United States.

TABLE 9—EXPORTS OF LIVE SHEEP AND GOATS (NUMBER) AND THEIR MEAT (METRIC TONS) BY NON-EU COUNTRIES WITH NEGLIGIBLE- OR CONTROLLED-BSE RISK

[2016–2019 annual averages to EU–27 group]

Non-EU countries	Meat of goats and sheep (HS:0204) in metric tons	Number of live sheep and goats (HS: 0104)
Argentina	1,060	0
Australia	14,205	6
Brazil	0	0
Canada	4	0
Chile	1,834	0
Colombia	0	0
Costa Rica	0	0
Japan	0	0
Iceland	1,571	0
India	0	0
Israel	0	0
Mexico	0	0
Namibia	0	0
New Zealand	116,661	12
Nicaragua	0	0
Norway	222	3
Panama	0	0
Paraguay	0	0
Peru	0	0
Rep. of Korea	0	0
Singapore	6	0
Switzerland	3	40
Taiwan	0	0
Uruguay	702	0
USA	0	0
TOTAL	136,262	58
Australia & New Zealand	130,866	18
All (except Australia & New Zealand)	5,396	40

Source: United Nations (*https://www.trademap.org/*) Department of Economic and Social Affairs, Statistics Division, Trade Statistics (HS2007 commodity codes) October 2020. HS:0204 & HS:0104.

Expected Benefits and Costs of the Rule

To evaluate potential effects of the rule, we estimated impacts for U.S. production, consumption, and prices of sheep and goat meat imports from EU and non-EU sources, as described. We use a net trade [14] welfare model, and data from the USDA Foreign Agricultural Service's Global Agricultural Trade System (GATS), Food and Agriculture Organization of the United Nations' FAO Stat, and the United Nations Commercial Trade Statistics (*https://comtrade.un.org*). The demand and supply elasticities used are –0.77 (Sande and Houston 2007) and 0.80 respectively (Sullivan, Wainio, and Roningen 1989). These are still the most recent estimated elasticities for sheep and goat meat that are available in the literature.

We modeled three levels of additional sheep meat imports by the United States: 1,582 MT, 3,165 MT, and 4,747 MT. These quantities are equal to approximately 5, 10, and 15 percent of the sum of (i) average EU–27 sheep and goat meat exports to non EU–27 markets, 2016–2019 (*i.e.,* 26,251 MT, see table 8), and (ii) average sheep and goat meat exports to EU–27 countries by other eligible countries, 2016–2019, excluding Australia and New Zealand (see table 9) of 5,396 MT. In sum, this is the EU–27's external volume of trade of the above-mentioned commodities. The largest assumed quantity (*i.e.,* 4,747 MT) is equivalent to less than 2 percent of average annual U.S. sheep and goat meat consumption (*i.e.,* 193,839 MT) during this same time period (see table 4).

Table 10 presents the changes that would result from the assumed increased imports. For the medium-level increase, 3,939 MT, the wholesale price would decline by approximately 1.53 percent and domestic production would fall by 878 MT. U.S. consumption would increase by 2,287 MT. Producer welfare would decline by about $8.67 million and consumer welfare would increase by about $23.7 million, yielding an annual net welfare gain of about $15.1 million.

[14] In this case ''net trade'' welfare model refers to the way we model the importing country (*i.e.,* USA) as a net trader (*i.e.,* either a net exporter when exports are greater than imports or net importer)—whatever is the specific case of the commodity in question (*i.e.,* goats and sheep and their meat in this case).

TABLE 10—ESTIMATED IMPACTS OF SHEEP MEAT IMPORTS AS A RESULT OF THE FINAL RULE, FOR THREE ASSUMED LEVELS OF IMPORTATION

Assumed additional sheep and goat meat imports per year, metric tons	1,582	3,165	4,747
Change in U.S. consumption, metric tons	1,143	2,287	3,430
Change in U.S. production,* metric tons	−439	−878	−1,317
Percentage change in U.S. price	−0.77	−1.53	−2.30
Change in consumer welfare (U.S. dollars)	$11,824,458	$23,725,979	$35,689,520
Change in producer welfare (U.S. dollars)	($4,344,373)	($8,664,768)	($12,955,727)
Annual net welfare gain (U.S. dollars)	$7,480,086	$15,061,211	$22,733,799

Note: The baseline data used are 5-year annual averages for production, consumption, price, exports and imports, as reported in the last row of table 3. The demand and supply elasticities used are −0.70 and 0.80, respectively. * U.S. production data is for sheep meat only, goat meat data is unavailable.

For each of the three assumed levels of sheep and goat meat imports, consumer welfare gains would outweigh producer welfare losses. The majority of establishments that may be affected by the final rule are small entities, and economic impacts are likely to be small as well. If an additional 3,165 MT of sheep and goat meat were to be imported by the United States because of this rule, the annual decrease in producer welfare per small entity would be about $67.15, or the equivalent of about 1.3 percent of average annual sales by small entities (table 11).

As another aspect of the rule, U.S. sheep and goat producers may benefit from resulting genetic improvements through increased imports of sheep and goat germplasm (breeding animals, embryos, and semen). These imports may yield advantageous genetic characteristics such as heavier bone and greater muscle expression, higher productivity and product quality, disease resistance, reproductive efficiency and greater feed efficiency. However, additional germplasm imports also are not expected to be significant.

TABLE 11—ECONOMIC IMPACT FOR U.S. SMALL ENTITIES OF ADDITIONAL ANNUAL SHEEP AND GOAT MEAT IMPORTS OF 3,165 METRIC TONS

Total decline in producer welfare [1]	$8.66 million.
Decrease in welfare incurred by small entities [2]	$6.07 million.
Average decrease per animal, small entities [3]	$2.17.
Average decrease per small entity [4]	$67.15.
Average decrease as a percentage of average sales by small entities [5]	1.3%.

[1] From table 10.
[2] Change in producer welfare multiplied by 70 percent, the percentage of total sales by sheep and lamb producers with annual revenues of not more than $750,000, that is, small entities. We assume that the change in producer welfare would be proportional to sales share.
[3] Decrease in producer welfare for small entities divided by 2.8 million, the number of sheep and lamb sold by small entities.
[4] Average decrease per animal multiplied by 31, the average of the number of sheep and lambs and goats sold per small entity.
[5] Average decrease per small entity divided by $5,000, the average annual revenue per small entity.

Costs of Preventing Fence-Line Contact

There are currently no APHIS-approved feedlots in the United States for imported sheep and goats. This rule will require that the operator of an approved feedlot prevent fence-line contact between other sheep or goats being fed for purposes other than direct movement to slaughter or that are outside the feedlot and sheep and goats imported for restricted feeding and eventual slaughter from regions not free of classical scrapie by a method acceptable to the APHIS Administrator. The Agency will work with individual operators to determine the best means of preventing such contact in their feedlots. As a commenter on the proposed rule noted, one way of preventing fence-line contact would be to use double fencing to create a separation between paddocks.

One recommended type of fencing for sheep and goats is a perimeter of woven wire and high-tensile electrified fence. As shown in table 12, one estimate places the initial cost for this type of fencing at about $1.00 per foot, for a quarter-mile (1,320 feet) straight perimeter permanent fence (Iowa State University, 2012). Average annual maintenance costs would be about 5 percent of construction costs and the estimated useful life would be 25 years.

TABLE 12—CONSTRUCTION COSTS FOR HIGH-TENSILE ELECTRIFIED WIRE FENCE

[Based on a 1,320 ft. fence]

Item	Amount	Cost per unit (dollars)	Total cost (dollars, rounded)
Wood posts (8-inch diameter)	6	30.20	181
Wood posts (4-inch diameter	4	9.70	39
Steel posts (6.5 ft.)	52	5.40	281
Insulators	285	0.38	108
Springs	5	7.60	38
Strainers	5	3.80	19
High tensile wire	6,600 ft.	0.03	178
Energizer	25	1.19	30
Cut-out switch	1	8.10	8
Ground/lightening rods	4	17.30	69

TABLE 12—CONSTRUCTION COSTS FOR HIGH-TENSILE ELECTRIFIED WIRE FENCE—Continued

[Based on a 1,320 ft. fence]

Item	Amount	Cost per unit (dollars)	Total cost (dollars, rounded)
Labor and equipment	18 hours	17.50	315
Total			1,266
Cost per foot			0.96

Source: Iowa State University, 2012. Estimated Costs for Livestock Fencing. Extension and Outreach, Ag Decision Maker, File B1–75. Gates are not included in the estimate. Values converted from 2011 to 2016 dollars using gross domestic product (GDP) deflator.

Another estimate of fencing costs provided by a representative of the National Lamb Feeders Association (NLFA) is $4.00 per linear foot, with the size of an average square pen 150 feet on each side. The NLFA representative anticipates that there could be as many as 20 feedlots that will apply for import approval. He also noted that existing feedlots with multiple pens already have no need for double fencing on one side between them because of the ''bunk line'' feeding, where pens are separated by space to allow the bunk to be easily filled. Most feedlots have back-to-back pens in a row and would only need to double-fence a pen along sides not separated by a bunk line from another pen.

The cost of double fencing for a feedlot operator will depend on the number, size, and configuration of existing pens, and the distance between the existing pen and the added fencing. Industry sources suggest two likely courses of action by feedlots that decide to apply for import approval: Use an existing pen for which double fencing would need to be constructed on three side (the fourth side would have a bunk line with another pen); or construct a new pen near an existing pen, and add the double fencing on three sides. In the first instance, the length of additional fencing, assuming a pen with a side of 150 feet and a 20-foot distance between the two fences, would be 450 feet (the three sides), plus 120 feet (two lengths of 20 feet at each of the two rear corners and a 20-foot length at each corner on the bunk-line side), for a total of 570 feet. In the second instance, there would be the new pen, 600 feet, plus the 570 feet for the second fence, as described, for a total of 1,170 feet.

Based on unit costs of between $1.00 and $4.00 per linear foot, and assuming that the length of fencing that would be required ranges between 570 and 1,170 feet, averaging 870 feet, we estimate that the cost per feedlot may average between $870 and $3,480. Assuming that 20 feedlots apply for import approval, the total cost for the industry may range between $17,400 and $69,600.

Alternatives to the Rule

An alternative to this rule would be to remove BSE-related restrictions on the importation of small ruminants, but not establish a notice-based approach for recognizing regions as free of scrapie. Under this alternative, APHIS would evaluate regions in accordance with part 92 for scrapie and other TSE status, and then initiate rulemaking in order to authorize importation of This alternative was rejected because it would mean forgoing recognized trade advantages of timelier notice-based actions in comparison to rule promulgation. Based on APHIS experience in an analogous subject area, the authorization of fruit and vegetable imports, rulemaking takes, in general, 18 months to 2 years, whereas notice-based authorizations generally average 6–12 months. This longer time frame also delays the time it takes for consumers to experience the welfare benefits associated with increased imports.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations, and small governmental jurisdictions. This final regulatory flexibility analysis describes expected impacts of this rule on small entities, as required by section 604 of the Act.

Need for and Objectives of the Rule

The objective of the rule is to change BSE and scrapie import and transit restrictions for live sheep, goats, and wild ruminants, their embryos, semen, and products and byproducts, in recognition of actual risks posed by these diseases. The rule would remove BSE restrictions on the importation of live sheep and goats and most products of sheep and goats. It would amend the import regulations for certain wild, zoological, or other non-bovine ruminant species by adding restrictions related to transmissible spongiform encephalopathies. It would also establish a notice-based approach for recognizing regions as free of scrapie.

The legal basis for this rule is the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), by which the Secretary of Agriculture may restrict the importation of any animal or article if the Secretary determines that the prohibition is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

Significant Issues Raised by Public Comment in Response to the Initial Regulatory Flexibility Analysis

There were no significant issues raised by public comment in response to the initial regulatory flexibility analysis.

Comments Filed by the Office of Advocacy of the U.S. Small Business Administration in Response to the Proposed Rule

There were no comments filed by the Office of Advocacy of the U.S. Small Business Administration in response to the Initial Regulatory Flexibility Analysis.

Potentially Affected Small Entities

The Small Business Administration (SBA) has established guidelines for determining which firms are considered small under the Regulatory Flexibility Act. This rule could affect 88,338 establishments categorized within the following industries and corresponding North American Industry Classification System codes: Animal (except poultry) slaughtering (NAICS 311611), meat processing (NAICS 311612), meat and meat product merchant wholesalers (NAICS 424470), sheep farming (NAICS 112410), and goat farming (NAICS 112420).

Under SBA standards, animal slaughtering and meat processing establishments with no more than 1,000 employees and meat and meat product wholesalers with no more than 150 employees are considered small. According to the 2012 Economic Census, there were 1,603 animal slaughtering establishments, of which

95 percent were considered small. Establishments with fewer than 20 employees accounted for over 81 percent of establishments, but their share of total sales was only 2.8 percent. In 2012, of the 1,381 U.S. companies that processed and sold meat, about 97 percent were small entities. Of the 2,295 establishments that were wholesaling meat and meat products that year, 96 percent were small. Thus, animal slaughterers, meat processors, and wholesalers that could be affected by the rule are predominantly small by SBA standards.

Sheep farming (NAICS 112410) and goat farming (NAICS 112420) establishments are classified as small if their annual receipts are not more than $750,000. According to the 2012 Census of Agriculture (most recent data on farm sizes), there were 88,338 farms that sold about 3.8 million lamb and sheep in the United States. Of these, 88,206 farms (99.9 percent) had combined sales of about 2.8 million head (about 70 percent of all lamb and sheep sold) and are considered small, with average sales of about 31 head and average annual receipts of about $5,000 in 2012. The remaining 0.1 percent of the farms sold a total of about 1 million lamb and sheep, and the farms had an average annual income from the sale of sheep and lamb of about $1.48 million.

In 2012, there were 63,844 farms that sold about 1.3 million goats for meat. The number of goats sold per farm in 2012 was about 20 head, compared to average lamb and sheep sales (all farms) of 43 head. We use the per farm statistics for lamb and sheep production in the following estimation of impacts for small entities, since the 2012 Census of Agriculture does not provide detailed size standards for goat farming. As shown in table 11, we can expect the impact for U.S. small-entity producers to be small. When we assume that an additional 3,165 MT of sheep and goat meat would be imported by the United States because of this rule, the annual decrease in producer welfare per small entity is estimated to be about $67.15 or the equivalent of about 1.3 percent of average annual sales by small entities.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Reporting and recordkeeping requirements associated with the final rule are discussed in the rule under the heading ''Paperwork Reduction Act.'' Under that heading, APHIS estimates that it will take 0.531 hours per response to comply with the paperwork and recordkeeping requirements of this rule.

Steps Taken by APHIS To Minimize Significant Economic Impacts on Small Entities

We had no initial information that would suggest significant impacts on small entities, and did not receive additional information concerning affected entities during the public comment period on the proposed rule that would alter this assessment. In the absence of apparent significant economic impacts, we have not identified steps that would minimize such impacts.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

APHIS is aware of growing interest among Tribal nations in rules that could result in price fluctuations, particularly after recent supply chain disruptions. APHIS invited general Tribal consultation during the proposed rulemaking process with no Tribal response. Recent evaluation for Tribal implications, however, indicate the potential for increased market variations in sheep, goat, and other ruminants warranting Tribal engagement.

APHIS collaborated with the USDA Office of Tribal Relations (OTR) to provide for a meaningful government-to-government consultation on these implications. This opportunity for consultation occurred on November 1, 2021, with 13 Tribal nations in attendance. The Tribes present did not express questions or concerns about the rule or its supporting documents. APHIS is committed to full compliance with Executive Order 13175 throughout the implementation of this rule.

Paperwork Reduction Act

In accordance with Section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the reporting and recordkeeping requirements included in the proposed rule and this final rule were previously approved under Office of Management and Budget (OMB) control numbers 0579–0040 and 0579–0101. The remaining reporting and recordkeeping requirements that were solely associated with the proposed rule to this final rule were submitted to OMB as a new information collection assigned OMB comment-filed number 0579–0453. The proposed rule allowed for public comment on the reporting and recordkeeping requirements. However, APHIS did not receive comments concerning the calculations for the information collection activities, their instruments (such as the import permits or health certificates), or reported burden.

Since publication of the proposed rule, the information collection procedures and forms are unchanged, except for the removal of one activity and adjustments in the estimates for seven activities. Information collected in accordance with the regulations of this final rule includes, but is not limited to, the names of the exporter and importer of the animal commodities; the origins of the animals or animal products to be imported; the health status of the animals or the processing methods used to produce animal products to be imported; the destination of delivery in the United States; and whether the animals or animal products were temporarily offloaded in another country during transit to the United States. APHIS removed the activity related to reporting of animals, poultry, or eggs offered for importation (VS Form 17–30) because this information is reported in another information collection. APHIS reduced the burden estimates for three activities because the number of respondents was overestimated and increased the burden estimates for four activities to account for rounding errors. Lastly, APHIS decreased the estimated number of respondents by 67 which in turn resulted in 906 fewer responses and 439 fewer burden hours. However, the public reporting burden estimated hours per response remains at 0.531 hours with 9 responses per respondent.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to

compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. However, less than 1 percent of the information required to be collected under this final rule can be processed electronically, either by downloading a fillable PDF file, emailing a document, or for respondents with accounts, using APHIS' electronic information systems such as ePermits, Veterinary Services Process Streamlining, or Automated Commercial Environment to process and submit information. The remainder of the collection activities cannot be processed electronically because there are instruments (such as permanent country marks, seals, or the VS 1–27, Permit for Movement of Restricted Animals) that must typically accompany the animals during transit. For assistance with E-Government Act compliance related to this final rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483, or the Veterinary Services contact listed above under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

9 CFR Part 92

Animal diseases, Imports, Livestock, Quarantine.

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

9 CFR Part 98

Animal diseases, Imports.

Accordingly, we are amending 9 CFR parts 92, 93, 94, 95, 96, and 98 as follows:

PART 92—IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS AND COMPARTMENTS

■ 1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 92.2 is amended by revising the OMB statement at the end of the section to read as follows:

§ 92.2 Application for recognition of the animal health status of a region or a compartment.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 3. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 93.400 is amended as follows:

■ a. By adding, in alphabetical order, definitions for *Certified status, Classical scrapie,* and *Country mark*;

■ b. By revising the definitions for *Designated feedlot* and *Flock*;

■ c. By adding, in alphabetical order, definitions for *Flock of birth, Flock of residence, Goat, Killed and completely destroyed, Non-classical scrapie,* and *Sheep*;

■ d. By removing the definition of *Suspect for a transmissible spongiform encephalopathy*; and

■ e. By adding, in alphabetical order, definitions for *Transmissible spongiform encephalopathies (TSEs)* and *TSE-affected sheep or goat.*

The additions and revisions read as follows:

§ 93.400 Definitions.

* * * * *

Certified status. A flock that has met requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program while participating in a program under the supervision of the national veterinary authority of the region of origin, as determined by an evaluation conducted by APHIS of the program.

* * * * *

Classical scrapie. Any form of scrapie that the Administrator has determined poses a significant risk of natural transmission.

* * * * *

Country mark. A permanent mark approved by the Administrator for identifying a sheep or goat to its country of origin.

* * * * *

Designated feedlot. A feedlot designated by the Administrator as one eligible to receive sheep and goats from regions not free of classical scrapie, and whose owner or legally responsible representative has signed an agreement as specified in § 93.435(c)(11) and is in full compliance with all the provisions of the agreement.

* * * * *

Flock. Any group of one or more sheep or goats maintained on a single premise, or on more than one premises under the same ownership and between which unrestricted movement is allowed; or two or more groups of sheep or goats under common ownership or supervision on two or more premises that are geographically separated, but among which there is an interchange or movement of animals.

Flock of birth. The flock into which a sheep or goat is born.

Flock of residence. The flock:

(1) Within which an individual sheep or goat was born, raised, and resided until exported to the United States; or

(2) In which the sheep or goat resided for breeding purposes for 60 days or more until exported to the United States; or

(3) In which sheep and goats for export were assembled for export to the United States and maintained for at least 60 days immediately prior to export, without any addition of animals or contact with animals other than through birth, on a single premises, or on more than one premises under the same ownership and between which unrestricted movement occurred.

Goat. Any animal of the genus *Capra.*

* * * * *

Killed and completely destroyed. Killed, or maintained under quarantine in a manner preventing disease spread until the animal is no longer living; and the remains have been disposed of in a manner preventing disease spread.

* * * * *

Non-classical scrapie. Any form of scrapie the Administrator has determined poses a low risk of natural transmission.

* * * * *

Sheep. Any animal of the genus *Ovis*.

* * * * *

Transmissible spongiform encephalopathies (TSEs). A family of progressive and generally fatal neurodegenerative disorders thought to be caused by abnormal proteins, called prions, typically producing characteristic microscopic changes, including, but not limited to, non-inflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and central nervous systems of affected animals.

TSE-affected sheep or goat. A sheep or goat suspected or known by the national veterinary authority of the region of origin to be infected with a transmissible spongiform encephalopathy prior to the disposal of the animal.

* * * * *

■ 5. Section 93.401 is amended by revising paragraph (a) and adding a heading for paragraph (b) to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) *General provisions.* No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter; [3] nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that is not a bovine, camelid, cervid, sheep, or goat is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products of such to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock of the United States.

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

(b) *Ruminants in transit.* * * *

* * * * *

■ 6. Section 93.404 is amended as follows:

■ a. Paragraphs (a)(2), (3), and (4) are redesignated as paragraphs (a)(3), (4), and (7), respectively;

■ b. By adding new paragraph (a)(2) and paragraphs (a)(5) and (6);

■ c. In newly redesignated paragraph (a)(7)(v), by removing ''paragraph (a)(4)(iv)'' and adding ''paragraph (a)(7)(iv)'' in its place;

■ d. In newly redesignated paragraph (a)(7)(vi), by removing ''paragraph (a)(4)(iv)(A)'' and ''paragraph (a)(4)(iv)(B)'' and adding ''paragraph (a)(7)(iv)(A)'' and ''paragraph (a)(7)(iv)(B)'', respectively, in their place; and

■ e. By revising the OMB statement at the end of the section.

The additions and revision read as follows:

§ 93.404 Import permits for ruminants and for ruminant test specimens for diagnostic purposes; and reservation fees for space at quarantine facilities maintained by APHIS.

(a) * * *

(2) In addition to the requirements in paragraph (a)(1) of this section, the importer must submit the following information along with the application for an import permit:

(i) For sheep or goats imported for immediate slaughter, or for restricted feeding for slaughter:

(A) The slaughter establishment to which the animals will be imported; or

(B) The designated feedlot in which sheep and goats imported for restricted feeding for slaughter will be maintained until moved to slaughter.

(ii) For sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter:

(A) The flock identification number, if imported to a flock, and the premises or location identification number, of the flock or other premises to which the animals are imported as listed in the Scrapie National Database.

(B) For sheep and goats from regions not free from classical scrapie, the importer must provide documentation that the animal has reached and maintained certified status in a scrapie flock certification program determined by the Administrator to provide equivalent risk reduction as the Export Category of the U.S. Scrapie Flock Certification Program. The documentation must specify the address, or other means of identification, of the premises and flock of birth, and any other flock(s) in which the animals have resided.

* * * * *

(5) In specific cases, a permit may be issued for ruminants that would otherwise be prohibited importation due to TSEs pursuant to this subpart, if the Administrator determines the disease risk posed by the animals can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures. These measures will be specified in the permit. If it is determined prior to or after importation that any pre-entry or post-entry requirements were not met, or the ruminants are affected with or have been exposed to TSEs, the ruminants, their progeny, and any other ruminants that have been housed with or exposed to the ruminants will be disposed of or otherwise handled as directed by the Administrator. Importers seeking a permit pursuant to this paragraph (a)(5) must send their request to the Administrator, c/o Strategy and Policy, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, or via the APHIS website at *https://www.aphis.usda.gov/import_export/animals/live_animals.shtml*.

(6) The Administrator may issue permits under paragraph (a)(5) of this section for male sheep determined to be AA at codon 136 and either RR, HR, KR, or QR at codon 171 and for female sheep determined to be AA at codon 136 and RR at codon 171 by the National Veterinary Services Laboratories or another laboratory approved by the Administrator. Such sheep must meet all requirements in this part for import other than the requirement that they originate in a flock or region free of classical scrapie. The permit will provide for post entry confirmation of the animal's scrapie susceptibility genotype and/or genetic testing for identity.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0224, and 0579–0453)

■ 7. Section 93.405 is amended as follows:

■ a. By adding a heading for paragraph (a) and removing paragraph (a)(4);

■ b. By revising paragraph (b);

■ c. By removing paragraph (c);

■ d. By redesignating paragraph (d) as paragraph (c);

■ e. By revising newly redesignated paragraph (c); and

■ f. By revising the OMB statement at the end of the section.

The addition and revisions read as follows:

§ 93.405 Health certificate for ruminants.

(a) *Issuance and required information.*

* * *

* * * * *

(b) *Sheep and goats*—(1) *Information required.* In addition to the statements required by paragraph (a) of this section, the certificate accompanying sheep or goats from any part of the world must also include the name and address of the importer; the number or quantity of sheep or goats to be imported; the purpose of the importation; the official

individual sheep or goat identification applied to the animals; and, when required by § 93.435, the permanent country mark and other identification present on the animal, including registration number, if any; a description of each sheep or goat linked to the official identification number, including age, sex, breed, color, and markings, if any; the flock of residence; the address (including street, city, State, and ZIP Code) of the destination where the sheep or goats are to be physically located after importation, including the premises or location identification number assigned in the APHIS National Scrapie Database and when applicable the flock identification number; the name and address of the exporter; the port of embarkation in the region of export; the mode of transportation, route of travel and port of entry in the United States; and, for sheep or goats imported for purposes other than immediate slaughter or restricted feeding for slaughter, the certificate must specify the region of origin and, for regions not free of scrapie, the address or other identification of the premises and flock of birth, and any other flock in which the animals have resided.

(2) *Additional statements.* The certificate accompanying sheep or goats from any part of the world, except as provided in paragraph (b)(4) of this section for sheep or goats imported for immediate slaughter, and in paragraph (b)(5) of this section for sheep or goats for restricted feeding for slaughter, must also state that:

(i) The sheep or goats originated from a region recognized as free of classical scrapie by APHIS; or the animals have reached and maintained certified status or equivalent status in a scrapie flock certification program or equivalent program approved by APHIS;

(ii) The sheep or goats have not commingled with sheep or goats of a lower health status, or resided on the premises of a flock or herd of lower health status, after leaving the flock of residence and prior to arrival in the United States;

(iii) Any enclosure, container or conveyance in which the sheep or goats had been placed during the export process, and which had previously held sheep or goats, was cleaned and disinfected in accordance with § 54.7(e)(2) of this chapter prior to being used for the sheep or goats;

(iv) None of the female sheep or goats is carrying an implanted embryo from a lower health status flock; or that any implanted embryo meets the requirements for import into the United States when implanted, and documentation as required in part 98 of this subchapter is attached;

(v) The veterinarian issuing the certificate has inspected the sheep or goats, and their flock(s) of residence, within 30 days of consignment for import to the United States, and found the animals and the flock(s) of residence to be free of any evidence of infectious or contagious disease;

(vi) As far as it is possible for the veterinarian who inspects the animals to determine, none of the sheep or goats in the flock(s) of residence has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States; and

(vii) The animals' movement is not restricted within the country of origin due to animal health reasons.

(3) *Test results.* The certificate accompanying sheep or goats from any part of the world, except as provided in paragraph (b)(4) of this section for sheep or goats imported for immediate slaughter, or in paragraph (b)(5) of this section for sheep or goats for restricted feeding for slaughter, must also include:

(i) The results of any testing required in the import permit; and

(ii) Any other information required in the import permit.

(4) *Sheep or goats imported for immediate slaughter.* For sheep or goats imported for immediate slaughter, in addition to the statements required under paragraph (a) of this section, the certificate must include statements that:

(i) The region where the sheep or goats originated is recognized as free of classical scrapie by APHIS; or

(ii) The region where the sheep or goats originated has not been recognized as free of classical scrapie by APHIS but the following criteria have been met:

(A) TSEs in sheep and goats are compulsorily notifiable to the national veterinary authority of the region;

(B) An effective classical scrapie awareness, surveillance, monitoring, and control system is in place;

(C) TSE-affected sheep and goats are killed and completely destroyed;

(D) The sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment and are fit for travel;

(E) The sheep and goats have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy; and

(F) The animals' movement is not restricted within the country of origin due to animal health reasons.

(5) *Sheep or goats for restricted feeding for slaughter.* For sheep or goats imported for restricted feeding for slaughter, in addition to the statements required under paragraph (a) of this section, the certificate must include statements that:

(i) The region where the sheep or goats originated is recognized as free of classical scrapie by APHIS; or

(ii) The region where the sheep or goats originated has not been recognized as free of classical scrapie by APHIS but the following criteria have been met:

(A) TSEs in sheep and goats are compulsorily notifiable to the national veterinary authority of the region;

(B) An effective classical scrapie awareness, surveillance, monitoring and control system is in place;

(C) TSE-affected sheep and goats are killed and completely destroyed;

(D) The sheep or goats showed no clinical sign of scrapie or any other infectious disease on the day of shipment and are fit for travel;

(E) The sheep or goats have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy;

(F) The animals' movement is not restricted within the country of origin due to animal health concerns;

(G) Female sheep and goats are not known to be pregnant, are not visibly pregnant, and female animals have not been exposed:

(*1*) To a sexually intact male at over 5 months of age; or

(*2*) To a sexually intact male within 5 months of shipment;

(H) The veterinarian issuing the certificate has inspected the sheep or goats for export, and their flock(s) of residence, within 30 days of consignment for shipment to the United States, and found the animals and the flock(s) of residence to be free of any evidence of infectious or contagious disease; and

(I) As far as it is possible for the veterinarian who inspects the animals to determine, none of the sheep or goats has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States.

(c) *Refusal of entry.* If ruminants are unaccompanied by the certificate as required by paragraphs (a) and (b) of this section, or if such ruminants are found upon inspection at the port of entry to be affected with a communicable disease or to have been exposed thereto, they shall be refused entry and shall be handled or quarantined, or otherwise disposed of as the Administrator may direct.

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0165, 0579–0234, 0579–0393, and 0579–0453)

§ 93.406 [Amended]

■ 8. Section 93.406(b) is amended by removing the references ''§§ 93.419 and 93.428(b)'' and adding ''§§ 93.428(b) and 93.435'' in their place.

§ 93.419 [Removed and Reserved]

■ 9. Section 93.419 is removed and reserved.

■ 10. Section 93.420 is amended in paragraph (a) introductory text by adding a sentence after the paragraph heading to read as follows:

§ 93.420 Ruminants from Canada for immediate slaughter other than sheep and goats.

(a) * * * The requirements for the importation of sheep and goats from Canada for immediate slaughter are contained in § 93.435. * * *

* * * * *

■ 11. Section 93.424 is amended by revising paragraph (a) to read as follows:

§ 93.424 Import permits and applications for inspection of ruminants.

(a) For ruminants intended for importation from Mexico, the importer shall first apply for and obtain from APHIS an import permit as provided in § 93.404: *Provided, that:* An import permit is not required for sheep or goats imported for immediate slaughter if the animal is offered for entry at a land border port designated in § 93.403(c).

* * * * *

■ 12. Section 93.428 is amended by revising paragraph (a) and the OMB statement at the end of the section to read as follows:

§ 93.428 Sheep and goats and native wild ruminants from Mexico.

(a) Sheep, goats, and native wild ruminants intended for import from Mexico must be imported in accordance with § 93.435, and shall be accompanied by a certificate issued in accordance with § 93.405 and stating, if such sheep and goats are shipped by rail or truck, that such animals were loaded into cleaned and disinfected cars or trucks for transportation direct to the port of entry. Notwithstanding such certificate, such sheep and goats shall be detained as provided in § 93.427(a) and shall be dipped at least once in a permitted scabies dip under supervision of an inspector.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

■ 13. Section 93.435 is revised to read as follows:

§ 93.435 Sheep and goats.

(a) *General provisions.* (1) Sheep and goats imported from anywhere in the world shall be accompanied by a certificate issued in accordance with § 93.405. If the sheep or goats are not accompanied by the certificate, or if they are found upon inspection at the port of entry to be affected with or exposed to a communicable disease, they shall be refused entry and shall be handled or quarantined, or otherwise disposed of, as the Administrator may direct.

(2) All imported sheep and goats must be officially identified at the time of presentation for entry into the United States with official identification devices or methods and which will allow the animals not imported for immediate slaughter or for feeding for slaughter to be traced at any time to the farm or premises of birth, and for animals imported for immediate slaughter or for feeding for slaughter to the flock of residence. Official identification devices may not be removed or altered at any time after entry into the United States, except by an authorized USDA representative at the time of slaughter. A list of the acceptable types of official identification devices or methods may be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/imports/live-animal-imports.*

(3) All imported sheep and goats other than for immediate slaughter or as provided in paragraph (c) of this section for restricted feeding for slaughter must be identified at the time of presentation for entry into the United States with a country mark using a means and in a location on the animal approved by the Administrator for this use. A list of the acceptable country marks may be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/imports/live-animal-imports.*

(4) Except as provided in paragraph (b) of this section for sheep or goats imported for immediate slaughter, and in paragraph (c) of this section for sheep or goats for restricted feeding for slaughter, the importer shall maintain records of the sale, death or other disposition of all imported animals including the official identification number(s) and country marks on the animals at the time of import; a record of the replacement of any lost identification devices linking the new official identification number to the lost device number; the date and manner of disposition; and the name and address of the new owner. Such records must be maintained for a period of 5 years after the sale or death of the animal. The records must be available for APHIS to view and copy during normal business hours.

(b) *Sheep and goats imported for immediate slaughter from anywhere in the world.* (1) Sheep and goats for immediate slaughter may only be imported into the United States from countries or regions determined to be free of classical scrapie by APHIS, or that have scrapie awareness, surveillance, and control programs evaluated and determined by APHIS to be effective.

(2) Sheep and goats imported for immediate slaughter must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(3) The ruminants must be moved directly from the port of entry to a recognized slaughtering establishment in conveyances that are sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by an authorized USDA representative.

(4) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33.

(c) *Sheep and goats imported for restricted feeding for slaughter.* (1) Sheep and goats for restricted feeding for slaughter purposes may only be imported into the United States from countries or regions determined to be free of classical scrapie by APHIS, or that have scrapie awareness, surveillance, and control programs evaluated and determined by APHIS to be effective.

(2) The sheep and goats must be imported only through a port of entry allowed in § 93.403 in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin. The seals may be broken either by an APHIS representative at the port of entry, or at the designated feedlot by an authorized APHIS representative. If the seals are broken by an APHIS representative, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the designated feedlot; and

(3) The sheep and goats shall be inspected by the port veterinarian or other designated representative at the port of entry to determine that the animals are free from evidence of

communicable disease and are considered fit for further travel; and

(4) The sheep and goats must be moved directly as a group from the port of entry to a designated feedlot; and

(5) The sheep and goats may not be commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot; and

(6) The sheep and goats may be moved from the port of entry only to a feedlot designated in accordance with paragraph (c)(11) of this section and must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 17–130 or other movement documentation stipulated in the import permit; and

(7) Upon arrival at the designated feedlot, the official identification for each animal must be reconciled by an APHIS veterinarian, or other official designated by APHIS, with the accompanying documentation; and

(8) The sheep and goats must remain at the designated feedlot until transported to a recognized slaughtering establishment. The sheep and goats must be moved directly to the recognized slaughtering establishment in a means of conveyance sealed by an accredited veterinarian, a State representative, or an APHIS representative with seals of the U.S. Government. The seals must be broken at the recognized slaughtering establishment only by an authorized USDA representative; and

(9) The sheep and goats must be accompanied to the recognized slaughtering establishments by APHIS Form VS 1–27 or other documentation stipulated in the import permits; and

(10) The sheep and goats must be slaughtered within 12 months of importation.

(11) To be eligible as a designated feedlot to receive sheep and goats imported for feeding, a feedlot must be approved by APHIS. To be approved by APHIS, the feedlot operator or his or her agent must enter into a compliance agreement with the Administrator. The compliance agreement must provide that the operator:

(i) Will monitor all imported feeder animals to ensure that they have the required official identification at the time of arrival to the feedlot; and will not remove official identification from animals unless medically necessary, in which case new official identification will be applied and cross referenced in the records. Any lost official identification will be replaced with eartags provided by APHIS for purposes of this paragraph (c)(11)(i) and will be linked as the new official identification with the lost identification. If more than one animal loses their official identification at the same time, the new official identification will be linked with all possible original identification numbers;

(ii) Will monitor all incoming imported feeder animals to ensure they have the required country mark, or will maintain all imported animals in separate pens from U.S. origin animals, and all sheep and goats that enter the feedlot are moved only for slaughter;

(iii) Will maintain records of the acquisition and disposition of all imported sheep and goats entering the feedlot, including the official identification number and all other identifying information, the age of each animal, the date each animal was acquired and the date each animal was shipped to slaughter, and the name and location of the plant where each animal was slaughtered. For imported animals that die in the feedlot, the feedlot will remove the official identification device if affixed to the animal, or will record any other official identification on the animal and place the official identification device or record of official identification in a file with a record of the disposition of the carcass;

(iv) Will maintain copies of the APHIS Forms VS 17–130 and VS 1–27 or other movement documentation deemed acceptable by the Administrator that have been issued for incoming animals and for animals moved to slaughter and that list the official identification of each animal;

(v) Will allow State and Federal animal health officials access to inspect its premises and animals and to review inventory records and other required files upon request;

(vi) Will keep required records for at least 5 years;

(vii) Will designate either the entire feedlot or pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter;

(viii) Will prevent fence-line contact with sheep or goats outside the designated feedlot;

(ix) Agrees that if inventory cannot be reconciled or if animals are not moved to slaughter as required, the approval of the feedlot to receive additional animals will be immediately withdrawn and any imported animals remaining in the feedlot will be disposed of as directed by the Administrator;

(x) Agrees that if an imported animal gives birth in the feedlot, the offspring will be humanely euthanized and the birth tissues and soiled bedding disposed of in a sanitary landfill or by another means approved by the Administrator; and

(xi) Agrees to maintain sexually intact animals of different genders over 5 months of age in separate enclosures.

(xii) For a feedlot to be approved to receive sheep or goats imported for feeding under this section, but which do not have a country mark, the compliance agreement must also provide that the feedlot will maintain all imported animals in separate pens from U.S. origin animals and that all sheep and goats that enter the feedlot are moved only for slaughter.

(d) *Other importations.* Sheep or goats imported other than as provided in paragraph (b) of this section for immediate slaughter or as provided in paragraph (c) of this section for sheep and goats imported for restricted feeding for slaughter must originate from a region recognized as free of classical scrapie by APHIS or from a flock that has certified status or equivalent status in a scrapie flock certification program or equivalent program approved by APHIS, or as provided in § 93.404(a)(5) or (6).

(e) *Sheep and goats transiting the United States.* Sheep or goats that meet the entry requirements for immediate slaughter in § 93.405 may transit the United States in accordance with § 93.401 regardless of their intended use in the receiving country.

(f) *Classical scrapie status of foreign regions.* APHIS considers classical scrapie to exist in all regions of the world except those declared free of this disease by APHIS.

(1) A list of regions that APHIS has declared free of classical scrapie is maintained on the APHIS website at *https://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.* Copies of the list are also available via postal mail, fax, or email upon request to Regionalization Evaluation Services, Strategy and Policy, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

(2) APHIS will add a region to the list in paragraph (f)(1) only after conducting an evaluation of the region in accordance with § 92.2 of this subchapter and finding classical scrapie is not likely to be present in its sheep or goat populations. In the case of a formerly listed region removed due to an outbreak, the region may be returned to the list in accordance with the procedures for reestablishment of a region's disease-free status in § 92.4 of this subchapter. APHIS will remove a region from the list of those it has declared free of classical scrapie upon determining classical scrapie exists there based on reports APHIS receives

of outbreaks of the disease in sheep or goats from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), from other sources the Administrator determines to be reliable, or upon determining that the region's animal health infrastructure, regulations, or policy no longer qualifies the region for such status.

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0101, and 0579–0453)

§ 93.505 [Amended]

■ 14. Section 93.505(a) is amended by removing the citation ''§ 94.24(b)(6)'' and adding the citation ''§ 94.31(b)(6)'' in its place.

PART 94—FOOT–AND–MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 15. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 16. Section 94.15 is revised to read as follows:

§ 94.15 Transit shipment of articles.

(a) Any meat or other animal product or material (excluding materials that are required to be consigned to USDA-approved establishments for further processing) eligible for entry into the United States, as provided in this part or in part 95 of this subchapter, may transit the United States by air and ocean ports and overland transportation if the articles are accompanied by the required documentation specified in this part and in part 95.

(b) Any meat or other animal product or material not eligible for entry into the United States, as provided in this part or in part 95 of this subchapter, may transit air and ocean ports only, with no overland movement outside the airport terminal area or dock area of the maritime port, in the United States for immediate export if the conditions of paragraphs (b)(1) through (4) of this section are met.

(1) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain under either Customs seal or foreign government seal during the entire time that it is in the United States.

(2) Before transit, the person moving the articles must notify, in writing, the authorized Customs inspector at both the place in the United States where the articles will arrive and the port of export. The notification must include the:

(i) Times and dates of arrival in the United States;

(ii) Times and dates of exportation from the United States;

(iii) Mode of transportation; and

(iv) Serial numbers of the sealed containers.

(3) The articles must transit the United States under Customs bond.

(4) The shipment is exported from the United States within 7 days of its entry.

(c) Pork and pork products from Baja California, Baja California Sur, Campeche, Chihuahua, Coahuila, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, and Yucatan, Mexico, that are not eligible for entry into the United States in accordance with this part may transit the United States via land border ports for immediate export if the following conditions of paragraphs (c)(1) through (4) of this section are met:

(1) The person moving the pork and pork products must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, Strategy and Policy, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *https://www.aphis.usda.gov/animal_health/permits/*).

(2) The pork or pork products are packaged at a Tipo Inspección Federal plant in Baja California, Baja California Sur, Campeche, Chihuahua, Coahuila, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, or Yucatan, Mexico, in leakproof containers and sealed with serially numbered seals of the Government of Mexico, and the containers remain sealed during the entire time they are in transit across Mexico and the United States.

(3) The person moving the pork and pork products through the United States notifies, in writing, the authorized Customs inspector at the United States port of arrival prior to such transiting. The notification must include the following information regarding the pork and pork products:

(i) Permit number;

(ii) Times and dates of arrival in the United States;

(iii) Time schedule and route to be followed through the United States; and

(iv) Serial numbers of the seals on the containers.

(4) The pork and pork products must transit the United States under Customs bond and must be exported from the United States within the time limit specified on the permit. Any pork or pork products that have not been exported within the time limit specified on the permit or that have not been transited in accordance with the permit or applicable requirements of this part will be destroyed or otherwise disposed of as the Administrator may direct pursuant to the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*).

(d) Poultry carcasses, parts, or products (except eggs and egg products) from Baja California, Baja California Sur, Campeche, Chihuahua, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, Tamaulipas, or Yucatan, Mexico, that are not eligible for entry into the United States in accordance with the regulations in this part may transit the United States via land ports for immediate export if the following conditions of paragraphs (d)(1) through (4) of this section are met:

(1) The person moving the poultry carcasses, parts, or products through the United States must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, Strategy and Policy, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *https://www.aphis.usda.gov/animal_health/permits/*).

(2) The poultry carcasses, parts, or products are packaged at a Tipo Inspección Federal plant in Baja California, Baja California Sur, Campeche, Chihuahua, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, Tamaulipas, or Yucatan, Mexico, in leakproof containers with serially numbered seals of the Government of Mexico, and the containers remain sealed during the entire time they are in transit through Mexico and the United States.

(3) The person moving the poultry carcasses, parts, or products through the United States must notify, in writing, the authorized U.S. Customs and Border Protection (CBP) inspector at the United States port of arrival prior to such transiting. The notification must include the following information regarding the poultry to transit the United States:

(i) Permit number;

(ii) Times and dates of arrival in the United States;

(iii) Time schedule and route to be followed through the United States; and

(iv) Serial numbers of the seals on the containers.

(4) The poultry carcasses, parts, or products must transit the United States under U.S. Customs bond and must be exported from the United States within the time limit specified on the permit. Any poultry carcasses, parts, or products that have not been exported within the time limit specified on the permit or that have not transited in accordance with the permit or applicable requirements of this part will be destroyed or otherwise disposed of as the Administrator may direct pursuant to the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*).

(e) Meat and other products of ruminants or swine from regions listed in § 94.11(a) and pork and pork products from regions listed in § 94.13 that do not meet the requirements of § 94.11(b) or § 94.13(a) may transit through the United States for immediate export, provided the provisions of paragraph (b) of this section are met, and provided all other applicable provisions of this part are met.

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0145, and 0579–0453)

§ 94.18 [Amended]

■ 17. Section 94.18 is amended in paragraph (a) by adding the word ''and'' before the citation ''94.23'' and removing '', and 94.27''.

§ 94.24 [Removed and Reserved]

■ 18. Section 94.24 is removed and reserved.

§ 94.25 [Removed and Reserved]

■ 19. Section 94.25 is removed and reserved.

■ 20. Section 94.26 is revised to read as follows:

§ 94.26 Gelatin derived from horses, swine, or non-bovine ruminants.

Gelatin derived from horses, swine, or non-bovine ruminants must be accompanied at the time of importation into the United States by an official certificate issued by a veterinarian employed by the national government of the region of origin. The official certificate must state the species of animal from which the gelatin is derived.

(Approved by the Office of Management and Budget under control number 0579–0453)

§ 94.27 [Removed and Reserved]

■ 21. Section 94.27 is removed and reserved.

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 22. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 95.1 [Amended]

■ 23. Section 95.1 is amended by removing the definitions of Positive for a transmissible spongiform encephalopathy and Suspect for a transmissible spongiform encephalopathy.

■ 24. Section 95.4 is amended as follows:

■ a. By revising the section heading and paragraphs (a), (b) introductory text, (b)(1), and (c)(1)(ii) and (iv);

■ b. By removing paragraphs (c)(2) and (3) and redesignating paragraphs (c)(4) through (8) as (c)(2) through (6), respectively;

■ c. In newly redesignated paragraph (c)(3), by revising the first sentence;

■ d. In newly redesignated paragraph (c)(5), by removing the reference ''(c)(5)'' and adding the reference ''(3)'' in its place;

■ e. By removing paragraphs (d) and (e);

■ f. By redesignating paragraph (f) and the Note to paragraph (f) as paragraph (d) and Note 1 to paragraph (d), respectively; and

■ g. By removing paragraph (g).

The revisions read as follows:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, tallow, tallow derivatives, and serum due to bovine spongiform encephalopathy.

(a) Except as provided in this section, or in § 94.15, any of the materials listed in paragraph (b) in this section derived from animals, or products containing such materials, are prohibited importation into the United States.

(b) The restricted materials are as follows:

(1) Processed animal protein, tankage, offal, tallow, and tallow derivatives, unless in the opinion of the Administrator, the tallow cannot be used in feed;

* * * * *

(c) * * *

(1) * * *

(ii) Cervids or camelids, and the material is not ineligible for importation under the conditions of § 95.5;

* * * * *

(iv) Ovines or caprines, and the material is not ineligible for importation under the conditions of § 95.5.

* * * * *

(3) If the facility processes or handles any processed animal protein, inspection of the facility for compliance with the provisions of this section is conducted at least annually by a representative of the government agency responsible for animal health in the region, unless the region chooses to have such inspection conducted by APHIS. * * *

* * * * *

§ 95.15 [Removed and Reserved]

■ 25. Section 95.15 is removed and reserved.

§ 95.40 [Removed and Reserved]

■ 26. Section 95.40 is removed and reserved.

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

■ 27. The authority citation for part 96 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.4.

§ 96.2 [Amended]

■ 28. Section 96.2 is amended as follows:

■ a. By removing paragraph (b)(1) and redesignating paragraph (b)(2) as paragraph (b)(1);

■ b. By adding a new reserved paragraph (b)(2); and

■ c. In paragraph (c)(3), by removing the words ''paragraphs (b)(2)(i) through (b)(3)(iv)'' and adding the words ''paragraph (b)(1)'' in their place.

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

■ 29. The authority citation for part 98 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 30. Section 98.2 is amended by adding, in alphabetical order, definitions for *Oocyte* and *Transmissible spongiform encephalopathies (TSEs)* to read as follows:

§ 98.2 Definitions.

* * * * *

Oocyte. The first and second maturation stages of a female reproductive cell prior to fertilization.

* * * * *

Transmissible spongiform encephalopathies (TSEs). A family of progressive and generally fatal neurodegenerative disorders thought to be caused by abnormal proteins, called prions, typically producing characteristic microscopic changes, including, but not limited to, noninflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and nervous systems of affected animals.

* * * * *

§ 98.3 [Amended]

■ 31. Section 98.3 is amended as follows:

■ a. In paragraph (d), by adding the words ''*except that,* for sheep and goats only, the donor sire must meet the scrapie requirements in § 98.35 instead of the requirements in § 93.435 of this chapter;'' after the words ''United States;'';

■ b. In paragraph (e), by:

■ i. Removing the ''part 92'' and adding the citation ''part 93'' in its place; and

■ ii. Adding the words ''*except that,* for sheep and goats only, the donor dam must meet the requirements for embryo donors in § 98.10(a) instead of the requirements in § 93.435 of this chapter;'' after the words ''United States;''; and

■ c. In paragraph (f), by removing ''§ 93.404(a)(2) or (3)'' and adding ''§ 93.404(a)(3) or (4)'' in its place.

■ 32. Section 98.4 is amended by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 98.4 Import permit.

* * * * *

(d) Applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included.

* * * * *

§ 98.5 [Amended]

■ 33. Section 98.5 is amended as follows:

■ a. By removing and reserving paragraph (b); and

■ b. In the OMB statement at the end of the section, by removing ''number 0579–0040'' and adding ''numbers 0579–0040 and 0579–0453'' in its place.

■ 34. Section 98.10a is revised to read as follows:

§ 98.10a Sheep and goat embryos and oocytes.

(a) Sheep and goat embryos or oocytes collected from donors located in, or originating from, regions recognized by APHIS as free of classical scrapie, or from a flock or herd having certified status in a scrapie flock certification program recognized by APHIS as acceptable, may be imported in accordance with §§ 98.3 through 98.8. In addition to the requirements of § 98.5, the health certificate must indicate that the embryos or oocytes were collected, processed, and stored in conformity with the requirements in § 98.3(g).

(b) In vivo-derived sheep and goat embryos or oocytes collected from donors located in, or originating from, regions or flocks not recognized by APHIS as free of classical scrapie, may be imported in accordance with §§ 98.3 through 98.8 and the following conditions:

(1) The embryos or oocytes must be accompanied by a health certificate meeting the requirements listed in § 98.5, and with the following additional certifications:

(i) The embryos or oocytes were collected, processed and stored in conformity with the requirements in § 98.3(g).

(ii) For in vivo-derived sheep embryos only: The embryo is of the genotype AAQR or AARR based on official testing of the parents or the embryo.

(iii) Certificates for sheep embryos not of the genotype AAQR or AARR, and for all goat embryos, must contain the following additional certifications:

(A) In the country or zone:

(*1*) TSEs of sheep and goats are compulsorily notifiable to the national veterinary authority of the region;

(*2*) A scrapie awareness, surveillance, monitoring, and control system is in place;

(*3*) TSE-affected sheep and goats are killed and completely destroyed; and

(*4*) The feeding to sheep and goats of meat-and-bone meal of ruminant origin has been banned and the ban is effectively enforced in the whole country.

(B) The donor animals:

(*1*) Have been kept since birth in flocks or herds where no case of scrapie had been confirmed during their residency; and

(*2*) Are permanently identified to enable a traceback to their flock or herd of origin, and this identification is recorded on the certificate accompanying the embryo(s) and linked to the embryo container identification; and

(*3*) Showed no clinical sign of scrapie at the time of embryo/oocyte collection; and

(*4*) Have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy; and

(*5*) Are not under movement restrictions within the country or region of origin as a result of exposure to a transmissible spongiform encephalopathy.

(2) [Reserved]

(c) Any additional certifications or testing requirements established by APHIS, based on genetic susceptibility of the embryo or embryo parents, and/or on scrapie testing of the embryo donor, will be listed in the APHIS import permit. Such certifications or required test results must also be recorded on the health certificate accompanying the embryo(s).

(d) Sheep and goat embryos or oocytes may only be imported for transfer to recipient females in the United States if the flock or herd where the recipients reside is listed in the National Scrapie Database; except APHIS may permit importation of sheep and goat embryos or oocytes to an APHIS-approved storage facility where they may be kept until later transferred to recipient females in a flock or herd in the United States listed in the APHIS National Scrapie Database, and under such conditions as the Administrator deems necessary to trace the movement of the imported embryos or oocytes. Imported sheep or goat embryos or oocytes not otherwise restricted by the conditions of an import permit may be transferred from a listed flock or herd to any other listed flock or herd, or from an embryo storage facility to a listed flock or herd, with written notification to the responsible APHIS Veterinary Services Service Center.

(e) The importer, the owner of a recipient flock or herd where delivery of the embryos or oocytes is made, or the owner of an APHIS-approved embryo or oocyte storage facility must maintain records of the disposition (including destruction) of imported or stored embryos or oocytes for 5 years after the embryo or oocyte is transferred or destroyed. These records must be made available during normal business hours to APHIS representatives on request for review and copying.

(f) For in vitro-derived and manipulated sheep or goat embryos and oocytes, APHIS will make a case-by-case determination or establish conditions in an import permit that includes any additional mitigations deemed necessary to prevent the introduction of disease as provided in § 98.10.

(g) The owner of all sheep or goats resulting from embryos or oocytes imported under this section shall:

(1) Identify them at birth with a permanent official identification number consistent with the provisions of § 79.2 of this chapter; such identification may not be removed except at slaughter and must be replaced if lost;

(2) Maintain a record linking the official identification number to the imported embryo or oocyte including a record of the replacement of lost tags;

(3) Maintain records of any sale or disposition of such animals, including the date of sale or disposition, the name and address of the buyer, and the animal's official identification number; and

(4) Keep the required records for a period of 5 years after the sale or death of the animal. APHIS may view and copy these records during normal business hours.

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0101, and 0579–0453).

■ 35. Section 98.13 is amended by adding paragraph (c) to read as follows:

§ 98.13 Import permit.

* * * * *

(c) Applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included.

* * * * *

§ 98.15 [Amended]

■ 36. Section 98.15 is amended as follows:

■ a. In paragraph (a) introductory text, by removing the words ''follows, except that, with regard to bovine spongiform encephalopathy, the following does not apply to bovines, cervids, or camelids.'' and adding the word ''follows:'' in their place;

■ b. In paragraph (a)(1)(i), by removing the words ''Bovine spongiform encephalopathy, contagious'' and adding the word ''Contagious'' in their place;

■ c. In paragraph (a)(2)(i), by removing the words ''Bovine spongiform encephalopathy, contagious'' and adding the word ''Contagious'' in their place;

■ d. In paragraph (a)(7)(i)(A), by removing the words ''Bovine spongiform encephalopathy, brucellosis'' and adding the word ''Brucellosis'' in their place; and

■ e. In paragraph (a)(8)(i)(A), by removing the words ''Bovine spongiform encephalopathy, brucellosis'' and adding the word ''Brucellosis'' in their place.

■ 37. Section 98.30 is amended by adding, in alphabetical order, a definition for *Establishment* to read as follows:

§ 98.30 Definitions.

* * * * *

Establishment. The premises in which animals are kept.

* * * * *

■ 38. Section 98.35 is amended as follows:

■ a. By revising paragraph (e) introductory text;

■ b. By removing paragraph (e)(1)(ii) and redesignating paragraphs (e)(1)(iii) and (iv) as paragraphs (e)(1)(ii) and (iii), respectively;

■ c. By revising newly redesignated (e)(1)(iii);

■ d. By adding new paragraph (e)(1)(iv);

■ e. By removing ''; and'' at the end of paragraph (e)(2)(iv) and adding a period in its place;

■ f. By revising paragraph (e)(3);

■ g. By adding paragraphs (e)(4) and (5); and

■ h. By revising the OMB statement at the end of the section.

The revisions and additions read as follows:

§ 98.35 Declaration, health certificate, and other documents for animal semen.

* * * * *

(e) The certificates accompanying sheep semen collected from rams that are not of the genotypes AARR or AAQR, and for all goat semen shall, in addition to the statements required by paragraph (d) of this section, state that:

(1) * * *

(iii) The donor animal is not, nor was not, restricted in the country of origin, or destroyed, due to exposure to a TSE.

(iv) Any additional certifications or testing requirements established by APHIS, based on genetic susceptibility of the semen donor, and/or on scrapie testing of the donor or semen, will be listed in the APHIS import permit. Such certifications or required test results must also be recorded on the health certificate accompanying the semen.

* * * * *

(3) Sheep and goat semen may only be imported for transfer to recipient females in the United States if the flock or herd in which recipients reside is listed in the National Scrapie Database; except that APHIS may permit importation of sheep and goat semen to an APHIS-approved storage facility where they may be kept until later transferred to recipient females in a flock or herd in the United States listed in the APHIS National Scrapie Database, and under such conditions as the Administrator deems necessary to trace the movement of the imported semen. Imported sheep or goat semen not otherwise restricted by the conditions of an import permit may be transferred from a listed flock or herd to any other listed flock or herd or from an approved semen storage facility to a listed flock or herd or another approved semen storage facility with written notification to the responsible APHIS Veterinary Services Service Center.

(4) The importer, the owner of a recipient flock or herd to which delivery of the semen is made, or the owner of an APHIS-approved semen storage facility must maintain records of the disposition (including destruction) of imported or stored semen for 5 years after the semen is transferred or destroyed. These records must be made available during normal business hours to APHIS representatives on request for review and copying.

(5) The owner of all sheep or goats resulting from semen imported under this section shall:

(i) Identify them at birth with a permanent official identification number consistent with the provisions of § 79.2 of this chapter; such identification may not be removed except at slaughter and must be replaced if lost;

(ii) Maintain a record linking the official identification number to the imported semen, including a record of the replacement of lost tags;

(iii) Maintain records of any sale or disposition of such animals, including the date of sale or disposition, the name and address of the buyer, and the animal's official identification number; and

(iv) Keep the required records for a period of 5 years after the sale or death of the animal. APHIS may view and copy these records during normal business hours.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

Done in Washington, DC, this 30th day of November 2021.

Jennifer Moffitt,

Undersecretary, Marketing and Regulatory Programs.

[FR Doc. 2021–26302 Filed 12–2–21; 8:45 am]

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FEDERAL REGISTER

Vol. 86 Friday,
No. 230 December 3, 2021

Part IV

The President

Federal Register
Vol. 86, No. 230
Friday, December 3, 2021

Presidential Documents

Title 3—

The President

Proclamation 10316 of November 30, 2021

National Impaired Driving Prevention Month, 2021

By the President of the United States of America

A Proclamation

Every year, thousands of lives are needlessly lost on our Nation's roadways because of alcohol—and drug-impaired driving. These are avoidable tragedies that leave deep holes in our Nation's families and communities. During National Impaired Driving Prevention Month, we reaffirm our commitment to preventing impaired driving. We remember the victims and honor their memory by making the responsible decision to drive sober and ensure that others do the same.

Driving while impaired by any substance—legal or illegal—is dangerous. Alcohol, illicit drugs, and even over-the-counter and prescription medications can impair a driver's judgment, decrease motor coordination, and slow the reaction time necessary to safely operate a motor vehicle. Alcohol-impaired driving has led to over 10,000 deaths each year.

My Administration is committed to reducing the number of impaired drivers and raising awareness about the dangers of driving impaired. The new Infrastructure Investment and Jobs Act calls for the National Highway Traffic Safety Administration to issue a new standard for ''advanced drunk and impaired driving prevention technology'' for new vehicles, which would help prevent impaired drivers from taking the wheel.

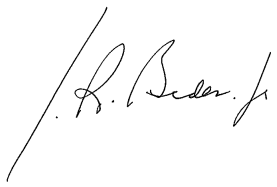
My Administration is building our capacity to end impaired driving by supporting innovative strategies that reduce impaired driving-related crashes, injuries, and fatalities while safeguarding against bias and ensuring racial equity. To identify and support people with substance use disorders, we are increasing impaired driving risk screening, supporting evidence-based prevention programs, and providing access to evidence-based treatment and recovery support services. My Administration is also raising awareness about the effects of impairment on driving ability through the *Drive Sober or Get Pulled Over* and *If You Feel Different, You Drive Different* national media campaigns.

While our technology continues to advance and may one day help solve the problem of impaired driving, everyone must take individual responsibility and pledge to never drive while impaired and to deter others from making that fateful decision.

During National Impaired Driving Prevention Month, we recommit ourselves to doing all we can to stop these preventable crashes and remember those who lost their lives as a result of impaired driving. We must also share our appreciation for the law enforcement officers who risk their lives each day to keep our communities safe while keeping impaired drivers off of our roadways.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim December 2021 as National Impaired Driving Prevention Month. I urge all Americans to make responsible decisions and take appropriate measures to prevent impaired driving.

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



[FR Doc. 2021–26456
Filed 12–2–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10317 of November 30, 2021

World AIDS Day, 2021

By the President of the United States of America

A Proclamation

For decades, World AIDS Day has been recognized as an opportunity for people around the world to stand together in the fight against HIV. This year on World AIDS Day, we are focused on addressing health inequities and inequalities and ensuring that the voices of people with HIV are at the center of our work to end the HIV epidemic globally.

While we have made remarkable progress in the 40 years since the first-known reported case of AIDS, this disease remains a serious public health challenge—and we join the international community to honor and remember the more than 36 million people, including 700,000 Americans, who have tragically died from AIDS-related illness since the start of the epidemic. We also renew our commitment to stand with the nearly 38 million people living with HIV around the world as we pursue our shared goal of ending the HIV epidemic.

The COVID–19 pandemic has added to the challenges our heroic health care and frontline workers face, yet they continue to deliver essential HIV prevention services and provide vital care and treatment to people living with HIV. The pandemic has also interrupted HIV research and highlighted the work that still remains to achieve equitable access to HIV prevention, care, and treatment in every community—particularly for communities of color, adolescent girls and young women, and the LGBTQI+ community.

My Administration remains steadfast in our efforts to end the HIV epidemic, confront systems and policies that perpetuate entrenched health inequities, and build a healthier world for all people. Earlier this year, I reinstated the White House Office of National AIDS Policy to coordinate our efforts to reduce the number of HIV infections across our Nation. This week, my Administration is releasing an updated National HIV/AIDS Strategy to decrease health inequities in new diagnoses and improve access to comprehensive, evidence-based HIV-prevention tools. This updated strategy will make equity a cornerstone of our response and bring a whole-of-government approach to fighting HIV.

My budget request includes $670 million to support the Department of Health and Human Services' Ending the HIV Epidemic in the U.S. Initiative—to reduce HIV diagnoses and AIDS-related deaths. My Administration has also strengthened the Presidential Advisory Council on HIV/AIDS by adding members from diverse backgrounds who bring the knowledge and expertise needed to further our Nation's HIV response.

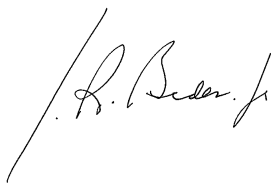
My Administration is committed to helping the world end the AIDS epidemic as a public health threat by 2030. Through the United States President's Emergency Plan for AIDS Relief (PEPFAR), we have saved more than 21 million lives, prevented millions of HIV infections, and supported at least 20 countries around the world to reach epidemic control of HIV or achieve their ambitious HIV treatment targets. This remarkable progress over the past 18 years has been made possible through strong, bipartisan United States leadership and American generosity. Now, together with partner governments and communities, my Administration is setting a bold vision for achieving sustained epidemic control of HIV by supporting equitable health

services and solutions, contributing to improved health for all in PEPFAR-supported countries, and working with the Global Fund to Fight AIDS, Tuberculosis and Malaria; UNAIDS; and other regional and local partners toward the goal of ending the HIV epidemic everywhere.

Ending the HIV epidemic is within our reach, and we are committed to finishing this work. On World AIDS Day, we rededicate ourselves to building on the progress of the last 4 decades; upholding and advancing human rights; supporting research, science, and data-driven solutions; expanding access to housing, education, and economic empowerment; and fighting stigma and discrimination. No one living with HIV should suffer the undeserved guilt and prejudice that too many continue to experience. We must innovate and explore new ways to help address HIV/AIDS in communities here at home and around the world.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim December 1, 2021, as World AIDS Day. I urge the Governors of the United States and its Territories, and the American people to join the HIV community in activities to remember those who have lost their lives to AIDS and to provide support, dignity, and compassion to those living with HIV.

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



[FR Doc. 2021–26458
Filed 12–2–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Executive Order 14056 of December 1, 2021

The National Space Council

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* The National Space Council (Council), as authorized under Title V of Public Law 100–685, advises and assists the President regarding national space policy and strategy. This order sets forth the Council's membership, duties, and responsibilities.

Sec. 2. *Membership of the National Space Council.* The Council shall be composed of:

(a) the Vice President, who shall be Chair of the Council;

(b) the Secretary of State;

(c) the Secretary of Defense;

(d) the Secretary of the Interior;

(e) the Secretary of Agriculture;

(f) the Secretary of Commerce;

(g) the Secretary of Labor;

(h) the Secretary of Transportation;

(i) the Secretary of Energy;

(j) the Secretary of Education;

(k) the Secretary of Homeland Security;

(l) the Director of the Office of Management and Budget;

(m) the Director of National Intelligence;

(n) the Director of the Office of Science and Technology Policy;

(o) the Assistant to the President for National Security Affairs;

(p) the Assistant to the President for Economic Policy;

(q) the Assistant to the President for Domestic Policy;

(r) the Assistant to the President and National Climate Advisor;

(s) the Chairman of the Joint Chiefs of Staff;

(t) the Administrator of the National Aeronautics and Space Administration; and

(u) the heads of other executive departments and agencies (agencies) and other senior officials within the Executive Office of the President, as determined by the Chair.

Sec. 3. *Functions and Operations of the Council.* (a) The Council shall advise and assist the President on space policy and strategy. In particular, it shall:

(i) review, develop, and provide recommendations to the President on space policy and strategy;

(ii) coordinate implementation of space policy and strategy;

(iii) synchronize the Nation's civil, commercial, and national security space activities in furtherance of the objectives of the President's national space policy and strategy;

(iv) facilitate resolution of differences among agencies on space-related policy and strategy matters;

(v) enable interagency cooperation, coordination, and information exchange on space activities; and

(vi) perform such other duties as the President may, from time to time, prescribe.

(b) The operation of the Council shall not interfere with the existing lines of authority in or responsibilities of any agency.

(c) The Council shall have a staff, headed by a civilian Executive Secretary appointed by the President.

(d) The Council shall meet at least annually.

(e) The Council shall consider and provide recommendations to the President on any space-related issue as determined by the Chair.

Sec. 4. *Responsibilities of the Chair.* (a) The Chair shall serve as the President's principal advisor on national space policy and strategy.

(b) The Chair shall establish procedures and set the agenda for Council sessions to address Presidential priorities.

(c) The Chair may recommend to the President candidates for the position of Executive Secretary.

(d) The Chair may invite the heads of other agencies, other senior officials in the Executive Office of the President, and other Federal employees to participate in Council meetings.

(e) The Chair or, upon the Chair's direction, the Executive Secretary, may develop budget recommendations for submission to the Director of the Office of Management and Budget that reflect the President's space policy and strategy, as well as provide advice concerning budget submissions by agencies related to the President's space policies and strategies.

Sec. 5. *National Space Policy Planning Process.* (a) The Council shall establish a process for developing and coordinating the implementation of national space policy and strategy.

(b) The head of each agency that conducts space-related activities shall, to the extent permitted by law, conform such activities to the President's national space policy and strategy.

(c) On space matters relating primarily to national security, the Council shall coordinate with the National Security Council (NSC) to develop space policy and strategy consistent with NSC priorities and practices.

Sec. 6. *Users' Advisory Group.* (a) The Council shall convene a Users' Advisory Group (Group) pursuant to section 121 of Public Law 101–611, composed of non-Federal representatives of industries and other persons involved in aeronautical and space activities.

(b) Members of the Group shall serve without compensation for their work for the Group. Members of the Group, while engaged in the work of the Group, may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in Government service (5 U.S.C. 5701–5707), consistent with the availability of funds.

(c) The Group shall report directly to the Council and shall provide advice or work product solely to the Council.

(d) The Group shall provide advice and recommendations to the Council on matters related to space policy and strategy, including Government policies, laws, regulations, treaties, international instruments, programs, and practices across the civil, commercial, and national security space sectors.

Sec. 7. *Administrative Provisions.* (a) To aid in the performance of the functions of the Council:

(i) the Office of Administration in the Executive Office of the President shall provide administrative support to the Council, to the extent permitted by law and within existing appropriations; and

(ii) legal advice to the Council with respect to its work and functions shall be provided exclusively by the Office of the Counsel to the President and the Counsel to the Vice President.

(b) To the extent practicable and permitted by law, including the Economy Act (31 U.S.C. 1535), and within existing appropriations, agencies serving on the Council, components of the Executive Office of the President, and interagency councils and committees that affect space policy or strategy shall make resources, including personnel, office support, and printing, available to the Council as reasonably requested by the Chair or, upon the Chair's direction, the Executive Secretary.

(c) Agencies shall cooperate with the Council through the Chair, or upon the Chair's request, the Executive Secretary, and provide such information and advice to the Council as it may reasonably request, to the extent permitted by law, including information regarding agencies' current and planned space activities.

(d) This order supersedes Executive Order 13803 of June 30, 2017 (Reviving the National Space Council), and Executive Order 13906 of February 13, 2020 (Amending Executive Order 13803—Reviving the National Space Council), and those orders are revoked. To the extent this order is inconsistent with any provision of any previous Executive Order or Presidential Memorandum, this order shall control.

(e) If any provision of this order or the application of such provision is held to be invalid, the remainder of this order and other dissimilar applications of such provision shall not be affected.

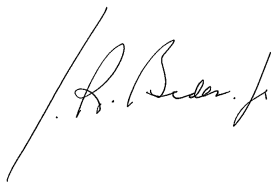
Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
December 1, 2021.

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