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:

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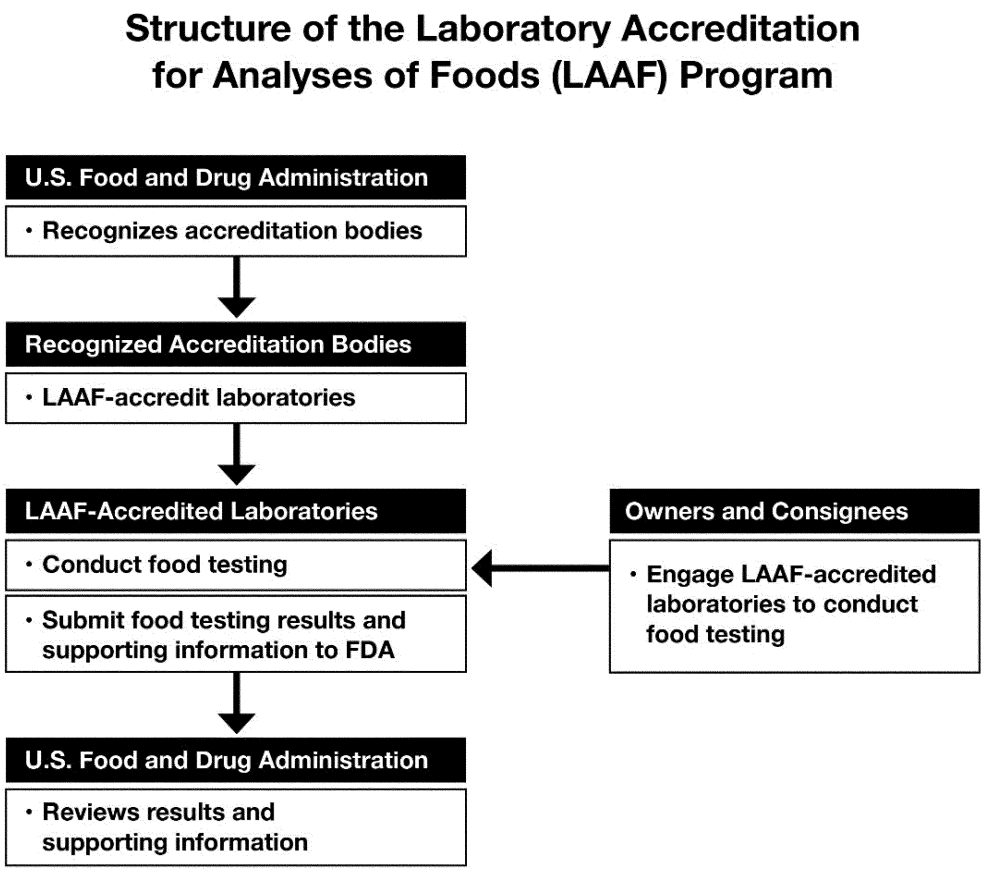
I. Executive Summary

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.

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Dated: November 15, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

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