4164-01-P

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend 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 such a 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, and produces reliable and valid test results.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE F*EDERAL REGISTER*] (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3325 for Laboratory Accreditation for Analyses of Foods. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to oira_submission@omb.eop.gov. All comments should be identified with the title, "Laboratory Accreditation for Analyses of Foods."

FOR FURTHER INFORMATION CONTACT: Timothy McGrath, Staff Director, Food and Feed Laboratory Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 3142, Rockville, MD 20857, 301-796-6591, email: timothy.mcgrath@fda.hhs.gov.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown Street, North Bethesda, MD 20852, 301-796-5733, email: PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

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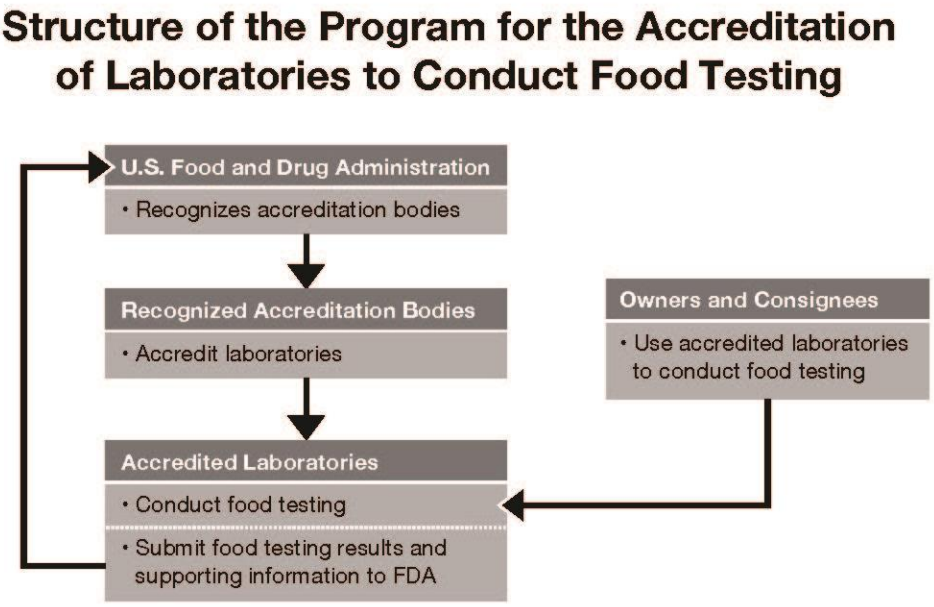
I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

This proposed rule, if finalized, would establish a new program for food testing by accredited laboratories. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), section 202(a), added section 422 to the FD&C Act (21 U.S.C. 350k), which requires us to establish this program.

You would be subject to this rule, if finalized, if you are a recognized accreditation body, an entity seeking to be a recognized accreditation body, an accredited laboratory, or an entity seeking to be an accredited laboratory, for purposes of food testing as specified in this proposed rule. You would also be subject to this rule if you are an owner or consignee required to use an accredited laboratory to conduct food testing as specified in this proposed rule. Although participation in this program is voluntary for laboratories, laboratories would only be able to conduct testing described in proposed § 1.1107 if they are accredited under this proposed program.

Under this proposed rule FDA would recognize accreditation bodies that would accredit laboratories to conduct food testing. The program structure is portrayed in the following diagram:



This proposed program for the testing of food by accredited laboratories would establish the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate, and, in turn, establishment of the program would substantially improve our capability to protect U.S. consumers from unsafe food.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule contains model standards that laboratories must meet in order to be and stay accredited. The proposed rule, if finalized, would establish a publicly available list of accreditation bodies and laboratories that have been recognized or accredited under this program. Results of food testing conducted by laboratories under the program would be required to be sent directly to FDA. Laboratories accredited under this program would be required to submit to FDA some analytical reports, but for certain laboratories less documentation would be required than we currently expect as part of a private laboratory analytic package.

This proposal contains eligibility requirements for accreditation bodies to qualify for recognition and requirements that accreditation bodies must meet once recognized, such as

requirements related competency and conflict of interest safeguards. The proposed rule also contains eligibility requirements for laboratories to qualify for accreditation by a recognized accreditation body and requirements that laboratories must meet once accredited, such as requirements related to conflicts of interest, analysis, and records. These requirements will help ensure the effectiveness of the recognized accreditation bodies and accredited laboratories under this program. This proposal also contains procedures we would follow to recognize accreditation bodies under this program and procedures for accreditation bodies to follow to accredit laboratories under this program. This proposed rule also contains regulatory procedures and requirements relating to our monitoring and oversight of recognized accreditation bodies and accredited laboratories.

This proposed rule would apply when food testing is conducted in certain circumstances. "Food testing" and "testing of food" would include the analysis of human or animal food. "Food testing" and "testing of food" would also include testing of the food growing or manufacturing environment (i.e., "environmental testing").

We seek comments on all aspects of this proposed rule.

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 proposed requirements, which outline what would be required of participants in the program for the testing of food by accredited laboratories. FDA also derives authority for these proposed 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 costs of the proposed rule, if finalized, would be incurred primarily by participating accreditation bodies, participating labs, shell-egg producers, sprouts producers, bottled water manufacturers, and owners and consignees of human and animal food offered for import covered by the proposed rule. We would incur costs to establish and maintain the program for recognizing accreditation bodies hoping to participate in our program, assessing participating accreditation bodies and participating labs, and for reviewing associated documents and reports. The present value of the cost of the proposed rule, if finalized, would range from $34 million to $78 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the cost would range from $39 million to $92 million.

The proposed rule, if finalized, would generate some quantified and unquantified benefits. Quantified benefits include cost-savings from the proposed clarifications of the process for compiling, submitting and reviewing analytical reports for human and animal food offered for import covered under the proposed rule, and a reduced burden from the proposed abbreviated reporting requirements. In addition, there would be savings from fewer false positive test results. We anticipate a reduction in the number of foodborne illnesses from fewer false negative test results for human and animal food offered for import covered under the proposed rule and for shell eggs, sprouts, bottled water, and other food subject to specific testing requirements covered under the proposed rule. Unquantified benefits could include fewer illnesses from deterring unsafe manufacturing practices by all entities affected by the proposed rule. The present value of the quantified benefits of the proposed rule, if finalized, would range from $26 million to $81 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the quantified benefits would range from $32 million to $98 million.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/Acronym	What It Means
ANSI	American National Standards Institute
BAM	Bacteriological Analytical Manual
CFR	Code of Federal Regulations
CPSC	Consumer Product Safety Commission
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
FR	Federal Register
FSMA	FDA Food Safety Modernization Act
FSVP	Foreign Supplier Verification Programs
GAO	Government Accountability Office
HHS	Health and Human Services
IBR	Incorporation by Reference
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MRA	Mutual Recognition Arrangement
NIST	National Institute of Standards and Technology
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
PRIA	Preliminary Regulatory Impact Analysis
IEC	International Electrotechnical Commission
U.S.C.	United States Code
WTO	World Trade Organization

III. Background

A. FDA Food Safety Modernization Act

On January 4, 2011, President Obama signed FSMA into law. FSMA is intended to allow FDA to better protect public health by helping ensure the safety and security of the U.S. food supply and enables us to focus more on preventing food safety problems rather than primarily reacting to them once they surface. FSMA also 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 a program for food testing by accredited laboratories, as proposed in this document.

B. Food Testing under FSMA

FSMA recognized that food testing could perform different roles in supporting a modern food safety system. For example, section 418(f)(4) of the FD&C Act (21 U.S.C. 350g) provides for the use of environmental and product testing programs as part of required verification that preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards (food testing under such requirements may be conducted for biological, chemical, physical, radiological hazards, or, most commonly, microbiological hazards). Section 805(c)(4) of the FD&C Act (21 U.S.C. 384a) states that verification activities under a foreign supplier verification program may include periodically testing and sampling shipments. Under these provisions, food testing is used to verify that control measures, including those related to suppliers, are controlling the identified hazards. In implementing these provisions in the regulations for preventive controls for human food and foreign supplier verification programs, we attempted to provide flexibility by specifying that they apply as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system. 21

CFR 117.165(a); accord 21 CFR 507.49(a) (parallel provision in the regulation for preventive controls for animal food); 21 CFR 1.506(d)(1)(ii)(B) (including sampling and testing of a food among other appropriate supplier verification activities).

FSMA, in establishing section 422 of the FD&C Act, also 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 accredited laboratories 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 (HHS), 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 through 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.

In food manufacturing or processing facilities, followup or corrective action testing is often conducted as part of corrective actions when an environmental pathogen or indicator organism (i.e., an organism that indicates conditions in which an environmental pathogen may be present) is found during environmental monitoring. See current good manufacturing practice and hazard analysis and risk-based preventive controls for human food proposed rule, 78 FR 3646 at 3816, January 16, 2013. Corrective action testing may also occur in response to the results of product testing, although testing cannot ensure the absence of a hazard. Id. at 3819.

The accredited laboratory testing requirement in this proposed rule would not apply to all corrective action testing, but would apply 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 food testing orders that we would issue "to address an identified or suspected food safety problem." As discussed in section VI.B.1, we have tentatively determined that an "identified food safety problem" could be present where a specific article of food violates a provision of the FD&C Act that relates to food safety and a "suspected food safety problem" could be present where there is reasonable suspicion that a specific article of food violates a provision of the FD&C Act that relates to food safety or where there is particularized suspicion of a food safety problem that does not necessarily render food violative. An example of a specific testing requirement in our FD&C Act regulations that would "address an identified or suspected food safety problem" and be subject to section 422(b)(1)(A)(i) of the FD&C Act is a requirement for bottled water producers to test, after corrective measures have been applied, 5 samples collected over a 24-hour period from the same site that previously tested positive for *Escherichia coli (E.coli).* See § 129.35(a)(3)(i) (21 CFR 129.35(a)(3)(i)). In this example, the presence of *E. coli* in the tested source water would constitute an "identified or suspected food safety problem" because its presence in the source water is not considered water of a safe quality as is required for bottled drinking water by § 129.35(a)(1).

C. Import-Related Food Testing and Detention Without Physical Examination (DWPE) Procedure

Section 422(b)(1)(B) of the FD&C Act requires accredited laboratory food testing where testing of food is conducted as part of testimony for the purposes of section 801(a) of the FD&C Act. Under section 801(a)(3) of the FD&C Act, we may refuse admission of an imported food

into the United States if the food is, or appears to be, adulterated or misbranded. Pending our decision to refuse admission, section 801(a) of the FD&C Act allows the owner or consignee of the imported article of food to introduce evidence regarding the admissibility of the food. See also 21 CFR 1.94(a). Owners and consignees often hire private laboratories to test the food product 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.

The DWPE procedure allows us to detain a product without physically examining it at the time of entry. We use the 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. Depending on the reason for DWPE, owners and consignees may hire private laboratories to test a food product in an attempt to overcome the appearance of the violation and release the food from detention.[1]

D. Testing of Imported Food by Private Laboratories

As the volume of food offered for import to the United States increased in recent decades, our use of the DWPE procedure also increased, as did concomitant food testing by private

[1] In both the domestic and import arenas, the owner or consignee of a food may accept that a food product is violative and offer to recondition the food to make it nonviolative (e.g., by subjecting an adulterated food to a treatment that cures the adulteration), divert human food for use as animal food, and/or recondition the food to make the food not subject to our enforcement authorities (e.g., by processing the food in a manner that makes it into a type of product we do not regulate). After food has been reconditioned and/or identified for diversion to animal food, the owner or consignee of the food (who we also refer to herein as the "importer" in the import context) may have food testing conducted on the product to demonstrate to us that the product is safe for the intended use.

laboratories on behalf of importers. From January 1, 2016, through December 31, 2017, we received food testing submissions, known as private laboratory analytical packages (PLAPs), from approximately 100 different private laboratories. See 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" (Ref. 1). Historically, we relied on Agency procedural documents and communications from FDA offices that review PLAPs to encourage private laboratories to meet certain standards for testing and sampling. We previously have observed that our recommended procedures for private laboratories were "not sufficiently specific," which may have contributed to a lack of consistency in standards for testing and sampling across FDA districts (requirements pertaining to sampling services and private laboratories used in connection with imported food proposed rule, 69 FR 23460 at 23468, April 29, 2004). In addition, the lack of regulatory requirements for PLAP content has sometimes complicated our scientific review of PLAP submissions from private laboratories.

Concerns also have periodically 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. 2, pages 26-35 and 137-140).

In attempts to address these issues, FDA and others have taken several actions to improve coordination between FDA and private laboratories and improve the safety of food imports. This

section describes several of these activities up to and including the enactment of FSMA section 202(a).

In 1996 we held several public meetings across the country to discuss how FDA might improve its policies and procedures relating to the use of private laboratories to test food offered for import. (61 FR 29416, June 10, 1996). These public meetings resulted in an action plan which suggested, among other things, that we establish consistent and objective standards for the format and content of food testing results and analytical information that private laboratories submit to us, that we require independent sampling of such food prior to the food's analysis by a private laboratory, and that we require the laboratory to send the results of all such food testing directly to us (see discussion of the plan in the 2004 proposed rule, 69 FR 23460, at 23460, April 29. 2004).

In 2003, we added a section on "Private Laboratory Guidance" to FDA's Office of Regulatory Affairs (ORA) Laboratory Manual (ORA Laboratory Manual) (Ref. 3). This document updated procedures for reviewing PLAPs (which contain sampling collection reports, testing results, and associated analytical information) submitted to us as testimony relevant to the admissibility, destruction, or reconditioning of FDA-regulated articles offered for import.

Recognizing a need for oversight over sampling services and private laboratories testing of imported food on behalf of importers, in the *Federal Register* of April 29, 2004, we proposed a rule on "Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food" (the 2004 proposed rule). We designed the 2004 proposed rule with the goals of deterring the importation of unsafe food, establishing uniformity in the practices of samplers and laboratories testing imported food for FDA regulatory purposes, and improving the reliability and scientific validity of the food testing analytical information that

FDA uses to make food import admissibility decisions. The proposed rule would have required, among other requirements, that samples of food to be tested be properly identified, collected, and maintained; that laboratories conducting food testing use validated or recognized analytical methods; and that laboratories conducting food testing submit the analytical results of the food testing directly to FDA. Id.

The 2004 proposed rule would not have required laboratories conducting food testing to be accredited because we determined that doing so would have been premature. Id. at 23464. We did, however, in the preamble to the 2004 proposed rule strongly encourage laboratories conducting such food testing to become accredited. Id. Most comments on the accreditation issue contended that accreditation to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories" (Ref. 4), would substantially enhance the effectiveness of the rule. We withdrew the 2004 proposed rule on August 5, 2005 (see 70 FR 64553 at 64590, October 31, 2005).[2]

In November 2007, an Interagency Working Group on Import Safety, made up of representatives from 12 federal departments and agencies, presented an Action Plan for Import Safety to President Bush containing recommendations and action steps to further improve the safety of imports entering the United States (Ref. 5). One of these action steps was that we issue guidance setting "standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved."

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[2] See https://www.govinfo.gov/content/pkg/GPO-UA-2005-10-31/pdf/GPO-UA-2005-10-31-8.pdf.

On January 29, 2008, the Government Accountability Office (GAO) recommended, in testimony to the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, that we consider accrediting private laboratories to test seafood. See GAO, "Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical," GAO-08-435T (Ref. 6), at page 7). This recommendation, which GAO had originally made in 2004, was intended to help us leverage outside resources and provide greater assurance about the quality of the laboratories importers use for seafood products subject to DWPE. See GAO, "Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed," GAO-04-246 (Ref. 7), at page 6.

On January 16, 2009, under the Action Plan for Import Safety, we issued a draft guidance document entitled "Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories" (the 2009 draft guidance) (Ref. 8), in which we recommended a voluntary accreditation program for laboratories conducting testing to support the admissibility of articles offered for import of all product types that FDA regulates. (See 74 FR 3056, January 16, 2009).

We acknowledged in the 2009 draft guidance that the landscape of laboratory accreditation had changed since we published the 2004 proposed rule, including a general trend toward laboratory accreditation and wider industry adoption of the ISO/IEC 17025 standard, as well as accreditation of FDA's own laboratories to the ISO/IEC 17025 standard. The 2009 draft guidance also noted that rigorous accreditation standards provide FDA and industry with greater confidence that laboratories receiving accreditation have sufficient technical capability, trained personnel, and quality management systems to perform the specific testing methods for which they are accredited. We further noted in the 2009 draft guidance that laboratory accreditation

bodies' continuing oversight over accredited laboratories would enhance the Agency's confidence in the accredited laboratories' analyses and results. To encourage laboratories to voluntarily seek accreditation, the 2009 draft guidance recommended that laboratories that became accredited would be permitted to submit "abbreviated" laboratory packages to FDA in lieu of full PLAPs. Under the 2009 draft guidance, abbreviated laboratory packages consisted of documents identifying the entry from the importer of record, a summary of analysis, and affirmation from the laboratory director regarding the accuracy of the sampling and analysis. Full PLAPs, in turn, include the details of the analyses performed, including underlying raw data and supporting materials such as sample collection reports, validation and verification studies, analyst training records, etc.

The 2009 draft guidance further recommended that accreditation bodies that accredit laboratories conducting import admissibility testing on FDA-regulated products should operate in accordance with ISO/IEC 17011:2004 "General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies", as this would help ensure the competency of the accreditation bodies. The 2009 draft guidance additionally recommended that accreditation bodies should be signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), by which they would agree to maintain conformity with the current version of ISO/IEC 17011 and ensure that all laboratories they accredit comply with appropriate laboratory standards. The 2009 draft guidance also recommended that accreditation bodies accredit laboratories for specific testing methodologies used to generate test results submitted to FDA, and that they do so by assessing laboratories' conformance to ISO/IEC

17025:2005.[3] The 2009 draft guidance noted "widespread agreement," including by our own laboratories, that ISO/IEC 17025 was the most internationally recognized and accepted standard for testing laboratories.

On the issue of sampling, the 2009 draft guidance recommended that accreditation bodies review laboratories' sampling procedures to ensure the integrity, accuracy, and representative quality of samples, including samples collected by laboratories themselves and samples collected by sampling services under contract to the laboratory. The 2009 draft guidance further recommended that importers provide us with advance notice that they intend to use a particular accredited laboratory and that an abridged laboratory package would be submitted under the guidance, and that accredited laboratories conducting the analysis directly submit to us the results of all testing on the articles at issue.

Almost all comments we received in response to the 2009 draft guidance supported our recommendation for laboratory accreditation. The 2009 draft guidance was never finalized and was withdrawn in May 2015 (see 80 FR 26059, May 6, 2015). However, we considered both the 2004 proposed rule and the 2009 draft guidance and the comments we received in response to both documents, in developing this proposal.

E. Current Industry Practices Relating to Accreditation Bodies, Accreditation of Laboratories, and Food Testing

FDA has not had a policy of weighing food testing results differently depending on whether the laboratory that conducted the food testing is accredited, and therefore we generally

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[3] FDA also recommended that laboratories incorporate in their implementation of ISO/IEC 17025 the factors established in the AOAC International's "Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, and Aid to Interpretation of ISO/IEC 17025:2005" (Ref. 9).

do not track the accreditation status of private laboratories that conduct food testing in either the domestic or import arenas. However, we are able to make some reasonable inferences and conclusions regarding the laboratories that have conducted testing related to imports, with the data we do have.

With regards to the testing of imported foods, our analysis of the data in our internal systems (Ref. 1) indicates that just over one hundred different private laboratories submitted (although in some cases the laboratory would submit the results and supporting information to the importer, who would then submit them to us) analyses and results to us between January 1, 2016, and December 31, 2017, of food offered for import that we had detained. Ten of those laboratories submitted approximately 84 percent of the analyses. By examining publicly available records from accreditation bodies regarding the accreditation status of those laboratories, we concluded that all 10 of those laboratories are accredited to ISO/IEC 17025. This indicates that the large majority of import-related food testing results that we receive come from laboratories that are accredited to ISO/IEC 17025. We found no laboratories conducting analyses in support of food offered for import that we had detained that were accredited to any standard other than ISO/IEC 17025. We also found that all of the accredited laboratories that submitted import-related food testing results were accredited by accreditation bodies that are full members of ILAC and signatories to the ILAC MRA, which requires signatories to have been peer evaluated in accordance with ISO/IEC 17011 to demonstrate competence. ILAC MRA signatories must maintain conformance with ISO/IEC 17011 (see, e.g., IAF/ILAC "Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body" (Ref. 10, p. 8)).

F. U.S. Government Policies on Consensus Standards

Implementation of section 422 of the FD&C Act occurs against the backdrop of broader U.S. federal policies on consensus standards 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, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (most recently revised on January 27, 2016) (Ref. 11), directs federal agencies to use voluntary consensus standards in their procurement and regulatory activities in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. OMB Circular A–119 states that the use of voluntary consensus standards, whenever practicable and appropriate, is intended to: (1) eliminate the cost to government of developing its own standards and decrease the cost of goods procured and the burden of complying with Agency regulation, (2) provide incentives and opportunities to establish standards that serve national needs, encouraging long-term growth for U.S. enterprises and promoting efficiency, economic competition, and trade, and (3) further the reliance upon private sector expertise to supply the Federal government with cost-efficient goods and services.

Additionally, as directed by OMB in Circular A-119 (Ref. 11), the National Institute of Standards and Technology issued policy guidance on Federal conformity assessment activities[4] (Federal conformity assessment guidance), published in the *Federal Register* of August 10, 2000 (65 FR 48894), and codified at 15 CFR part 287. The guidance recommends that, as appropriate, Federal Agencies use relevant guides or standards for conformity assessment practices from domestic and international standardizing bodies (e.g, the ISO, the IEC, and the Codex

[4] The Federal conformity assessment guidance defines conformity assessment activities, in part, as "any activity concerned with determining directly or indirectly that requirements are fulfilled" (see 15 CFR 287.2).

Alimentarius Commission).[5] The guidance also notes that each agency retains the responsibility, and authority, to select the conformity assessment activities and procedures (i.e., guides and standards) that will best meet its legislative mandates and programmatic objectives.

Further, section 422(a)(6) of the FD&C Act requires us to "consult existing standards for guidance" in the course of developing model standards that a laboratory must meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology.

In developing this proposed rule, two relevant voluntary consensus standards stood out as containing globally-recognized and widely-used requirements relevant to the program for food testing by accredited laboratories: ISO/IEC 17011:2017, "Conformity Assessment--Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies" (ISO/IEC 17011:2017) (Ref. 12), for accreditation bodies that would be recognized under the program, and ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories" (ISO/IEC 17025:2017) (Ref. 13), for laboratories that would be accredited under the program.

Although we are proposing to require accreditation bodies to meet ISO/IEC 17011:2017 entirely, we are proposing to not require accredited laboratories to meet certain aspects of ISO/IEC 17025:2017 that would be inconsistent with section 422 of the FD&C Act or would be impractical for use in our program. We are also proposing to require accredited laboratories to meet certain requirements in addition to ISO/IEC 17025:2017. For further discussion on this

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[5] The Codex Alimentarius Commission, established by Food and Agriculture Organization of the United Nations and the World Health Organization (WHO) in 1963 develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

issue, please see sections VI.C and VI.D (regarding the proposed requirements under this program for accreditation bodies) and sections VI.F and VI.G (regarding the proposed requirements under this program for laboratories). For information on accessing these consensus standards, please see section III.G.

We invite public comment on whether the voluntary consensus standards we cite are the appropriate standards upon which to base this rulemaking.

G. Incorporation by Reference

We are proposing to incorporate the following consensus standards by reference, with the approval of the Director of the *Federal Register* in accordance with 5 U.S.C. 553(a) and 1 CFR part 51:

- ISO/ IEC 17011:2017, "Conformity Assessment--Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies," Second edition, November 2017 (Ref. 12), and
- ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories," Third edition, November 2017 (Ref. 13).

For an overview of ISO/IEC 17011:2017, please see section VI.C. of the preamble. For an overview of ISO/IEC 17025:2017, please see section VI.F of the preamble.

The consensus standards proposed to be incorporated by reference are available to the public in four different ways: (1) generally, the most convenient way for interested parties to view these consensus standards is via the special link created by the American National Standards Institute (ANSI), which is a private non-profit organization that supports the U.S. voluntary standards and conformity assessment system. ISO/IEC 17011:2017 and ISO/IEC 17025:2017 are available to view through the following link free of charge:

https://www.surveymonkey.com/r/KFJMZ67. Please note that you must have certain software on your computer (available free of charge through following the process on this website) and complete a registration form (when prompted by the process on this website) to view these consensus standards via the website facilitated by ANSI. Alternatively, interested parties may: (2) examine these standards at Dockets Management Staff at FDA at the locations listed in proposed §§ 1.1113(b) and 1.1138(a)(2), (3) purchase copies of these standards from ISO or from IEC, or (4) purchase copies of these standards from any other source from which the user is assured that the copy to be received is an accurate and current version of the standard.

IV. FSMA Public Meetings, Comments Related to Other FSMA Rulemakings, and Stakeholder Input

Since the enactment of FSMA, we have reached out to stakeholders in the food industry, the international community, standards organizations, accreditation and certification bodies, consumer groups, government agencies, and other interested parties to gain input and perspective on how to best implement FSMA. Such interested parties have also provided comments to us at their own initiative and requested meetings with us at their own initiative to discuss our implementation of FSMA. The input and perspectives we gained through these comments and meetings helped shape this proposed rule.

Since the enactment of FSMA, we have also received several comments from interested parties specifically regarding our implementation of section 422 of the FD&C Act. We received many such comments in response to our solicitation of comments regarding our implementation of other aspects of FSMA, for example, with regards to the accreditation of third-party auditors (see section 808 of the FD&C Act, added by FSMA section 307), hazard analysis and risk-based preventative controls (see section 418 of the FD&C Act, added by FSMA section 103), and

standards for produce safety (see section 805 of the FD&C Act, added by FSMA section 105). The most common issue discussed in those comments related to what scenarios should require food testing to be conducted by accredited laboratories under section 422(b)(1) of the FD&C Act. Other issues discussed in such comments include the circumstances under which we should allow variance from the requirement to submit to FDA the results of all tests conducted under this proposed program. There were also a small number of comments regarding the implementation of section 422 of the FD&C Act submitted to the docket established to help FDA identify existing ways of achieving meaningful burden reduction while still allowing us to achieve our public health mission and fulfill our statutory obligations. To the extent practicable, we tried to consider all comments in drafting this proposed rule. However, to ensure that we consider your comment in the context of this rulemaking, you should resubmit in response to this proposed rule any comment(s) you previously submitted regarding our implementation of section 422 of the FD&C Act.

Since the enactment of FSMA, we have also met with several stakeholders, some of who requested meetings with FDA to discuss their current programs and to share their views and recommendations for our implementation of section 422 of the FD&C Act, and others whom we contacted in order to learn from their relevant experience and subject matter expertise. Topics for our meetings with these stakeholders included the general structure and function of the program, the standards to which accreditation bodies, sampling services, and laboratories should adhere in order to be recognized or accredited under this proposed program, and how sampling services should be addressed in the program. We discuss issues relevant to this rulemaking that were covered during these meetings in Section VI, Description of the Proposed Rule of this NPRM.

In this proposed rule we have intended to draft a practical, flexible, and effective approach to the program for the testing of foods by accredited laboratories. We seek comments on all aspects of this proposal, including comments about any potential impacts of this proposed rule.

V. Legal Authority

We are issuing this proposed 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 proposed rule would allow FDA to efficiently enforce section 422 of the FD&C Act. Thus, our legal authority for this proposed 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 (21 U.S.C. 2252), 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.

VI. Description of the Proposed Rule

In section 422 of the FD&C Act Congress directs us to establish a program for the testing of food by accredited laboratories. We are proposing to add new subpart R, "Accreditation of Laboratories to Conduct Food Testing," to part 1 (21 CFR Part 1) ("General Enforcement Regulations") and amend our regulations in parts 11 ("Electronic Records; Electronic

Signatures"), and 16 ("Regulatory Hearing before the Food and Drug Administration") (21 CFR parts 11 and 16) to establish and implement a program for food testing by accredited laboratories, as required by section 422 of the FD&C Act. We are also proposing to amend part 129 (21 CFR Part 129) ("Processing and Bottling of Bottled Drinking Water") to ensure that the requirements in part 129 are consistent with the requirements of section 422 of the FD&C Act. We are also proposing to revise certain testing provisions in part 1, Subpart M ("Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications"), in the interest of consistency with this proposed rule and in response to additional information we have gathered, in developing this proposed rule, about the number and capacity of laboratories accredited under ISO/IEC 17025 to conduct food testing.

We also note that in November 2017, ISO/IEC released new versions of ISO/IEC 17011 and ISO/IEC 17025. ISO/IEC 17011 and ISO/IEC 17025 were last revised in 2004 and 2005, respectively. The new versions of ISO/IEC 17011 and 17025--ISO/IEC 17011:2017 and 17025:2017--do not represent fundamental changes to the previous versions of ISO/IEC 17011 and ISO/IEC 17025. Rather, the new versions of ISO/IEC 17011 and ISO/IEC 17025 have been technically revised to more accurately reflect current best practices of accreditation bodies and of testing and calibration laboratories.

A. Proposed General Provisions (Proposed §§ 1.1102 through 1.1103)

1. What Definitions Apply to this Subpart? (Proposed § 1.1102)

We propose to define several terms used in this rule (see proposed § 1.1102). Where possible, we propose to rely on existing statutory and regulatory definitions. Proposed § 1.1102 states that definitions and interpretations contained in section 201 of the FD&C Act (21 U.S.C. 321) will apply to this rule, except as those terms are otherwise defined in this section. We also

note here that grammatical variations of the terms defined in proposed § 1.1102 have the same meaning as the defined term, modified as grammatically appropriate. For example, the term to "accredit," although not specifically defined by proposed section § 1.1102, would mean to bestow accreditation, in accordance with how the term "accreditation" would be defined by this rule.

Where necessary to provide clarity to this rule, we have developed some additional definitions that align with existing law and regulations, as well as with current practices of the international community, accreditation bodies, food testing laboratories, and the food industry. We seek comments on these proposed definitions, including with respect to whether any of the proposed definitions are unnecessary and with respect to whether any additional terms we use in this proposed rule should be defined.

We propose to define "accreditation" to mean a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this program to conduct food testing under this program using one or more methods of analysis. In developing the definition of accreditation, we considered the use of the term accreditation in section 422 of the FD&C Act. Specifically, section 422(a)(6) of the FD&C Act directs us to develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and section 422(b)(1) of the FD&C Act provides that food testing under this program may only be conducted by laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies by a recognized accreditation body. These provisions indicate that accreditation under section 422 of the FD&C Act requires a determination by a recognized accreditation body that a laboratory meets our model standards for a specified analytical testing methodology. We also

considered the meaning of accreditation in international standards on accreditation, including ISO/IEC 17011:2017 (Ref. 12), which defines accreditation as an attestation "conveying formal demonstration" of a conformity assessment body's competence to carry out specific conformity assessment tasks. In the context of the proposed rule, recognized accreditation bodies would accredit laboratories that they determine meet the applicable requirements of the rule.

The term accreditation as it is used in the proposed rule, refers only to a recognized accreditation body's determination that a laboratory meets the applicable requirements of this program and does not refer to any accreditation outside of this program. For example, although conformance to certain aspects of ISO/IEC 17025:2017 is a prerequisite to becoming accredited by a recognized accreditation body under this proposed rule, the term accreditation, as used in this proposed rule, does not refer to accreditation to ISO/IEC 17025 or to any other standard.

We propose to define "accredited laboratory" to mean a laboratory that a recognized accreditation body has determined meets the applicable requirements of this program and has been accredited to conduct food testing using one or more methods of analysis under this program.

We propose to define "analyst" to mean an individual who analyzes samples. The term refers to a single individual and does not refer to any other type of entity that is treated as a person for certain legal purposes.

Proposed § 1.1102 would define "food," as having the meaning given in section 201(f) of the FD&C Act, except that it would not include pesticides as defined in 7 U.S.C. 136(u), consistent with the definition of food used in the FSMA Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) (part 1, Subpart L) and Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

(accredited third-party certification) (part 1, Subpart M) regulations. We have tentatively determined there is no significant reason to define food differently in this proposal. We have not identified a need for food testing under this program to address pesticides as articles of food.

We propose to define "food testing" and "testing of food" to mean the analysis of food product samples or environmental samples. The terms food testing in sections 422(b)(1) and 422(d) of the FD&C Act, and testing of food in section 422(a)(1)(A) of the FD&C Act, are not defined in the statute. We see two possible ways to interpret and apply these terms. As noted, the FD&C Act has a definition of food at section 201(f), and it therefore may be a reasonable assumption that food testing means only the testing of food as food is defined under section 201(f). Under this approach, food testing would mean only product testing (where product testing includes testing of any food product, including raw materials or other ingredients, in-process foods, or finished products).

The alternative interpretation, which we propose, would interpret food testing to include product testing as well as environmental testing (e.g., testing from the growing, harvesting, manufacturing, processing, packing, or holding environment). We have tentatively concluded that the meaning of food testing, a term that appears only in section 422 of the FD&C Act, is ambiguous and may be interpreted to encompass both product testing and testing that is related to food, that is, environmental testing. Food testing is distinct from "product testing," used in section 418(f)(4) of the FD&C Act, and "environmental testing programs" and "environmental monitoring programs," which are used in sections 418(f)(4) and 418(o)(3)(C) of the FD&C Act, respectively. We note that section 202(a) of FSMA is located in title II of FSMA, which is entitled improving capacity to detect and respond to food safety problems, and section 422(b)(1)(A) of the FD&C Act requires accredited laboratory performance of food testing to

address an identified or suspected food safety problem. Given the role of environmental testing in determining both the source of contamination and in determining whether such contamination has been eliminated, interpreting food testing to exclude environmental testing would not cover an important method to detect and respond to identified and suspected food safety problems. Additionally, if food testing does not include environmental testing, our laboratory accreditation program would be unable to accredit laboratories to perform environmental testing or to issue model laboratory standards for environmental testing even though the food testing industry performs both food product tests and environmental tests. We invite comment on this interpretation.

We propose to define "food testing order" to mean an order issued by FDA under § 1.1108 of this subpart requiring food testing to be conducted under this program by or on behalf of an owner or consignee. We are proposing specific requirements related to food testing orders in §§ 1.1107, 1.1108, and 1.1174 of this proposed rule.

We propose to define "owner or consignee" as 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)(1); the food product or environment that is the subject of the order issued under § 1.1107(a)(2); the food product or environment that is the subject of food testing conducted under § 1.1107(a)(3); the article of food for which food testing is being conducted under § 1.1107(a)(4); or the food subject to an import alert for which food testing is conducted under § 1.1107(a)(5). Anyone meeting this definition of owner or consignee would be required to use an accredited laboratory to conduct food testing as specified in this proposed rule.

We propose to define "recognition" to mean a determination by FDA that an accreditation body meets the applicable requirements of the program and is authorized to

accredit laboratories under the program. This definition aligns with the use of the term recognition and "recognized" in section 422 of the FD&C Act, which uses these terms to describe the status we will accord to an accreditation body that we have determined meets certain requirements and may therefore accredit laboratories to conduct food testing under this program.

We propose to define "recognized accreditation body" to mean an accreditation body that FDA has determined meets the applicable requirements of the program and is authorized to accredit laboratories under the program. As previously discussed, this definition aligns with the use of the term recognition and recognized in section 422 of the FD&C Act, which uses these terms to describe the status we will accord to an accreditation body that we have determined meets certain requirements and may therefore accredit laboratories to conduct food testing under this program. This proposed definition of recognized accreditation body follows from our proposed definitions of recognition and accreditation body.

We propose 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." If food testing is required to be conducted on a specific food product or environment under this rule, and the sample that is collected from that food or environment is not representative of the food or environment at issue, then analysis of the sample would not produce information that is meaningful. We propose to use the qualifier "to a scientifically acceptable degree" because we acknowledge there are practical limits to how accurately a sample can represent the characteristics and qualities of the food product or environment from which it was collected. Furthermore, what constitutes a representative sample in the context of a certain food product or environment may be a scientific determination that depends on the environment, food matrix, and analyte at issue, among other potential factors.

FDA's Investigations Operations Manual, Chapter 4 – Sampling, includes some considerations which may inform the identification and collection of a representative sample (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual).

Depending on the food testing to be conducted, it may be appropriate to analyze a single sample that is representative of the food product or environment from which it was collected, to analyze a composite of multiple samples collected from the food product or environment from which it was collected, and/or to analyze a representative sample, taken in the laboratory, of the original representative sample.

We propose to define "sampler" as an individual or individuals who perform sampling. The term sampler would refer to single individuals and would not refer to any other type of entity that is treated as a person for certain legal purposes.

We propose to define "scope of accreditation" as referring to the methods of analysis for which the accredited laboratory is accredited. We also propose to clarify that references in this rule to accreditation "in-whole" refers to all methods in the accredited laboratory's scope of accreditation and accreditation "in-part" refers to only certain methods in the accredited laboratory's scope of accreditation. We note that section 7.8 of ISO/IEC 17011:2017 (Ref. 12) requires accreditation bodies to provide information to the laboratories they accredit that identifies their scope of accreditation.

2. Who is Subject to this Subpart? (Proposed § 1.1103)

The proposed rule would apply to recognized accreditation bodies, entities seeking to become recognized accreditation bodies, accredited laboratories, entities seeking to become accredited laboratories, and owners and consignees who are required to use accredited

laboratories for the food testing under this program. Although participation by accreditation bodies and laboratories in this program is voluntary, only accreditation bodies recognized by us under this program would be able to accredit laboratories to conduct food testing under this program, and only laboratories accredited by an accreditation body recognized by us under this program would be able to conduct food testing under this program. However, if finalized, it will not be voluntary for owners and consignees to conduct food testing conducted as described in proposed § 1.1107(a).

B. Proposed Provisions about General Requirements of this Rule (Proposed §§ 1.1107 through 1.1109)

We have proposed various provisions outlining the general requirements of the food testing program, including when food testing would have to be conducted under this rule, when and how we would issue food testing orders, and how we would make information about recognized accreditation bodies and accredited laboratories available to the public.

1. Under What Circumstances Must Food Testing be Conducted Under this Subpart by an Accredited Laboratory? (Proposed § 1.1107)

Proposed § 1.1107 would require that food testing must be conducted under this rule 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 (in the FD&C Act or implementing regulations) that address an identified or suspected food safety problem (we elaborate on these explicit corrective action testing requirements below, but, in short, they are located at 21 CFR 112.146(a), (c) and (d), 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), 118.6(e), and 129.35(a)(3)(i) (regarding the requirement to test five samples from the same sampling site that originally tested positive for *E. coli*)); (2) as required by FDA in a

food testing 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. 350l) 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 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.

a. Ownership of laboratories that may conduct food testing.

We note that section 422(b)(1)(A) of the FD&C Act provides that food testing must be conducted under this proposed program whenever food testing is conducted "by or on behalf" of an owner or consignee, while section 422(b)(1)(B) of the FD&C Act provides that food testing must be conducted under this rule whenever such testing is conducted on behalf of an owner or consignee in support of admission of an imported article of food and to support removal from an import alert through successful consecutive testing. We tentatively conclude that the "by or on behalf" language of section 422(b)(1)(A) of the FD&C Act means that both laboratories owned by owners or consignees and independent, or third-party laboratories, that conduct food testing "on behalf of" owners and consignees, must be accredited under this proposed program in order to conduct food testing under section 422(b)(1)(A) of the FD&C Act. Similarly, the "on behalf of" language of section 422(b)(1)(B) of the FD&C Act requires independent laboratories to be accredited under this proposed program in order to conduct food testing "on behalf" of owners and consignees under section 422(b)(1)(B) of the FD&C Act.

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 this provision would mean that only independent laboratories may be accredited to conduct food testing of imports under section 422(b)(1)(B) of the FD&C Act. Under this interpretation, laboratories owned by owners or consignees would be prohibited from conducting such import-related food testing. Otherwise, such "in-house" laboratories would be able to conduct import-related food testing without being accredited through our proposed program, which seems to be contrary to the intent of this program.

Under this interpretation, laboratories owned by owners or consignees would be eligible to conduct food testing under section 422(b)(1)(A) of the FD&C Act but not section 422(b)(1)(B), thereby raising 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, and to avoid any inconsistency with treaties or international agreements to which the United States is a party, we tentatively conclude 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. In addition, we are not aware of information indicating

that laboratories owned by owners or consignees of foreign foods are less able to become accredited under this proposed program or to conduct food testing under section 422(b)(1)(B) of the FD&C Act than independent laboratories.

b. Considerations in interpreting "identified or suspected food safety problem" in section 422(b)(1)(A) of the FD&C Act.

Section 422(b)(1)(A)(i) and (ii) of the FD&C Act both require, in relevant part, that food testing must be conducted by a laboratory accredited under the food testing program that would be established by this proposed rule, if finalized, when applied to address an identified or suspected food safety problem. Because the circumstances that may constitute a food safety problem are highly fact dependent, we are not proposing an exhaustive list of circumstances that would constitute an "identified or suspected food safety problem." Instead, in proposed § 1.1107(a)(1), we are proposing to codify the circumstances in existing FD&C Act regulations that address an identified or suspected food safety problem and thus trigger the requirement to use an accredited laboratory under this program. We also discuss as part of this rulemaking additional examples of identified or suspected food safety problems to explain the circumstances in which we tentatively conclude would allow for the issuance of food testing orders under proposed § 1.1107(a)(2). In proposed § 1.1107(a)(3) we are proposing to require the use of an accredited laboratory in additional circumstances where FDA determines it is appropriate to address an identified or suspected food safety problem.

The statute does not define the terms "identified or suspected food safety problem" or "food safety problem" and the term "food safety problem" is not used elsewhere in the FD&C Act. However, the section titles of FSMA indicate that "food safety problems" are the problems that FSMA is intended to address: Title I of FSMA is entitled "Improving Capacity to Prevent

Food Safety Problems," while Title II is entitled "Improving Capacity to Detect and Respond to Food Safety Problems." In the preamble to the preventive controls for human food proposed rule, we noted that food safety problems may be associated with biological, chemical, physical, or radiological hazards (78 FR 3646 at 3667). (We subsequently categorized radiological hazards as a subset of chemical hazards, see 80 FR 55908 at 55950, September 17, 2015).

In considering the circumstances that could constitute an identified or suspected food safety problem, we note that Congress did not require the presence of specific health risks, as in the reasonable probability of serious adverse health consequences or death to humans or animals standard, as a prerequisite to requiring the use of an accredited laboratory under section 422(b)(1)(A) of the FD&C Act. In the preventive controls for human food rule, we indicated that an "unanticipated food safety problem" could occur where a preventive control is not properly implemented, including circumstances where a pathogen or appropriate indicator organism is present in a ready-to-eat product detected through product testing, or an environmental pathogen or appropriate indicator organism is detected through environmental monitoring, or where a preventive control is found to be ineffective. See 21 CFR 117.150(b)(1)(i) and (ii) and 117.150(a)(1)(i) and (ii). Depending on the circumstances, we tentatively conclude that a positive indicator organism test would not necessarily constitute even a "suspected" food safety problem. For example, because *Listeria* spp. will occasionally be found in a food production environment, our current thinking is that, depending on certain factors, a single positive *Listeria* spp. on a food-contact surface in a facility would not necessarily constitute a suspected food safety problem. We tentatively conclude 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, such as certain violations of section 402 of the FD&C Act (21 U.S.C. 342).

Section 422(b)(1)(A) of the FD&C Act does not limit the factors that can generate suspicion of a food safety problem, and we believe a variety of circumstances could generate such suspicion depending on the circumstances, including the presence of *Listeria monocytogenes* on a food-contact surface; the presence of multiple positives for *Listeria* spp. on a food-contact surface; and potential contamination events. We are proposing that the element of suspicion in a "suspected food safety problem" typically be particularized, that is, have a basis in fact about a particular article or articles of food (e.g., a lot or batch) or food production environment (e.g., a specific facility), as opposed to being satisfied by the common or usual characteristics of a food (e.g., whether a food is considered "high-risk" because of its inherent characteristics, such as pH or water activity) or the manner in which such food is typically produced. Under this proposal, suspicion that a specific article of food violates a provision of the FD&C Act or implementing regulations related to food safety would constitute a suspected food safety problem.

For these reasons, we tentatively conclude that the routine product testing and environmental monitoring requirements at § 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 and not because a food safety problem is suspected or identified. See 80 FR 55908 at 56062.

Although we are not proposing an exhaustive list of identified or suspected food safety problems, in proposed § 1.1107(a)(1), (a)(2), or (a)(3), we are proposing to codify testing requirements in § 1.1107(a)(1) and (a)(3) that address an identified or suspected food safety

problem, which provides examples of circumstances that would constitute an identified or suspected food safety problem.

c. Proposed § 1.1107(a)(1) and section 422(b)(1)(A)(i) of the FD&C Act.

Because section 422(b)(1)(A)(i) of the FD&C Act applies to "specific" testing requirements, we propose to interpret section 422(b)(1)(A)(i) to apply only to provisions of the FD&C Act or its implementing regulations that explicitly require food testing.

We have identified nine explicit testing requirements in our regulations that we tentatively conclude address an identified or suspected food safety problem. Each of these explicit testing requirements is required as followup, or corrective action, testing after a routine test is positive for a pathogen or indicator organism. Five of these testing requirements are in our regulations on production, storage, and transportation of shell eggs (specifically, the testing requirements of §§ 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), and 118.6(e)), three are in our standards for the growing, harvesting, packing, and holding of sprouts (specifically, the testing requirements of § 112.146(a), (c), and (d)), and one is in our regulations on the processing and bottling of bottled drinking water (specifically, one of the testing requirements of § 129.35(a)(3)(i)). More specifically, testing would have to be conducted under this program under proposed § 1.1107(a)(1), if finalized, under the following circumstances: With respect to production, storage, transportation of shell eggs:

- Section 118.4(a)(2)(iii) requires that if the environmental test required in paragraph (a)(2)(i) of § 118.4 is positive, you must begin egg testing, as specified in § 118.6, within 2 weeks of the start of egg laying.
- Section 118.5(a)(2)(ii) requires that if the environmental test at 40 to 45 weeks is positive, then you must begin egg testing (described in § 118.6), unless you divert eggs to

treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing must be obtained within 10 calendar days of receiving notification of the positive environmental test.

- Section 118.5(b)(2)(ii) requires that if the environmental test at 4 to 6 weeks after the end of a molting process is positive, then you must begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10 calendar days of receiving notification of the positive environmental test.
- Section 118.6(a)(2) requires that if you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.
- Section 118.6(e) requires that if you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using sampling and methodology in §§ 118.7 and 118.8, for the life of the flock.

With respect to our standards for the growing, harvesting, packing, and holding of sprouts:

- Section 112.146 requires that, if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment you must conduct additional testing of surfaces and areas surrounding the areas where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in

a niche; conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated; and conduct finished product testing when appropriate.

With respect to the processing and bottling of bottled drinking water:

- Section 129.35(a)(3)(i) requires that a source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.

Many explicit testing requirements in our regulations are not subject to section 422(b)(1)(A)(i) of the FD&C Act because they require routine or verification testing, as opposed to testing to address an identified or suspect food safety problem. For example, none of the various testing requirements in our infant formula regulations at 21 CFR part 106 would require the use of an accredited laboratory under this program because they are routine testing requirements for each production aggregate of infant formula manufactured.

Section 422(b)(1)(A)(ii) of the FD&C Act requires, in pertinent part, that food testing must be conducted under this proposed rule whenever food testing is conducted by or on behalf of an owner or consignee as required by the Secretary of HHS, as the Secretary deems appropriate, to address an identified or suspected food safety problem. As such, we are interpreting section 422(b)(1)(A)(ii) of the FD&C Act to give FDA the authority to specify additional circumstances where food testing will be required to be conducted under this program, provided that the food testing is conducted to address an identified or suspected food safety problem. Unlike our authority under section 422(b)(1)(A)(i) of the FD&C Act, which gives us the authority to require food testing to be conducted under this program in response to "specific

testing requirements," we are interpreting section 422(b)(1)(A)(ii) to give us authority to require testing to be conducted under this program in the absence of an existing explicit requirement to conduct testing under the FD&C Act or its implementing regulations. Therefore, we are proposing in § 1.1107(a)(2) to require that food testing be conducted under this rule whenever food testing is conducted by or on behalf of an owner or consignee as required by FDA in a food testing order. We explain food testing orders in more detail in section VI.B.2 where we discuss proposed § 1.1108 (which addresses the question of when and how FDA will issue a food testing order).

Proposed § 1.1107(a)(3) would require that food testing be conducted under this program when food testing is conducted to address an identified or suspected food safety problem and presented to FDA as part of evidence for an informal hearing before a mandatory recall order under section 423(c) of the FD&C Act, 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. Although these three enforcement authorities do not require food testing, if owners and consignees elect to conduct food testing in response to proceedings under these authorities, and such food testing addresses an identified or suspected food safety problem, this proposal would require such food testing to be conducted by a laboratory accredited under this proposed program.

This proposed requirement is authorized under section 422(b)(1)(A)(ii) of the FD&C Act, which states that testing must be conducted under the accredited laboratory program whenever such testing is conducted as required by the Secretary of HHS, as the Secretary deems appropriate, to address an identified or suspected food safety problem. As explained previously

in the discussion of food testing orders under proposed section § 1.1107(a)(2), we are interpreting section 422(b)(1)(A)(ii) of the FD&C Act to give FDA the authority to specify additional circumstances where food testing will be required to be conducted under this program in the absence of an explicit requirement to conduct food testing under the FD&C Act or its implementing regulations, provided that the food testing is conducted to address an identified or suspected food safety problem. As such, we are proposing in § 1.1107(a)(3) to require owners or consignees to conduct food testing under this program whenever they elect to conduct food testing under the circumstances specified in § 1.1107(a)(3). We tentatively conclude that it is appropriate to require food testing related to these important public health enforcement authorities to be conducted under this program because all three of those circumstances could involve situations where food testing might be conducted to address an identified or suspected food safety problem.

Specifically, FDA's mandatory food recall authority gives us the authority to order a responsible party to recall an article of food where we determine that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) and there is a reasonable probability that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals. Before such an order is issued, FDA must provide the responsible party with an opportunity to request an informal hearing. Under the provision proposed here, if the results of food testing intended to address an identified or suspected food safety problem are submitted as evidence for the hearing, such tests must be conducted by a laboratory accredited under this program.

Section 415(b)(1) of the FD&C Act provides that if the Secretary of HHS determines that food manufactured, processed, packed, received, or held by a facility registered under section 415 of the FD&C Act has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of a facility that: (1) created, caused, or was otherwise responsible for such reasonable probability or (2) packed, received, or held such food. Section 415(b)(3)(A) of the FD&C Act provides that if, after providing opportunity for an informal hearing, the Secretary of HHS determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. We are proposing in § 1.1107(a)(3), that if any such corrective action plan includes food testing to address an identified or suspected food safety problem, such food testing must be conducted by a laboratory accredited under this program.

Under section 304(h) of the FD&C Act, FDA can order administrative detention of food if there is reason to believe that an article of food is adulterated or misbranded. If FDA issues an order to administratively detain food, FDA will provide an opportunity to appeal the detention as specified under section 304(h)(4)(A) of the FD&C Act. We are proposing that if the results of testing intended to address an identified or suspected food safety problem are submitted to appeal the detention, such tests must be conducted by a laboratory accredited under this program. See proposed § 1.1107(a)(3).

Use of a laboratory accredited under this program in the context of these three enforcement authorities will increase our confidence in the food testing conducted in response to identified or suspected food safety problems of great significance to public health. By requiring

that food testing be conducted in a manner in which we have added confidence, we will be in a better position to make appropriate decisions that protect public health.

Section 422(b)(1)(B)(i) of the FD&C Act requires, in pertinent part, that food testing must be conducted under the food testing program that would be established by this proposed rule, if finalized, whenever food testing is conducted on behalf of an owner or consignee in support of admission of an article of food under section 801(a) of the FD&C Act (i.e., food that is imported or offered for import into the United States). We are proposing this requirement in § 1.1107(a)(4) of this proposed rule.

As explained in section III.C., under section 801(a)(3) of the FD&C Act, we may refuse admission of an article of food imported or offered for import into the United States if the food is, or appears to be, adulterated or misbranded. Pending our decision to refuse admission, section 801(a) of the FD&C Act allows the owner or consignee of the imported article of food to introduce testimonial evidence regarding the admissibility of the food. Under § 1.94(a), such testimony must be confined to matters relevant to the admissibility or destruction of the article of food and may be introduced orally or in writing.

Owners and consignees often hire private laboratories to test the food and submit to us the results of the testing, along with associated analysis and data, as testimony to establish that the imported food complies with the FD&C Act. Currently, if we determine that the sampling methods and testing results are valid and that they demonstrate the detained food product does not appear to violate the FD&C Act, we will release the food from detention and allow it to proceed into the United States. Again, if this rule is finalized, an owner or consignee whose entry has been detained under 801(a) of the FD&C Act would need to use a lab accredited under this program in order to use the test results as testimonial evidence supporting admission.

We note that to the extent that a question exists as to whether section 422(b)(1)(B)(i) of the FD&C Act applies to food testing to demonstrate compliance with section 805 of the FD&C Act for purposes of supporting admission of an article of food under section 801(a)(3) of the FD&C Act, we tentatively conclude that it does not apply. FSMA amended the FD&C Act to add section 805 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). An article of food is subject to refusal of admission under section 801(a)(3) of the FD&C Act if it appears that the importer of the food "is in violation of such section 805," that is, fails to comply with the FSVP regulations with respect to that food. See also § 1.514(a). Significantly, this provision in section 801(a)(3) of the FD&C Act relates to the compliance status of the *importer*, and not the food. Consequently, the relevant inquiry for purposes of this provision of section 801(a)(3) of the FD&C Act is whether an importer has followed FSVP requirements. By contrast, section 422(b)(1)(B)(i) of the FD&C Act relates directly to the compliance status of articles of food.

Given the different focus of the FSVP provision in section 801(a)(3) of the FD&C Act from the focus of section 422(b)(1)(B)(i) of the FD&C Act, we tentatively conclude that it is reasonable to not apply section 422(b)(1)(B)(i) of the FD&C Act to food testing related to FSVP. That is, we tentatively conclude that it is reasonable to not require accredited laboratory to conduct food testing under this program for purposes of the FSVP rule.

Section 422(b)(1)(B)(ii) of the FD&C Act requires that food testing must be conducted under the food testing program that would be established by this proposed rule, if finalized,

whenever food testing is conducted on behalf of an owner or consignee to support the removal of food from an import alert through successful consecutive testing. We are proposing this food testing requirement in § 1.1107(a)(5) of this proposed rule.

An import alert conveys evidence that FDA can use to detain, without first physically examining, incoming products that appear to violate the FD&C Act. The alert communicates that the Agency has enough evidence or other information to refuse admission of future shipments of an imported article, without first physically examining (sampling) the shipments. Put another way, the import alert indicates that there is enough evidence to detain the product without physical examination. There are a variety of factors that could lead FDA to place a product, manufacturer, shipper, grower, geographical area, and/or country on import alert. For example, questions could have been raised in an inspection of the manufacturing site, concerns might be raised by a recall, or there could be a history of problems and no signs that appropriate actions were taken to remedy the cause. In order for FDA to consider removing a product and/or firm from import alert, FDA must have evidence that the conditions that gave rise to the appearance of a violation have been resolved and the Agency has confidence that future entries will be in compliance with FDA laws and regulations. Often, individual import alerts include specific information regarding removal from DWPE. At the present time, many import alerts indicate that it would be helpful for responsible entities to present to FDA evidence of at least five shipments to the United States that have been found to not be violation.

In contrast to section 422(b)(1)(B)(i) of the FD&C Act, which applies exclusively to specific articles of food that are imported or offered for import into the United States, section 422(b)(1)(B)(ii) of the FD&C Act applies to food generally. As such, we tentatively conclude that section 422(b)(1)(B)(ii) of the FD&C Act applies whenever successful consecutive testing

supports the removal of food from an import alert, including testing on specific articles of food that are imported or offered for import into the United States and less common situations where food testing is conducted on food that is not being imported or offered for import into the United States. For example, section 422(b)(1)(B)(ii) of the FD&C Act would also apply if the results from successful consecutive testing of environmental swabs or of food that is being imported or offered for import in a foreign country are presented as evidence demonstrating that a manufacturer should be removed from an import alert. At present, most successful consecutive testing conducted for food under an import alert is conducted on specific articles of food that are imported or offered for import into the United States--and thus fall under both sections 422(b)(1)(B)(i) and (ii) of the FD&C Act (and proposed §§ 1.1107(a)(4) and (a)(5)). However, we assume that Congress intended section 422(b)(1)(B)(ii) of the FD&C Act to have an independent meaning. (Norman J. Singer & J.D. Shambie Singer, 1A Sutherland Statutory Construction § 21:1 (7th ed. 2018) which states that "[c]ourts should construe a statute, if possible, so no term is rendered superfluous or meaningless.") Therefore, we interpret section 422(b)(1)(B)(ii) of the FD&C Act to apply in part to food testing not covered by section 422(b)(1)(B)(i) of the FD&C Act, including successful consecutive testing for food under import alert that is not conducted on specific articles of food that are imported or offered for import into the United States.

Finally, we note that we are not, as part of this rulemaking, defining the number of successful consecutive tests that would be required or recommended to support removal from import alert. Instead, this proposed rule would require that if you use successful consecutive testing as a means to support removal of food from an import alert, then such testing must be conducted under this program. (For procedural information on removal from DWPE, see section

9-8 of FDA's Regulatory Procedures Manual at https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm.)

In accordance with section 422(b)(1) of the FD&C Act, proposed § 1.1107(b) would require that whenever food testing is required to be conducted in accordance with this program, as described in proposed § 1.1107(a), analysis of the collected samples must be conducted by accredited laboratories that are accredited for the appropriate analytical method or methods by a recognized accreditation body.

Proposed § 1.1107(c) would require, with one exception, that such food testing may only be conducted on samples taken after the articles of food have arrived in the United States. As part of our import admissibility process, this policy allows us to verify that the requirements of § 1.94(a) are met--i.e., that the testimony is relevant to admissibility in that the article(s) of food that is sampled and tested is the same article(s) of food being offered for import into the United States. Importantly, this policy would also help to ensure that the tested sample(s) accurately represents the condition of the article when presented for admission, thereby ensuring the evidence presented by the owner or consignee is representative of the article(s) offered for import. Proper and valid analysis of a sample is not relevant testimony about admissibility if the analyzed sample is not representative of the article of food imported or offered for import into the United States. Based on best available science and grounded in years of experience, we know that the process of getting a food item from where it was produced abroad to a U.S. port of entry is such that change in the item or analyte may occur. For example, bacteria may grow in the time it takes to transport an article of food from the point of export to the United States, or a new contaminant may be intentionally or inadvertently introduced in transit. Accordingly, when

specific articles of food are imported or offered for import into the United States, our general policy would be that the sample must be taken after arrival.

We are also proposing, however, an exception to that sampling policy for circumstances in which we determine that a sample taken prior to arrival is representative of the article of food offered for import into the United States and thereby satisfies those evidentiary requirements. We would make such a determination on a case-by-case basis, based on clear evidence that the product sampled and analyzed is actually the product offered for import. We would communicate our determination in writing to the owner/consignee. We invite comment on this proposed exception and whether, in addition to applying the exception on a case-by-case basis, we could extend the exception to apply to a set of defined circumstances. We invite comment on whether there are specific circumstances under which we could make a determination that could be applied broadly, say to a particular commodity or analyte generally, that sampling taken prior to export is representative of the article(s) offered for import? If so, what are those circumstances, and what evidence would give us assurance that sampling of all such articles prior to export would be representative of all articles arriving in the United States?

As discussed above, we are proposing to interpret section 422(b)(1)(B)(ii) of the FD&C Act such that testing conducted under paragraph (ii) (under an import alert that requires successful consecutive tests) would encompass both testing of specific articles of food imported or offered for import and other testing related to an import alert. For import alerts where food product testing is generally sufficient evidence to overcome the appearance of the violation(s), although at present it is standard practice for a responsible entity seeking to have a food product removed from import alert to submit evidence of at least five non-violative shipments, it is possible that in some circumstances other testing could constitute relevant evidence. Examples

of other, potentially relevant, testing might be environmental swabbing of a production facility, or food testing unconnected to a shipment of food offered for import into the United States. Our proposed sampling policy in § 1.1107(c) would not apply to testing under an import alert that is unrelated to articles of food offered for import, because in circumstances unrelated to shipments, transit and timing issues would not present likely barriers to the relevance of the testing evidence.

2. When and How Will FDA Issue a Food Testing Order? (Proposed § 1.1108)

Proposed § 1.1108 would, if finalized, establish our procedure for issuing food testing orders. Specifically, proposed § 1.1108(a) provides that we may require an owner or consignee of an article of food to conduct food testing, or to have food testing conducted on their behalf, under this program, to address an identified or suspected food safety problem related to the article of food. As described previously, our authority for proposed § 1.1108 comes from section 422(b)(1)(A)(ii) of the FD&C Act, which provides that food testing must be conducted under the food testing program described in section 422 of the FD&C Act, whenever such testing is conducted by or on behalf of an owner or consignee, as required by FDA, as FDA deems appropriate, to address an identified or suspected food safety problem.

Proposed § 1.1108(b) elaborates that the food testing order will specify the food product or environment to be tested; whether the food testing may be conducted using an 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. We tentatively conclude that the language in section 422(b)(1)(A)(ii) of the FD&C Act stating that food testing must be conducted as required by FDA and as FDA

deems appropriate grants FDA discretion to specify the terms and conditions of a food testing order to address an identified or suspected food safety problem.

Proposed § 1.1108(c) provides that food testing orders would contain all of the elements required by 21 CFR 16.22(a) and would thereby constitute notice of an opportunity for a regulatory hearing under 21 CFR part 16. Proposed § 1.1108 further provides that an affected owner or consignee would be able to request a regulatory hearing on a food testing order under proposed § 1.1174.

3. How Will FDA Make Information About Recognized Accreditation Bodies and Accredited Laboratories Available to the Public? (Proposed § 1.1109)

Proposed § 1.1109 provides that (except as provided by proposed § 1.1109(b), which we discuss below) we would place on our website a list, which would be readily accessible to the public, of recognized accreditation bodies and accredited laboratories in the food testing program. We would establish and display this list in accordance with section 422(a)(1)(B) of the FD&C Act, which requires us to establish a publicly available registry of accreditation bodies recognized by FDA and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information deemed appropriate by the FDA about such bodies and laboratories.

The proposed list would include the name of and contact information for each recognized accreditation body and accredited laboratory in our program. We propose that it is also appropriate for the list to include, for each recognized accreditation body, the duration of the recognized accreditation body's recognition, and, for each accredited laboratory, the scope of accreditation, as well as the name and contact information of the recognized accreditation body that accredited the accredited laboratory. We also propose that the list include the recognition

status of each accreditation body that has been recognized (i.e., whether the accreditation body's recognition is active, or whether it has been put on probation or revoked by FDA, relinquished by the accreditation body, or allowed to expire by the accreditation body), the date of any such change in recognition status, the accreditation status of each laboratory that has been accredited (i.e., whether the laboratory's accreditation is active, or whether the laboratory's accreditation is withdrawn or revoked or it has been put on probation by a recognized accreditation body or FDA (including whether by FDA or by a recognized accreditation body), or the laboratory has relinquished its accreditation (in-whole or in-part)), and the date of any such change in accreditation status.

We believe this additional information beyond the name and contact information of recognized accreditation bodies and accredited laboratories would be appropriate to include in the list because it would make the list more useful and increase transparency. For example, if we did not include information about whether an accreditation body had its recognition revoked by FDA, and we instead simply deleted the accreditation body from the list, there could be ambiguity with respect to whether the deletion was for cause or whether the accreditation body voluntarily relinquished its recognition. We believe that users of the list would find the distinction between those two alternatives to be important. In addition, if a laboratory voluntarily relinquished its accreditation in-part, it might want the list to make clear that the reduction in its scope of accreditation was a voluntary action.

Proposed § 1.1109(b) reiterates section 422(a)(4) of the FD&C Act, which grants us the authority to, when in the interest of national security, determine in coordination with the Secretary of Homeland Security the time, manner, and form in which the list described in proposed § 1.1109(a) is made publicly available. In the absence of a determination to the

contrary under proposed § 1.1109(b), the list would remain publicly and readily available at all times on our website and display all information specified by proposed § 1.1109(a).

C. Proposed Provisions about Recognition of Accreditation Bodies (Proposed § 1.1113)

Section 422(a)(2) of the FD&C Act requires that FDA provide for the recognition of laboratory accreditation bodies that meet the criteria established by FDA for accreditation of laboratories to conduct food testing. Accordingly, this proposed rule proposes certain criteria that accreditation bodies must meet to become recognized by FDA to accredit laboratories under this program.

1. What Requirements Must an Accreditation Body Meet to be Recognized by FDA? (Proposed § 1.1113)

Proposed § 1.1113 would require that, to become recognized by FDA, an accreditation body seeking recognition by FDA must: (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 (Ref. 12); (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.

ILAC was established to create an international arrangement between member accreditation bodies to develop and harmonize laboratory and inspection body accreditation practices. Currently more than 90 accreditation bodies are signatories to the ILAC MRA. To become an ILAC MRA signatory, an accreditation body must commit itself to maintaining conformity with the current version of ISO/IEC 17011 and to ensuring that all laboratories it accredits comply with appropriate laboratory standards. Under this proposed rule, accreditation

bodies would be required to meet ISO/IEC 17011:2017, which is incorporated by reference. Therefore, we are proposing that in order to be recognized as an accreditation body, an accreditation body must be a signatory to the ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017. If at some point in the future ISO/IEC 17011:2017 is updated, FDA would consider whether to amend the codified consistent with that update, allowing an adequate transition period.

Requiring recognized accreditation bodies to be signatories to the ILAC MRA that have demonstrated competence to ISO/IEC 17011:2017 and to be members in good standing of ILAC would also be consistent with our withdrawn 2009 draft guidance, in which we recommended that accredited laboratories be ILAC MRA signatories. We also considered the rationale stated by the Consumer Product Safety Commission (CPSC) in its 2013 rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies" (78 FR 15836, March 12, 2013), for requiring accreditation bodies to be signatories to the ILAC MRA. In particular, we agree with CPSC that requiring accreditation bodies to be signatories to the ILAC MRA that have demonstrated competence to ISO/IEC 17011, and not accepting any other arrangement, would: (1) keep the accreditation program as simple as possible for use by interested parties (in our case, owners and consignees, accreditation bodies, and laboratories); (2) avoid any perceived notions of barriers to fair trade practices; establish a program that is manageable within Agency resources; and (3) maintain consistency in the procedures used by the recognized accreditation bodies (see 78 FR 15836 at 15857).

Proposed § 1.1113(b) would require that, to become recognized by FDA, an accreditation body seeking recognition by FDA must demonstrate that it meets the requirements of ISO/IEC 17011:2017. ISO/IEC 17011:2017 specifies the general requirements 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). ISO/IEC 17011 is widely accepted, both domestically and internationally, and its incorporation by reference should allow us to utilize a framework that is familiar to accreditation bodies and the food industry.

Proposed paragraph (c) would require that to be recognized under this program, an accreditation body must possess certain scientific/technical expertise. Because the food testing that occurs under this program is important to public health, the laboratories conducting these food tests must be able to properly and accurately apply a particular test method, in an appropriate circumstance. Thus, it is vital that test methods be validated[6] and verified as necessary (see § 1.1151(a)), and that laboratories demonstrate their capability by participating in comparison programs such as proficiency testing (see § 1.1138(a)(1)(ii)). Under this proposed rule, we would be relying on recognized accreditation bodies to substantively review some validation and verification studies, as well as accredited laboratories' proposed alternatives to proficiency tests, as part of their consideration of whether laboratories are competent to conduct the test methods for which they are seeking accreditation (see § 1.1138(a)(1)). Thus, we would expect recognized accreditation bodies to serve a function that accreditation bodies have not traditionally performed.

Accordingly, to be recognized in this program, we expect an accreditation body to be able to substantively review validation studies; to have the scientific knowledge to meaningfully

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[6] The terms validate, validation, verify, and verification are used in this proposed rule in the specific context of conducting food testing. Other rules we have issued, particularly some rules we have issued pursuant to FSMA, use one or more of these terms in other contexts. The terms validate, validation, verify, and verification, as used in contexts other than the context of conducting food testing, may have different meanings than they do in the context of this proposed rule.

assess whether a study indicates that a proposed test method detected the identified hazard (or analyte) with sufficient accuracy and precision. We would expect recognized accreditation bodies to assess verification studies to determine whether the test method at issue may be properly applied to a particular food/analyte combination (e.g., strawberries/*salmonella*). We would also expect recognized accreditation bodies to be able to assess an accredited laboratory's determination under proposed § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method, and to be able to assess whether a proposed alternative to a proficiency test would adequately demonstrate the laboratory's competence to conduct a test method. In these ways, we would expect accreditation bodies to possess and apply substantive scientific/technical knowledge. We acknowledge that for most if not all accreditation bodies, obtaining such scientific knowledge will require either hiring qualified in-house staff or contracting with assessors with the necessary experience and expertise. We have accounted for that cost in our proposed regulatory impact analysis.

Again, this function of a recognized accreditation body is important to the public health, and we plan to robustly monitor this aspect of their performance. To that point, we intend to communicate our expectations for the assessment of validation and verification studies, and alternatives to proficiency tests, to the recognized accreditation bodies. We may consider issuing guidance on this topic, making ourselves available for technical assistance such as via regular roundtable meetings/conference calls with recognized accreditation bodies, and we welcome suggestions of other measures we could employ to support the recognized accreditation bodies in this function. We also welcome comments on this proposed provision.

Proposed § 1.1113(d) provides that an accreditation body seeking recognition must demonstrate it is capable of complying with this subpart's requirements for recognized

accreditation bodies, which refers in part to requirements that are specific to this program and not contained in ISO/IEC 17011:2017. These requirements are primarily specified by proposed §§ 1.1119 through 1.1125. For example, those proposed requirements specify that before we will recognize an accreditation body, it must demonstrate to us that it has policies, standard operating procedures, and other appropriate programs and measures in place to meet the proposed impartiality and conflict of interest requirements of proposed § 1.1119 and to make appeals procedures publicly available in accordance with proposed § 1.1121.

Another example of how paragraphs (b) and (d) of proposed § 1.1113 interact involves certain recordkeeping requirements of ISO/IEC 17011:2017 and additional recordkeeping requirements for recognized accreditation bodies under this proposed rule. ISO/IEC 17011:2017 (Ref. 12) section 9.4.2 requires accreditation bodies to have in place procedures by which records are retained for whatever period of time comports with the accreditation bodies' contractual duties, and proposed § 1.1124 would require that recognized accreditation bodies electronically maintain, for 5 years after the date of creation of the records, records created while they are recognized. Accordingly, under proposed § 1.1113(b) and (d) and § 1.1124, an accreditation body seeking recognition would have to demonstrate the capability to implement records procedures to retain records for a period consistent with its contractual and legal obligations, which would include an obligation under proposed § 1.1124 to maintain certain records, for at least 5 years after the date of creation of the records, created while the accreditation body is recognized.

We discuss the documentation needed to meet the requirements of proposed § 1.1113(a)-(d) where we discuss proposed § 1.1128, below.

We invite comment on proposed § 1.1113's requirements for an accreditation body to become recognized under this program. If comments opposing these proposed requirements are submitted, we request comment on what alternative requirements or qualifications an accreditation body should have to be eligible for recognition to accredit laboratories under this program.

D. Proposed Provisions about Requirements for Recognized Accreditation Bodies (Proposed §§ 1.1118 through 1.1125)

Section 422 of the FD&C Act provides that food testing under this program may only be conducted by laboratories accredited by accreditation bodies that we have recognized. Section 422(a)(2) of the FD&C Act directs us to establish the criteria for recognition of accreditation bodies and section 422(a)(7)(B) directs us to promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act. Accordingly, this proposed rule would establish certain criteria and obligations that recognized accreditation bodies must continue to meet to remain recognized. We have proposed these general requirements for recognized accreditation bodies to remain recognized at §§ 1.1118 through 1.1125, and we discuss these requirements below.

1. What Are the General Requirements for Recognized Accreditation Bodies to Remain Recognized? (Proposed § 1.1118)

For recognized accreditation bodies to remain recognized, proposed § 1.1118 would require them to continue to: (a) be a full member of the ILAC and a signatory to the ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017; (b) meet, with respect to activities under this subpart, the requirements of ISO/IEC 17011:2017, which would be incorporated by reference under this rule; (c) demonstrate that it possesses sufficient scientific/technical expertise

to be able to substantively assess certain work of the laboratories it accredits; and (d) comply with the proposed requirements for recognized accreditation bodies. The additional requirements referenced by proposed § 1.1118(d) are primarily specified by proposed §§ 1.1119 through 1.1125. See our discussion at section VI.C, above, for more information about these proposed criteria.

2. What Requirements Apply to How a recognized Accreditation Body Must Protect Against Conflicts of Interest? (Proposed § 1.1119)

We believe that protecting against conflicts of interest among participants in this program is critical to the integrity of this proposed program. We are proposing that recognized accreditation bodies take certain steps to safeguard against conflicts of interest in addition to meeting the impartiality requirements of ISO/IEC 17011:2017. Under proposed § 1.1119(a)(1), a recognized accreditation body would need to ensure that it, and its officers, employees, or other agents involved in accreditation activities, does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it accredits. Section 4.4.11 of ISO/IEC 17011:2017 (Ref. 12) prohibits an accreditation body from offering or providing any food testing services (and from offering or providing any other services that may affect its impartiality). However, we have tentatively concluded that it is also important to prevent a recognized accreditation body from having a financial interest in, managing, or otherwise controlling any laboratory (or any affiliate, parent, or subsidiary) that it accredits, and to explicitly extend that prohibition to officers, employees, and other agents of the recognized accreditation body, in order to protect against conflicts of interest. To ensure the effectiveness of proposed § 1.1119(a)(1), we also have tentatively concluded that it is important to extend the conflict of interest safeguards in this provision to subsidiaries, affiliates, and parent organizations

of the laboratory. We seek comments with regards to whether proposed § 1.1119(a)(1) would impose an undue burden on any existing financial, managerial, or control interest that accreditation bodies may currently have in food testing laboratories and/or whether there are other measures that could prevent such an interest from creating a conflict of interest.

Under proposed § 1.1119(a)(2), a recognized accreditation body would be required to prohibit officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory that they accredit or that are seeking their accreditation that conducts food testing. We seek comment on whether this proposal is sufficient to protect against conflicts of interest related to money, gifts, gratuity, and other items of value.

Proposed § 1.1119(b) provides that the prohibited money, gift, gratuity, or other item of value described by proposed § 1.1119(a)(2) does not include payment of fees for accreditation services, reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory, and onsite lunch, of a de minimis value, provided during the course of an assessment or reassessment, if necessary to facilitate the efficient conduct of the assessment.

Under proposed § 1.1119(c), the financial interests of spouses and children younger than 18 years of age would be imputed to a recognized accreditation body's officers, employees, and other agents involved in its accreditation activities. We have included a similar imputation provision in other regulations, including the FSMA accredited third-party certification regulation. See 21 CFR 1.657(c)) and 21 CFR 516.141(g). We believe this provision would help ensure the integrity of the food testing program.

We seek comment on proposed § 1.1119 and whether there are any other potential conflicts interest for recognized accreditation bodies that should be addressed in this proposed

program. For any comment recommending that we address other types of conflicts, we request recommended measures to address such conflicts, and any references or documents that are available to support the recommendation.

3. How Must a Recognized Accreditation Body Evaluate Laboratories Seeking Accreditation and Oversee the Performance of Laboratories it Accredits? (Proposed § 1.1120)

We anticipate that many laboratories that seek accreditation in our proposed program already will be accredited to ISO/IEC 17025:2017 by an accreditation body to which we have granted recognition. To provide flexibility to such participants, we are proposing laboratory assessment requirements for our program that build upon, and could be combined with, the existing assessments of laboratories that accreditation bodies conduct under ISO/IEC 17011:2017 during an accreditation cycle. For example, if an accreditation body has conducted an onsite assessment of an ISO/IEC 17025:2017 accredited laboratory in the past 2 years, proposed § 1.1120(c) would potentially allow the initial assessment for accreditation to our program to be conducted remotely, and to only address whether the laboratory meets the unique requirements of our program that are not required by ISO/IEC 17025:2017 (see proposed § 1.1138(a)(1) and (c)). If such an onsite assessment has not been conducted in the past 2 years, an accreditation body's initial assessment of a laboratory for accreditation in our program would be required to be conducted onsite and would be required to address whether the laboratory meets all the requirements of our program, including the requirements of ISO/IEC 17025:2017 specified in proposed § 1.1138(a)(2) and (b).

Where the initial assessment for accreditation to our program is conducted remotely under proposed § 1.1120(c), proposed § 1.1120(e) and (f) would require the recognized accreditation body to conduct its first assessment of the sample of the scope of accreditation of

the accredited laboratory onsite, and no later than 2 years after the accreditation body last conducted an onsite assessment of the laboratory, in accordance with ISO/IEC 17011:2017. These proposed requirements are intended to ensure that recognized accreditation bodies conduct onsite assessments of accredited laboratories in our program at least every 2 years. We regard periodic onsite assessments as necessary to effectively evaluating a laboratory. In addition, proposed § 1.1120(g) would require that the reassessment of an accredited laboratory (see ISO/IEC 17011:2017 (Ref. 12, at section 7.9.4)) at the end of the laboratory's accreditation cycle be conducted onsite.

However, when conducting an "onsite" assessment, if conducting a particular assessment activity onsite will not aid in the assessment of a laboratory, proposed § 1.1120(b), (e), and (g), would allow such activities to be conducted remotely. Our intent is that this exception would allow assessment activities such as document review or followup inquiries to a laboratory after an onsite visit to be conducted remotely. Proposed § 1.1120(h) would allow any assessments conducted by a recognized accreditation body other than the assessments referred to in § 1.1120(a), (e), and (g)--that is, the initial assessment, sample of the scope of accreditation, and reassessment--to be conducted entirely remotely if it will not aid the assessment to conduct them onsite.

4. What Appeal Procedures Must a Recognized Accreditation Body Provide for Appeals of Decisions to not Grant Accreditation? (Proposed § 1.1121)

Proposed § 1.1121 provides that a laboratory may appeal a decision by the recognized accreditation body to not grant the accreditation (in-whole or in-part) that the laboratory sought, and the recognized accreditation body must consider the appeal, in accordance with the

requirements of § 1.1118(b). We are proposing this provision because ISO/IEC 17011:2017 does not explicitly state what actions by the accreditation body a laboratory may appeal.

Proposed § 1.1121 would require recognized accreditation bodies to establish and implement certain written procedures for addressing appeals from laboratories challenging a recognized accreditation body's decision to not grant the accreditation (in-whole or in-part) that the laboratory sought. Specifically, proposed § 1.1121 provides that, in addition to meeting the requirements of § 1.1118(b) related to appeals, the recognized accreditation body must establish and implement written procedures to make the appeals procedures publicly available, and use a competent person(s), who may or may not be external to the recognized accreditation body, is free from bias or prejudice and has not participated in the accreditation decision, and is not the subordinate of a person who participated in the accreditation decision, to review and decide appeals. We have tentatively concluded that the requirements of proposed § 1.1121 are important supplemental requirements to ISO/IEC 17011:2017 (Ref. 12) section 7.13 that would provide additional protections to laboratories and help ensure transparency of the program. We seek comments on these proposed requirements, including with respect to whether these proposed requirements would significantly differ from the current appeals practices of accreditation bodies.

5. 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? (Proposed § 1.1122)

Proposed § 1.1122(a) would require recognized accreditation bodies to withdraw the accreditation of a laboratory it accredits when the accredited laboratory substantially fails to comply with this rule. Although section 7.11 of ISO/IEC 17011:2017 (Ref. 12) specifies certain

circumstances that would require the accreditation body to initiate the process for withdrawing the accreditation of the laboratory--including fraudulent behavior--it does not articulate a general standard for when accreditation bodies should initiate the process for withdrawing accreditation.

Although we are proposing that withdrawal of accreditation be initiated by a "substantial" failure to comply with this subpart--and not by minor or de minimis violations--we note that the failure or refusal by the accredited laboratory to take appropriate corrective action (as it is required to do under ISO/IEC 17025:2017 (Ref. 13) at section 8.7) to prevent subsequent minor violations may rise to the level of substantial failure to comply with this rule. For example, if on a single occasion an accredited laboratory fails to provide FDA with documentation of the sampler's qualifications as required by §1.1152(c)(2), that in and of itself would not generally be considered a substantial violation. However, frequent and recurring failure by a laboratory to submit all required components of a full analytical report, even when each instance constitutes a minor violation, combined with a failure or refusal by the accredited laboratory to take appropriate corrective action to prevent such mistakes from recurring, may in certain circumstances be grounds for withdrawal of accreditation.

Proposed § 1.1122(b) provides that a recognized accreditation body may put an accredited laboratory it accredits on probation if the recognized accreditation body determines that the laboratory demonstrates deficiencies in performing its functions under this program that are less serious than would justify withdrawal of the accredited laboratory's accreditation (in-whole or in-part) under proposed § 1.1122(a), and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a reasonable specified period of time. Our intent is that probation would allow recognized accreditation bodies to work with

laboratories they accredit to bring such laboratories into compliance with the program without having to resort to withdrawing accreditation.

As noted, this proposed rule refers to reduction of an accredited laboratory's scope of accreditation by a recognized accreditation body as withdrawal of accreditation in-part. Proposed § 1.1122(c) clarifies that when there are grounds for withdrawal of accreditation, but the deficiencies affect only certain analytical methods within the accredited laboratory's scope of accreditation, the recognized accreditation body may withdraw the accredited laboratory's scope of accreditation for only those affected analytical methods. This provision is meant to facilitate limited withdrawal of accreditation when warranted.

Under proposed § 1.1122(d) a recognized accreditation body may require from a laboratory that it accredits the submission of records that the accredited laboratory would be required to maintain under proposed § 1.1153, in order to assist the recognized accreditation body in determining whether a withdrawal of accreditation (in-whole or in-part) or probation is warranted.

Proposed § 1.1122(e) describes the process a recognized accreditation body must follow when withdrawing the accreditation of an accredited laboratory under this program. Under proposed § 1.1122(e), the recognized accreditation body must notify the laboratory of the withdrawal of the laboratory's accreditation, and the notification must specify whether the withdrawal of accreditation is in-whole or in-part, and if it is in-part, to which testing methods it applies. The notification must also describe the grounds on which the accreditation was withdrawn and state the procedures for appealing the withdrawal.

Proposed § 1.1122(f) provides that the recognized accreditation body would have to: (1) notify the laboratory of its probationary status; (2) describe the grounds for the probation; (3)

identify all deficiencies that the laboratory must correct for the recognized accreditation body to lift the probation; and (4) either inform the laboratory that it has a specific timeframe to take particular corrective actions with respect to the identified deficiencies or require the laboratory to submit a plan to the recognized accreditation body for approval that identifies the appropriate corrective actions the laboratory will take to resolve the identified deficiencies and that identifies appropriate timeframes for resolution. Our intent is that while probation is in effect, the recognized accreditation body will work with the accredited laboratory to bring it into compliance with the requirements of the program.

Proposed § 1.1122(g) describes the consequences of withdrawal of accreditation (in-whole or in-part) or probation. If a recognized accreditation body withdraws the accreditation of a laboratory in-whole, the laboratory would be immediately ineligible to conduct food testing under this rule. If the recognized accreditation body withdraws the accreditation of a laboratory in-part, the laboratory would be immediately ineligible to conduct food testing under this rule with respect to only the specific methods for which accreditation was withdrawn. An accredited laboratory's substantial failure to comply with this rule would undermine the integrity and validity of this proposed program and of the laboratory's affected food testing conducted under this proposed rule. Withdrawal of the laboratory's accreditation would ensure that the laboratory does not continue to conduct the affected food testing under this rule. This consequence is in accordance with the requirement in section 422(b)(1) of the FD&C Act that food testing under section 422 may only be conducted by laboratories that are accredited by recognized accreditation bodies for the methods of analysis appropriate for such food testing. An accredited laboratory that is put on probation by an accreditation body under this proposed rule would be permitted to continue to conduct food testing under this subpart, because it would still be

accredited under this program. However, an accredited laboratory that is put on probation under this proposed rule would not be able to submit abridged analytical reports under § 1.1152(d).

Proposed § 1.1122(h) discusses requirements related to how the recognized accreditation body must handle appeals of withdrawals of accreditation (in-whole or in-part). Under proposed § 1.1122(h), a laboratory may appeal a decision by the recognized accreditation body to withdraw the accreditation (in-whole or in-part) of the laboratory, and the recognized accreditation body must consider the appeal in accordance with the requirements of ISO/IEC 17011:2017 (Ref. 12) (specifically, ISO/IEC 17011:2017 at section 7.13). In addition to meeting the requirements of ISO/IEC 17011:2017 related to appeals, the recognized accreditation body must establish and implement written procedures to make the appeals procedures publicly available; and to use a competent person(s), who may or may not be external to the recognized accreditation body, who is free from bias or prejudice and has not participated in the withdrawal decision, and is not the subordinate of a person who participated in the withdrawal decision, to review and decide appeals.

6. What Reports and Notifications Must a Recognized Accreditation Body Submit to FDA? (Proposed § 1.1123)

Proposed § 1.1123 would require recognized accreditation bodies to submit to FDA reports of their internal audits and notices of matters affecting their recognition and the accreditation status of laboratories they accredit, among other notices.

In proposed § 1.1123 and other provisions in this proposed rule, we are proposing that information submitted to FDA be submitted electronically and in English. Electronic submission of information will help ensure we have ready access to information needed for monitoring and oversight of the program and promote the overall efficiency of the program. We have also

tentatively concluded that requiring electronic submission would not be significantly burdensome for the accreditation bodies and laboratories in this program. FDA plans to establish an electronic portal for this program and recognized accreditation bodies would be able to submit all required notification and reports through that portal.

Proposed § 1.1123(a) would require all reports and notifications submitted to FDA under this proposed section to include contact information for the accreditation body associated with the report or notification and, if applicable, contact information for the laboratory associated with the report or notification. Proposed § 1.1123(b) would require recognized accreditation bodies to submit to FDA electronically, in English, a report of the results of the internal audit required by section 9.7 of ISO/IEC 17011:2017 (Ref. 12) and the results of the audit of its compliance with the requirements of § 1.1118(c) and (d), which would be required by proposed § 1.1125, no later than 45 days after completing the internal audit. Proposed § 1.1123(b) further provides that the report of the recognized accreditation body's internal audit must include a description of the internal audit conducted; a description of any identified deficiencies; a description of any corrective actions taken and any corrective action the recognized accreditation body will take, including the timeline for such corrective actions; and 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. The report does not have to be the same report used internally by the recognized accreditation body, but must be comprehensive enough to demonstrate whether the accreditation body is complying with the requirements of ISO/IEC 17011:2017 and the requirements of § 1.1118(c) and (d). Such reports would provide us with important information about the extent to which the recognized accreditation body is monitoring its own performance

under this program, any deficiencies the recognized accreditation body discovered about its activities, and any corrective actions implemented to address such deficiencies.

Because recognized accreditation bodies must conduct such internal audits under ISO/IEC 17011:2017 and to maintain their ILAC membership, proposed § 1.1123(b) would not require the recognized accreditation body to engage in duplicative internal audits. We also believe that providing 45 days for the recognized accreditation body to compile and submit this report is a reasonable amount of time that strikes a balance between our interest in reviewing information that is important to our oversight of the program and providing the recognized accreditation body sufficient time to initiate any appropriate corrective actions and develop a meaningful internal audit report. If the internal audit results in the recognized accreditation body discovering information that must be submitted to FDA immediately under proposed § 1.1123(c), we expect the recognized accreditation body to submit that particular information to us immediately, within 48 hours, in accordance with proposed § 1.1123(c).

Section 422(a)(1)(C) of the FD&C Act requires, as a condition of recognition, that recognized accreditation bodies report to us any changes that would affect the recognition of such recognition body. To implement this provision, proposed § 1.1123(c)(1) would require the recognized accreditation body to notify us immediately of any changes it is aware of that would affect its recognition, including a description of the change, and, if the change is one made by the recognized accreditation body, an explanation for the purpose of the change. Proposed § 1.1123(c)(1) would cover 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. A change that prevents or undermines the accreditation body's compliance with this proposed program may result in revocation of recognition under proposed § 1.1131. We would encourage recognized accreditation bodies to contact us if there are uncertainties about whether a change should be reported under proposed § 1.1123(c)(1).

Proposed § 1.1123(c)(2) through (6) would require recognized accreditation bodies to immediately notify us, within 48 hours, of certain information related to the accreditation status of laboratories they accredit or that have sought their accreditation. Immediate notice is essential so that we can take timely action to update the public website described by proposed § 1.1109; accept food testing results from newly accredited laboratories; refuse to accept food testing results from laboratories that are no longer accredited for the food testing at issue; and take any other actions as appropriate based on such information.

Proposed § 1.1123(c)(2) and (3) would require recognized accreditation bodies to submit information to us about their grants and denials of accreditation (in-whole or in-part) of laboratories. If a recognized accreditation body received a request for accreditation (which includes a request from a laboratory to add testing methods to its scope of accreditation) from a laboratory, and the recognized accreditation body granted accreditation for certain testing methods in the laboratory's request but denied accreditation for other testing methods in the laboratory's request, proposed § 1.1123 would only require that a recognized accreditation body provide us with a single notification encompassing this information, as long as the notification includes all of the information that would be required under proposed § 1.1123(c)(2) and (3).

Proposed § 1.1123(c)(2) and (3) would require the notification to include the scope of accreditation requested by the laboratory, the scope of accreditation granted and/or denied, and

the ground for such denial, and the date of such grant. This information would be useful for our program oversight. For example, it would allow us to monitor accreditation activities, including situations where a laboratory appears to be successively applying for, and being denied, accreditation from different recognized accreditation bodies without changing its practices or application to remedy the basis or bases for the previous denial(s).

Proposed § 1.1123(c)(4) would require a recognized accreditation body to notify us immediately if it receives notice that an accredited laboratory it accredits intends to relinquish its accreditation (in-whole or in-part). Proposed § 1.1123(c)(4) would also require such notification to include the scope of accreditation to which the relinquishment applies, and the effective date of the relinquishment.

Proposed § 1.1123(c)(5) would require a recognized accreditation body to notify us immediately when it withdraws (in-whole or in-part) its accreditation of a laboratory. Proposed § 1.1123(c)(5) would also require such notification to include the scope of accreditation to which the withdrawal applies, and the grounds for the withdrawal.

Proposed § 1.1123(c)(6) would require a recognized accreditation body to notify us immediately when it puts an accredited laboratory on probation. Proposed § 1.1123(c)(6) would also require such notification to include the grounds for the probation, and any date by which the recognized accreditation body has determined the accredited laboratory must take appropriate corrective action.

Having information on the reason(s) for probation or withdrawal of accreditation, and whether such withdrawal is in-whole or in-part, is important to us because it may affect whether and how we conduct any followup actions with regards to the laboratory in question or how we review food testing results from the laboratory in the future.

Proposed § 1.1123(c)(7) would require recognized accreditation bodies to notify us immediately when the recognized accreditation body knows that an accredited laboratory it accredits has committed fraud or submitted material false statements to FDA. We note that we would also typically expect the recognized accreditation body to initiate its process to withdraw accreditation of the laboratory in this circumstance (in accordance with ISO/IEC 17011:2017 (Ref. 12) section 7.11.2). Proposed § 1.1123(c)(7) would require the notification to include a description of the basis for the accreditation body's knowledge of the fraud or material false statements, a description of the alleged fraud or material false statements, and the actions taken by the accreditation body with respect to such laboratory. Recognized accreditation bodies may be in a better position than us in many cases to determine whether an accredited laboratory has committed fraud or submitted material false statements to the FDA, due to recognized accreditation bodies' role in monitoring the laboratories they accredit. Furthermore, although proposed § 1.1152(j) would require accredited laboratories to immediately notify us of any changes that would affect an accredited laboratory's compliance with the program requirements or that would otherwise affect the laboratory's accreditation, an accredited laboratory that has committed fraud or submitted material false statements to us may be unlikely to notify us that it did so.

7. What Records Requirements Must a Recognized Accreditation Body Meet? (Proposed § 1.1124)

This proposed rule identifies specific types of records a recognized accreditation body would be required to control and maintain to document compliance with applicable requirements. The recognized accreditation body also would be required to provide FDA access to such records.

Proposed § 1.1124(a) provides that, in addition to meeting the records requirements of ISO/IEC 17011:2017 (as required by proposed § 1.1118(b)), an accreditation body that has been recognized must electronically maintain records demonstrating its compliance with the program, created while it is recognized, for 5 years after the date of creation of the record. The requirements of § 1.1124 would apply to accreditation bodies that have been recognized even if they later are no longer recognized. We are proposing this requirement because maintenance of such records could be vital to our management of this program.

We are not proposing to require records subject to this proposed section to be maintained in English. In accordance with our position on this issue in the accredited third-party certification final rule, we are proposing to allow recognized accreditation bodies to maintain and submit records in languages other than English, provided that they electronically submit an English translation within a reasonable time thereafter. We decline to set a specific timeframe for submission of the translation because the circumstances surrounding each request will differ (e.g., varying number of documents/pages). Further, we are proposing under § 1.1124(b) to require that if FDA requests records electronically, the records must be submitted no later than 10 business days after the date of the request, with the exception that records covered by the immediate notification provision in § 1.1123(c) would be required to be submitted within 48 hours. By allowing records to be submitted in a language other than English, we think that it will not be unduly burdensome for recognized accreditation bodies to provide most requested records electronically within 10 days.

We have tentatively concluded that the records maintenance and access requirements in proposed § 1.1124 are necessary for us to adequately monitor recognized accreditation bodies, as we are directed to do by section 422(a)(7) of the FD&C Act. For example, access to such

records could facilitate our determination of whether revocation of the accreditation body's recognition is warranted.

Proposed § 1.1124(c) further clarifies that recognized accreditation bodies must not prevent or interfere with FDA's access to the records accredited laboratories it accredits are required to maintain under proposed § 1.1153. When FDA requests, under proposed § 1.1153 or proposed § 1.1159, that a laboratory submit or provide FDA access to records the laboratory would be required to maintain under proposed § 1.1146(b) or proposed § 1.1153, we expect that the recognized accreditation body that accredits the laboratory would not interfere with our access to such records. Maintaining freedom of access to such records is important to facilitate FDA's ability to provide general oversight of the food testing program, with respect to both recognized accreditation bodies and accredited laboratories.

8. What Internal Audit Requirements Must a Recognized Accreditation Body Meet? (Proposed § 1.1125)

Proposed § 1.1125 would require a recognized accreditation body to audit its compliance with the requirements under § 1.1118(c) and (d) as part of the internal audit that a recognized accreditation body conducts under § 1.1118(b). Requiring recognized accreditation bodies to monitor their conformance to the requirements that are specific to this program, as well as to the requirements of ISO/IEC 17011:2017, would ensure that accreditation bodies' internal audits cover all the requirements of this program. As discussed, proposed § 1.1123(b)(1) would require the results of this audit to be submitted to us.

E. Proposed Provisions about Procedures for Recognition of Accreditation Bodies (Proposed §§ 1.1128 through 1.1133)

In these sections we propose how an accreditation body may apply for recognition under this rule, propose procedures for recognition, probation, revocation, and relinquishment of recognition of accreditation bodies, and propose how FDA would oversee recognized accreditation bodies.

1. How Does an Accreditation Body Apply to FDA for Recognition or Renewal of Recognition? (Proposed § 1.1128)

This proposed rule would establish procedures for accreditation bodies to follow when applying to FDA for recognition or renewal of recognition. Proposed § 1.1128(a) would provide that an accreditation body seeking recognition must submit an application to FDA demonstrating that it meets the eligibility requirements of proposed § 1.1113, which describes the proposed requirements for accreditation bodies to become recognized to accredit laboratories to conduct food testing under this program.

Similarly, proposed § 1.1128(b) would require an accreditation body seeking renewal of its recognition to submit a renewal application to us demonstrating that it continues to meet the requirements of this program.

Proposed § 1.1128(c) clarifies that accreditation bodies applying for recognition or renewal of recognition must submit documentation of conformance with ISO/IEC 17011:2017, and documentation of ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017, in meeting the requirements of proposed § 1.1113(a) and (b) or proposed § 1.1118(a) and (b), as applicable. Although we recognize that documentation of ILAC MRA signatory status under this program represents a determination that an accreditation body has demonstrated competence to ISO/IEC 17011:2017, proposed § 1.1128(c) would require independent documentation that an accreditation body demonstrates competence to ISO/IEC

17011:2017 to provide us additional assurance that an accreditation body meets the specific requirements of the standard. Independent documentation of ISO/IEC 17011:2017 competence could include the report of a peer evaluation by a regional cooperation group or ILAC conducted as part of the ILAC MRA application and evaluation process. An accreditation body applying for recognition or renewal of recognition also would be required to submit documentation demonstrating it meets the requirements for accreditation bodies that are specific to this program under proposed § 1.1113(c) and (d) or proposed § 1.1118(c) and (d), as applicable. We would expect documentation of proposed § 1.1113(c) and (d) to come in the form of documents such as standard operating procedures, records procedures, the resumes of the scientific and technical staff or contractors who review validation and verification studies, and examples of contracts the accreditation body uses in its activities, while documentation of proposed § 1.1118(c) and (d) would consist of documents created during the accreditation body's term of recognition, such as the internal audit required under proposed § 1.1125. We request comments on what additional documents would demonstrate that an accreditation body meets the requirements of proposed § 1.1113(c) and (d) and proposed § 1.1118(c) and (d).

Where the application for recognition or renewal of recognition does not sufficiently demonstrate that the accreditation body meets the requirements for recognition by FDA, it may be necessary for FDA to review additional documentation to determine whether the accreditation body meets the recognition requirements of the program, and FDA also may, as is noted by proposed § 1.1129(b), request and conduct an onsite assessment of the applicant if necessary. Such additional documentation may include the accreditation body's reviews, assessments, and investigations of laboratories; results of the accreditation body's self-monitoring and internal audits; documents and other information regarding the accreditation body's authority,

qualifications (including the expertise and training of its employees that assess laboratories that conduct food testing), resources, quality assurance program, and recordkeeping, reporting, notification, and monitoring procedures. For applications for renewal of recognition, FDA may also review documents and other information of one or more of the laboratories that are accredited by the recognized accreditation body.

Applications for recognition and renewal are subject to certain requirements for the form and manner of submission. Under paragraphs (d) and (e) of proposed § 1.1128 the accreditation body must submit to FDA a signed application (signed by the applicant or by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition), accompanied by any supporting documents, electronically and in English. We also propose to require an applicant to provide any translation or interpretation services we need to process the application. This may include providing translators or interpreters for FDA staff conducting onsite assessments of the applicant. We invite comment on our proposal to require submissions in English and to require translation or interpretation services as necessary.

2. How Will FDA Review Applications for Recognition and Applications for Renewal of Recognition? (Proposed § 1.1129)

Under proposed § 1.1129(a), FDA would review an accreditation body's recognition or renewal application for completeness and would notify the applicant of any deficiencies. We are proposing to review applications on a first-in, first-out basis according to the date the accreditation body submits the completed application. However, we may prioritize the review of specific applications based on program needs. To encourage applicants to supply any missing information promptly, we will not place an application in the queue for review until it is

complete. Allowing incomplete applications in the queue might hold up applications that are ready for review, but were submitted later in time.

Under proposed § 1.1129(b), FDA would evaluate applications to determine whether the applicant meets the requirements for recognition or renewal of recognition. The evaluation may include an onsite assessment of the accreditation body. For renewal applications, if FDA does not reach a final decision before an accreditation body's recognition terminates by expiration, FDA may extend the terms of recognition for a specified period of time or until FDA reaches a final decision on the renewal application. Proposed § 1.1129(b) further provides that FDA would notify the applicant, in writing, regarding whether the application has been approved or denied, and that we may make such notification electronically.

Under proposed § 1.1129(c), we would notify applicants of our decision to approve the application for recognition or renewal through issuance of recognition that would list any conditions associated with the recognition, including the duration of recognition.

Proposed § 1.1129(d) would allow us to grant recognition to an accreditation body for up to 5 years at a time (except if FDA needs to extend the term of recognition while it makes a renewal determination, as described at proposed § 1.1129(b)), although we will determine the length of recognition on a case-by-case basis. We are proposing the 5-year upper limit in accordance with section 422(a)(7) of the FD&C Act, which requires us to (in pertinent part), periodically, and in no case less than once every 5 years, reevaluate accreditation bodies recognized under this program to assess whether they meet the criteria for recognition. We do not necessarily expect to grant every recognition at the maximum 5-year duration. We believe that shorter terms of recognition may potentially be appropriate in the initial years of the food testing program or for any accreditation bodies with fewer years of experience accrediting

laboratories to conduct food testing. When we proposed the same duration for recognition of accreditation bodies for the accredited third-party certification regulation, we received support for the proposal and for the flexibility to determine the length of recognition on a case-by-case basis, although we also did receive some comments expressing concern that we did not propose a fixed duration of recognition (80 FR 74570 at 74601). As we noted in the accredited third-party certification final rule, where appropriate, we would grant recognition for the maximum duration of 5 years. Id. However, we also recognize it may be appropriate for the duration of recognition to vary depending on a number of factors, such as accreditation body experience and, for example, whether the accreditation body has had problems meeting the recognition requirements in the past.

Under proposed § 1.1129(e), if we deny a recognition or renewal application, we would notify the applicant, through an issuance of a notification of denial of recognition or denial of renewal application, that the accreditation body's recognition or renewal application has been denied. The notification of denial of recognition or denial of renewal application would state the basis for the denial and describe the procedures for requesting reconsideration of the application under § 1.1171.

Proposed § 1.1129(f) provides that an applicant whose application for renewal or recognition was denied by FDA must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records it is required to maintain under proposed § 1.1124(a) and to make them available to FDA as required by proposed § 1.1124(b). Proposed § 1.1129(f) would also require that the contact information for the custodian must include, at a minimum, an email address and the street address where the records required by

proposed § 1.1124 will be located. As noted previously, under proposed § 1.1124 accreditation bodies that have been recognized must electronically maintain, for at least 5 years after the date of creation of the records, records subject to proposed § 1.1124 that were created during the term of recognition.

Under proposed § 1.1129(g), FDA would promptly issue a notice of the denial of the application for renewal of recognition of the accreditation body to all laboratories accredited by the accreditation body whose application for renewal of recognition was denied.

Under proposed § 1.1129(h), FDA would provide public notice on the website described in proposed § 1.1109 of the issuance of a denial of a renewal application and include the date of the issuance of the denial of a renewal application. This is the same approach we took in the accredited third-party certification regulation with respect to denials of renewal applications. See 21 CFR 1.631(h). We believe notification of denial of renewal would be important information to make easily available to interested parties and the public.

3. How will FDA oversee recognized accreditation bodies? (Proposed § 1.1130)

As noted above, section 422(a)(7)(A) of the FD&C Act requires us to periodically, and in no case less than once every 5 years, reevaluate recognized accreditation bodies. Section 422(a)(7)(B) of the FD&C Act requires us to promptly revoke the recognition of a recognized accreditation body for failure to meet the requirements of section 422 of the FD&C Act.

As we discuss above, proposed § 1.1129(d) provides that we may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition. Proposed § 1.1130(a) provides that we will assess each recognized accreditation body to determine its compliance with the applicable requirements of this proposed rule by no later than 4 years after the date of recognition for a 5-year recognition period, or by no later than the midterm point for a

recognition period of less than 5 years. Accordingly, we propose to assess recognized accreditation bodies at least once during their period of recognition, in addition to any assessment we may have conducted during our review of an application for recognition and in addition to any assessment we may conduct during a review of an application for renewal of recognition. Proposed § 1.1130(a) provides that our assessment of a recognized accreditation body may include review of records, an onsite assessment of the accreditation body, and onsite assessments of accredited laboratories the recognized accreditation body accredits, with or without the recognized accreditation body present (we would conduct such onsite assessments under proposed § 1.1159).

Proposed § 1.1130(b) provides that we may conduct additional assessments of a recognized accreditation body, at any time, to determine the recognized accreditation body's compliance with the applicable requirements of the program. We may or may not notify the recognized accreditation body that we will be conducting such an assessment, which may be onsite.

Our assessments of recognized accreditation bodies under proposed § 1.1130 may be as brief or as extensive as is warranted and may include our review of an accreditation body's accreditations, assessments, and investigations of laboratories; results of an accreditation body's internal audits; documents and other information accreditation bodies are required maintain under §§ 1.1118 and 1.1124 regarding the accreditation body's authority, qualifications, resources, quality assurance program, and recordkeeping, reporting, notification, and monitoring procedures.

4. When Will FDA Revoke the Recognition of an Accreditation Body or put a Recognized Accreditation Body on Probation? (Proposed § 1.1131)

This proposed rule would establish the criteria and procedures for revocation of recognition of an accreditation body. Section 422(a)(7)(B) of the FD&C Act requires us to promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act. Accordingly, if a recognized accreditation body ceases to meet the criteria for recognition we establish under section 422 of the FD&C Act, we must revoke the recognized accreditation body's recognition.

Under proposed § 1.1131(a), we would revoke the recognition of an accreditation body if it fails to meet the requirements of this program, or where FDA determines the accreditation body has committed fraud or submitted material false statements to FDA.

Examples of what would qualify as a failure by a recognized accreditation body to meet the requirements of this program would include:

- Refusing to allow FDA to access records as required by proposed § 1.1124, to allow FDA to conduct an onsite assessment under proposed § 1.1130, or to allow FDA to otherwise conduct an assessment under proposed § 1.1130. Denial of access and ability to perform our oversight functions would prevent us from meeting our statutory responsibilities under section 422 of the FD&C Act to periodically reevaluate accreditation bodies and to promptly revoke the recognition of an accreditation body found not to be in compliance with section 422 of the FD&C Act.
- Demonstrating bias or lack of objectivity when conducting activities under this rule would violate the impartiality requirements of ISO/IEC 17011:2017, which recognized accreditation bodies must meet in accordance with § 1.1118(b).
- Failing to take timely and appropriate corrective action in accordance with ISO/IEC 17011:2017 (Ref. 12) section 9.5 (which proposed § 1.1118(b) of this rule would require

the recognized accreditation body to comply with) after the recognized accreditation body identifies, or should have identified, that the recognized accreditation body is not operating in conformance with one or more requirements of this proposed rule.

Fraud or the submission of material false statements by recognized accreditation bodies would undermine our ability to implement the program and would undermine the program's integrity and credibility. We request comment on whether this section should also allow for FDA to revoke a recognized accreditation body's recognition for "other good cause." If you submit a comment in favor of adding such a provision, we request the comment provide one or more examples of what would constitute such other good cause (and yet would not otherwise support revocation under the proposed § 1.1131(a)).

Proposed § 1.1131(b)(1) provides that, when we revoke an accreditation body's recognition we would notify the accreditation body that its recognition has been revoked through the issuance of a revocation stating the grounds for revocation, the procedures for requesting a regulatory hearing on the revocation under proposed § 1.1173, and the procedures for requesting reinstatement of recognition under proposed § 1.1133.

Proposed § 1.1131(b)(2) would require the accreditation body to, within 10 business days of the date of issuance of revocation, notify us electronically, in English, of the name of the custodian who will maintain records and make them available to FDA as required by proposed § 1.1124. Proposed § 1.1131(b)(2) further provides that the contact information for the custodian must include, at a minimum, an email address and the street address where the records will be located. As we have discussed previously, the accreditation body's responsibility under this proposed rule to maintain certain records created while it was recognized does not end when the accreditation body is no longer recognized.

Proposed § 1.1131(c) provides that if we determine that a recognized accreditation body has demonstrated deficiencies in performing its functions under this proposed rule that are less serious and more limited than those identified in proposed § 1.1131(a), and it is reasonably likely that the accreditation body will be able to correct such deficiencies within a reasonable period of time, we may temporarily put the recognized accreditation body on probation, rather than revoke its recognition, and request that the accreditation body take appropriate corrective actions. We expect that the probationary status of a recognized accreditation body would allow us to work with the recognized accreditation body to bring it into compliance with the requirements of the program without having to resort to the more permanent remedy of revoking recognition.

Proposed § 1.1131(d) provides that the probationary status of the recognized accreditation body would remain in effect until the recognized accreditation body demonstrates to our satisfaction that it has successfully addressed the deficiencies specified by FDA within the time period identified by FDA. Proposed § 1.1131(d) also provides that, alternatively, the probationary period would end if we determine that revocation of recognition is warranted. We would likely determine that revocation of recognition is appropriate if the accreditation body fails or refuses to take appropriate corrective actions, or otherwise does not comply with the conditions specified by the notification of probation within the timeframe specified, or if appropriate, an otherwise reasonable timeframe.

Proposed § 1.1131(e) provides that if we put the recognized accreditation body on probation, we would formally notify the accreditation body of its probation. The notification would describe the grounds for the probation, identify all deficiencies that must be corrected for us to lift the probation, would identify a specified period of time to take certain corrective actions to address the deficiencies specified by us.

Proposed § 1.1131(f) would provide that an accreditation body that has had its recognition revoked may not accredit laboratories under this program or continue to oversee the laboratories it has previously accredited. This provision would also clarify that a recognized accreditation body that has been put on probation by FDA is expected to continue to oversee laboratories that it has accredited under this subpart and is permitted to continue to accredit laboratories under § 1.1120 of this subpart. We would normally anticipate that such an accreditation body would continue to fulfill its responsibilities under this program during the probationary period. Note that FDA may conduct additional oversight of recognized accreditation bodies that are on probation, to help ensure quality and competency on the part of that particular accreditation body (and by extension for the integrity of the overall program).

Proposed § 1.1131(g) provides that FDA would issue a notice of the probation or revocation of recognition to all laboratories accredited by the accreditation body whose recognition was revoked or who was put on probation. In proposed § 1.1164, we address the effects on accredited laboratories of the revocation of the recognition of their accreditation bodies.

Proposed § 1.1131(h) clarifies that we would also provide notice on the website described in proposed § 1.1109, in accordance with proposed § 1.1109, of our issuance of probation or revocation of recognition of the accreditation body. This is consistent with the provisions of proposed § 1.1109.

We solicit comments on our tentative conclusions regarding possible grounds for probation and revocation of recognition, and with respect to the procedures and requirements we have proposed here related to revocation and probation of recognition.

5. What Must a Recognized Accreditation Body Do if it Wants to Voluntarily Relinquish its Recognition or Does Not Want to Renew its Recognition? (Proposed § 1.1132)

Proposed § 1.1132 requires a recognized accreditation body that voluntarily relinquishes its recognition before the recognition period terminates by expiration to follow certain procedures. Relinquishment on the initiative of the accreditation body is distinct from revocation of recognition under proposed § 1.1131 and is a mechanism provided to recognition bodies in the accredited third-party certification regulation and under FDA's mammography program. See 21 CFR 1.635 and 21 CFR 900.3(e). We are proposing certain procedural requirements, similar to those in the mammography and third-party accreditation programs, which accreditation bodies would be required to follow in relinquishing recognition or when a recognized accreditation body intends to allow its recognition to expire without seeking renewal. We believe these procedures are necessary to ensure an orderly transition for laboratories accredited by an accreditation body that is relinquishing its recognition or allowing it to expire and for us to make necessary adjustments in the program based on that relinquishment or expiration.

Proposed § 1.1132(a) describes the procedures that a recognized accreditation body would need to follow when it intends to relinquish its recognition or when it wishes to allow its recognition to expire without seeking renewal. In order to voluntarily relinquish its recognition or allow it to expire, a recognized accreditation body would need to notify FDA electronically and in English at least 60 days before voluntarily relinquishing its recognition or allowing its recognition to expire.

Proposed § 1.1132(a) would also require the recognized accreditation body to provide the name and contact information of the custodian who will maintain the records required under proposed § 1.1124 after the date of relinquishment or the date its recognition expires, as

applicable, and make such records available to FDA as required by proposed § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by proposed § 1.1124 will be located.

Under proposed § 1.1132(b), we would require the accreditation body to notify the laboratories it had accredited that the accreditation body intends to relinquish its recognition or to allow its recognition to expire, specifying the date on which relinquishment or expiration will occur, and at least 60 days in advance.

Proposed § 1.1132(c) states that we would provide notice on the website described in proposed § 1.1109 of the voluntary relinquishment or expiration of recognition of an accreditation body. This provision is consistent with the provisions of proposed § 1.1109, which would establish what information we would display on the website described by § 1.1109.

6. How Does an Accreditation Body Request Reinstatement of Recognition? (Proposed § 1.1133)

This proposed section describes the procedures that an accreditation body would have to follow when seeking reinstatement of its recognition. The procedures the accreditation body would be required to follow would differ depending on whether we revoked the accreditation body's recognition or the accreditation body voluntarily relinquished its recognition or allowed its recognition to expire.

Under proposed § 1.1133(a), an accreditation body that has had its recognition revoked may seek reinstatement of recognition by submitting a new application for recognition under proposed § 1.1128. The accreditation body must also submit evidence to us that the grounds for revocation have been resolved, including evidence addressing the cause(s) or condition(s) that

were the basis for revocation, and it must identify measures it implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

Under proposed § 1.1133(b), an accreditation body that previously relinquished its recognition or allowed its recognition to expire may seek recognition by submitting a new application for recognition under proposed § 1.1128.

F. Proposed Provisions about Accreditation of Laboratories (Proposed § 1.1138)

This proposed rule would establish the requirements for a laboratory seeking accreditation by a recognized accreditation body to test food in this program. Section 422(a)(2) and (a)(5) of the FD&C Act mention independent private laboratories, laboratories run and operated by Federal agencies, States, localities, and foreign laboratories, as examples of laboratories that recognized accreditation bodies may accredit under this program, so long as they meet accreditation requirements for our program. We expect a variety of these types of laboratories would apply to this program. With regard to States in particular, it is our understanding that State and public university laboratories currently conduct a significant portion of the shell egg testing which would be covered by this proposed rule. We therefore believe some state laboratories would apply.

Section 422 of the FD&C Act contains requirements for laboratories to be accredited, including that they have a demonstrated capability to conduct one or more sampling and analytical testing methodologies for food (section 422(a)(2)) and that they meet model laboratory standards that FDA is required to develop (section 422(a)(6)).

Section 422(a)(6) of the FD&C Act further requires that the model laboratory standards include methods to ensure that: (1) appropriate analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are

certified as true and accurate (section 422(a)(6)(A)(i)); (2) internal quality systems are established and maintained (section 422(a)(6)(A)(ii)); (3) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited (section 422(a)(6)(A)(iii)); and (4) individuals who conduct the analyses are qualified by training and experience to do so (section 422(a)(6)(A)(iv)). Section 422(a)(6)(B) of the FD&C Act also authorizes us to include in the model laboratory standards any other criteria we determine are appropriate.

Section 422(a)(6) of the FD&C Act directs us to consult existing standards for guidance in developing the model laboratory standards for use in qualifying laboratories for accreditation. As discussed, we have consulted, and propose to incorporate by reference, ISO/IEC 17025:2017. The model laboratory standards we are proposing consist of ISO/IEC 17025:2017, which laboratories would be required to meet (except for a few provisions, as we discuss in more detail below) to become accredited in accordance with proposed § 1.1138(a)(2), and our additional proposed requirements in §§ 1.1146 through 1.1158. For example, ISO/IEC 17025:2017 (Ref. 13) section 7.9 requires accredited laboratories to establish a process for evaluating and responding to complaints, which we tentatively conclude would fulfill the model laboratory standard requirement of section 422(a)(6)(A)(iii) of the FD&C Act.

We carefully considered whether to include a sampling accreditation requirement in the proposed rule. Proper sampling procedures are essential in order for analytical testing results to convey meaningful information about the food product or environment at issue. Accreditation for sampling could increase confidence in the training and procedures of samplers and potentially help ensure the collection of representative samples.

According to our analysis (Ref. 1) of the applicable data stored in our internal systems, from January 1, 2016, to December 31, 2017, approximately 63 percent of sampling conducted for analysis in support of admission of food offered for import that we had detained without physical examination was conducted by five entities accredited for sampling under ISO/IEC 17025. Approximately 37 percent of such sampling conducted during that time was conducted by more than 300 entities not accredited for sampling under any standard.

It is our understanding that whereas under the 2005 version of ISO/IEC 17025 only laboratories are eligible for accreditation, starting with the 2017 version of ISO/IEC 17025, entities that do not conduct any analyses (i.e., an entity that solely collects samples) may be considered for accreditation for sampling under ISO/IEC 17025. It is also our understanding that it will take some time to develop and implement this new policy. Some of the larger laboratory accreditation bodies in the United States indicated that demand for accrediting entities that only conduct sampling is still relatively small, and thus far, these accreditation bodies have not performed accreditation assessments of such entities. (See Meeting Minutes, "Sampling Accreditation Discussion with A[ccreditation] B[odie]s," November 13, 2017 (Ref. 14).) As 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.

Given these considerations, we are not proposing requirements for the accreditation of sampling in this proposed rule. However, we strongly encourage all samplers to consider accreditation, and we may reassess our position after accreditation bodies have gained experience with accrediting entities that only conduct sampling. We will watch developments in this area with interest, and would be willing to consider expanding the proposed program to include accreditation of laboratories and sampling services to perform sampling in the future.

While we are not proposing requirements for accreditation of samplers, we invite comment on the matter. More specifically, what is the current capacity of accredited sampling entities, both laboratories and sampling services (i.e., entities that only perform sampling)? Are there attributes unique to sampling that present challenges in terms of the continued development of this field? What existing standards (e.g., ISO/IEC 17025, ISO 9001, ISO/IEC 17020) would be best to use as a basis for developing a more comprehensive and focused consensus sampling standard? What are the critical detailed requirements that should be included in a consensus sampling standard to ensure food safety? What standards are currently employed to assess samplers, are they effective, and in what ways are they insufficient?

We note that because we are not proposing accreditation for sampling under this proposed rule, we would not expect laboratories seeking to become accredited under this program to demonstrate the capability to conduct sampling methods under this program if finalized. If we were to propose to require accreditation for sampling under the authority of section 422 of the FD&C Act in the future, at that time we would likely propose that entities seeking to become accredited for sampling would have to demonstrate the capability to conduct one or more methods of sampling for food testing.

What Requirements Must a Laboratory Meet to Become Accredited by a Recognized Accreditation Body? (Proposed § 1.1138)

Proposed § 1.1138 states the requirements a laboratory must meet to be accredited by a recognized accreditation body to conduct food testing under this program.

Section 422(a)(2) of the FD&C Act requires, in pertinent part, that this program provide for the accreditation of laboratories with a demonstrated capability to conduct one or more analytical testing methodologies for food and section 422(b)(1) of the FD&C Act requires, in

pertinent part, that food testing under this program be conducted by laboratories that have been accredited for the appropriate analytical testing methodology. We have considered these two provisions and propose to interpret section 422(b)(1) as requiring laboratories to be accredited on a method-specific basis, and to interpret section 422(a)(2) of the FD&C Act to mean that a laboratory may become accredited even if it seeks to be accredited for a single method. Accordingly, proposed § 1.1138(a)(1) would require that a laboratory seeking to be accredited must demonstrate that it is capable of conducting each method of food testing for which it seeks to be accredited. The laboratory would have to do so by meeting the requirements described under proposed § 1.1138(a)(1)(i) and (ii).

Proposed § 1.1138(a)(1)(i) and (ii) clarify how an accredited laboratory must demonstrate it is capable of conducting each method for which it seeks to be accredited. Proposed § 1.1138(a)(1)(i) provides that a laboratory must do so by submitting information related to validation or verification studies.

Validation studies are required in certain circumstances by ISO/IEC 17025:2017 (Ref. 13) section 7.2, which we have already incorporated by reference, but which we would explicitly require in proposed § 1.1151(c)(1). For example, a validation study would be required when a laboratory seeks to be accredited for a non-standard method or for a standard method it will use outside the method's intended application. Validation is meant to demonstrate that a method is suitable for the intended purpose.

Method verification is meant to verify that the laboratory can properly apply the method for a specific intended use, specifically with respect to the limit of detection or probability of detection. We would require verification studies in proposed § 1.1151(d)(1), and proposed § 1.1151(d)(2) would require an accredited laboratory to record certain information related to a

verification study (e.g., the results of the verification, supporting analytical data) (we discuss proposed § 1.1151(d)(1) and (2) in more detail in section VI.G.7). Under this program, a laboratory may demonstrate that it is capable of conducting a particular method by submitting to the recognized accreditation body the verification study information required in proposed § 1.1151(d)(2).

To be clear, under this program a laboratory may fulfill the requirements of proposed § 1.1138(a)(1)(i) by submitting to the recognized accreditation body either validation study information or verification study information.

Proposed § 1.1138(a)(1)(ii) provides that the laboratory must also, in order to demonstrate it is capable of conducting a method of food testing for which it seeks to be accredited, pass, or have passed within the past year, a proficiency test for the method(s), subject to the exception that if the laboratory determines there is no proficiency testing program available that addresses the method, or that proficiency testing for the method is otherwise impracticable, the accredited laboratory may instead subject, or have subjected in the past year, the method to an appropriate comparison program. This proposed requirement and exception reflect a similar requirement and exception in AOAC International's Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2005 (April 2015 revision) (AOAC 17025 Guidelines) (Ref. 9) at section 5.9.1. Proposed § 1.1138(a)(1)(ii) further provides that the laboratory's determination there is no proficiency testing program available that addresses the method must be reviewed, and approved or denied (as appropriate), by the recognized accreditation body from which the laboratory is seeking accreditation. For more information

about the exception in proposed § 1.1138(a)(1)(ii), please see our discussion of proposed § 1.1148(a)(2) below at section VI.G.3.

Under proposed § 1.1138(a)(2) a laboratory seeking accreditation under this program must demonstrate it meets (or, with respect to activities the laboratory may only conduct once accredited, is capable of meeting) the requirements of ISO/IEC 17025:2017. ISO/IEC 17025:2017 sets general standards for the competence of testing laboratories, including general management requirements such as impartiality and quality assurance. There are, however, a few provisions in ISO/IEC 17025:2017 that we propose to exclude from our requirements, as reflected in proposed § 1.1138(b). Section 7.3 of ISO/IEC 17025:2017 (Ref. 13), which addresses sampling, would be excluded because, as discussed previously, we are not proposing accreditation of sampling (see the introduction to section VI.F for additional discussion of this issue). We also are not proposing to require laboratories to meet ISO/IEC 17025:2017 section 7.8, which describes requirements for reporting test results to customers, to avoid potential conflicts with proposed § 1.1152, which contains requirements for the food testing results and supporting documentation that are necessary for us to assess the validity of food testing conducted under this program. We are also proposing in § 1.1138(b) that laboratories seeking accreditation are not required to meet, or demonstrate that they are capable of meeting, requirements 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 rule. For example, ISO/IEC 17025:2017 section 7.1.1(d) would require the laboratory to ensure that the methods it uses are capable of meeting the customers' requirements, ISO/IEC 17025:2017 section 7.2.1.4 indicates that the laboratory's customer may choose the method of analysis to be used for food testing, and ISO/IEC 17025:2017 section 7.2.1.7 would

restrict the laboratory from deviating from a method if the customer does not accept the deviation. As such, requiring accredited laboratories to meet all of the customer requirement provisions of ISO/IEC 17025:2017 could create potential conflicts with the requirements of section 422 of the FD&C Act.

Proposed § 1.1138(c) would require laboratories seeking accreditation to demonstrate they are capable of meeting and operating in conformance with all of this subpart's requirements for accredited laboratories. For example, under proposed §§ 1.1152 and 1.1153 laboratories would have to meet certain requirements specific to this program relating to reporting, notifications, and records, and under proposed § 1.1148 laboratories would have to meet certain quality assurance requirements specific to this program and beyond the requirements in ISO/IEC 17025:2017. A laboratory would have to demonstrate that it has implemented written procedures to meet those requirements of this proposed rule so that it will be able to comply with such requirements once it is accredited.

G. Proposed Requirements for Accredited Laboratories (Proposed §§ 1.1146 through 1.1153)

Proposed §§ 1.1146 through 1.1153 would establish certain model laboratory standards that accredited laboratories must meet to remain accredited. In accordance with section 422(a)(6)(A) of the FD&C Act, these model laboratory standards would help ensure that appropriate analytical procedures and commercially available techniques are followed and reports of analyses are certified as true and accurate; internal quality systems are established and maintained; procedures exist to evaluate and respond promptly to complaints regarding analyses for which the laboratory is accredited; and individuals who conduct analyses are qualified by training and experience to do so. In accordance with section 422(a)(6)(B) of the FD&C Act, we have also proposed additional requirements that laboratories would have to meet to remain

accredited, such as certain requirements relating to methods of analysis, notifications and submissions to FDA, and recordkeeping.

1. What Are the General Requirements for Accredited Laboratories to Remain Accredited? (Proposed § 1.1146)

Proposed § 1.1146 provides that for an accredited laboratory to remain accredited, the accredited laboratory must be capable of conducting each method of analysis for the testing of food for which it is accredited, continue to conform to the applicable provisions of ISO/IEC 17025:2017, and fulfill the additional requirements of this subpart. For a discussion of why we believe these ISO/IEC 17205:2017 requirements are important for laboratories to meet to be accredited under this proposed rule, please see our previous discussion of proposed § 1.1138 in section VI.F.1.

2. What Impartiality and Conflict of Interest Requirements Must Accredited Laboratories Meet? (Proposed § 1.1147)

Proposed § 1.1147 would require accredited laboratories to meet certain requirements related to impartiality and conflicts of interest in addition to those impartiality and conflict of interest requirements of ISO/IEC 17025:2017 they would have to meet in accordance with proposed § 1.1146(b).

ISO/IEC 17025:2017 contains several requirements related to impartiality and conflicts of interest that accredited laboratories would have to meet under proposed § 1.1146(b). For example, ISO/IEC 17025:2017 (Ref. 13) 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 that, if a risk

to impartiality is identified, the laboratory must be able to demonstrate how the laboratory eliminates or minimizes the risk.

However, we have tentatively determined that additional requirements related to impartiality and conflicts of interest are appropriate in the context of this rule. With certain exceptions, proposed § 1.1147(a) would prohibit the accredited laboratory's officers, employees, contractors, and agents involved in food testing 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 accredited laboratory. Proposed § 1.1147(b)(1) and (2) provide the caveats that the prohibited items of value specified in proposed § 1.1147(a) do not include payment of fees for food testing services or reimbursement of direct costs associated with the food testing by the accredited laboratory. With respect to accredited laboratories that are owned by the owner or consignee of the food that is tested or to be tested, proposed § 1.1147(b)(3) provides that the prohibited items of value specified in proposed § 1.1147(a) also do not include the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

Proposed § 1.1147(c) would require the owner or consignee's payment to the accredited laboratory for food testing services and/or reimbursement of direct costs associated with food testing to be independent of whether the test results indicate the tested food is or appears to be violative. It is crucial that the accredited laboratory be able to conduct its testing without fear of receiving reduced payment or no payment from the owner or consignee if the food testing results are violative. We seek comment with respect to whether there are more effective provisions that might achieve the aim of impartial food testing.

3. What Quality Assurance Requirements Must Accredited Laboratories Meet? (Proposed § 1.1148)

Proposed § 1.1148 would establish quality assurance requirements accredited laboratories must meet for proficiency testing and the use of reference materials and quality control samples, in addition to the ISO/IEC 17025:2017 quality assurance requirements accredited laboratories would need to meet under proposed § 1.1146(b). Specifically, under proposed § 1.1146(b), accredited laboratories would have to develop, maintain, and implement a complaints program (see ISO/IEC 17025:2017 (Ref. 13) section 7.9), a program to control nonconforming testing work (see ISO/IEC 17025:2017 section 7.10), a program to continually improve (see ISO/IEC 17025:2017 section 8.6), a corrective action program (see ISO/IEC 17025:2017 section 8.7), an internal audit program (see ISO/IEC 17025:2017 section 8.8), a management review program (see ISO/IEC 17025:2017 section 8.9), and policies for ensuring the validity of test results (see ISO/IEC 17025:2017 section 7.7).

As described by ISO/IEC 17025:2017, proficiency testing evaluates laboratory performance against established criteria. ISO/IEC 17025:2017 (Ref. 13) section 7.7.2 provides that accredited laboratories must participate in proficiency testing and/or interlaboratory comparison programs other than proficiency testing. ISO/IEC 17011:2017 (which applies to accreditation bodies), indicates that the accreditation body's review of proficiency test results may help it assess laboratories, but ISO/IEC 17011:2017 does not require accreditation bodies to require the laboratories they accredit to participate in a proficiency testing program (ISO/IEC 17011:2017 (Ref. 12) at section 3.24 n. 1). Although both ISO/IEC standards address proficiency testing, we are proposing more specific proficiency testing requirements in this document to support the regular evaluation of the performance of accredited laboratories in this program.

Proposed § 1.1148(a)(1) would require accredited laboratories to participate in a proficiency testing program or programs, provided by a competent proficiency testing organization, and ensure that proficiency testing is conducted at least once per year for each method within the accredited laboratory's scope of accreditation (subject to an exception in proposed § 1.1148(a)(2), which we discuss below). In developing proposed § 1.1148(a), we considered how various existing standards address the frequency and coverage of laboratory proficiency testing. Some accreditation bodies that accredit food testing laboratories require laboratories they accredit to conduct proficiency testing on their entire scope of accreditation over a four-year accreditation period and participate in at least one proficiency testing activity per year. (See, e.g., "R103--General Requirements: Proficiency Testing for ISO/IEC Laboratories," American Association for Laboratory Accreditation (Ref. 15), at p. 6; and "Accreditation Requirements: ISO/IEC 17025 Testing Laboratories (Non-Forensics)," ANSI/ASQ National Accreditation Board (Ref. 16), at pp. 4-5). We note that if only one proficiency testing activity takes place each year, the bulk of proficiency testing for a laboratory's scope of accreditation could occur at one time during the laboratory's accreditation period. We tentatively conclude that requiring yearly proficiency testing for each method on a laboratory's scope of accreditation would encourage more periodic proficiency testing throughout the accreditation period. This element of proposed § 1.1148(a) is based on the AOAC 17025 Guidelines (Ref. 9) at section 5.9.1, which provides that laboratories participate in at least one proficiency test annually for each "test, type of test/method, and/or technique on the scope of accreditation". Periodic proficiency testing throughout the four-year accreditation period should also help the accredited laboratory manage its other ongoing quality assurance activities (e.g., its control of nonconforming testing work under ISO/IEC 17025:2017 (Ref. 13)

section 7.10 and its program to continually improve under ISO/IEC 17025:2017 section 8.6). We seek comments on our proposed requirements for the frequency of proficiency testing.

We are proposing to require in § 1.1148(a)(1) that the proficiency test provider be "competent." We note that ISO/IEC 17043:2010, "Conformity Assessment--General Requirements for Proficiency Testing" (Ref. 17) provides specific standards for proficiency test providers. We are requesting comment on whether, and if so, under what circumstances, we should require accredited laboratories to only use proficiency test providers accredited to ISO/IEC 17043 for proficiency testing under this proposed rule.

Proposed § 1.1148(a)(2) describes an exception to the proposed proficiency testing requirement. Proposed § 1.1148(a)(2) states that if the accredited laboratory determines there is no proficiency testing program available that addresses a particular method of analysis in the accredited laboratory's scope of accreditation, or that participating in a proficiency testing program for the particular method is otherwise impracticable, the accredited laboratory may subject that method to an appropriate comparison program. The laboratory's determination must be reviewed, and approved or denied (as appropriate), by the recognized accreditation body that accredits the laboratory. The AOAC 17025 Guidelines (Ref. 9) at section 5.9.1 provide a helpful list of examples of such alternative comparison programs.

Proposed § 1.1148(b) would require accredited laboratories to ensure their procedures for monitoring the validity of the results of testing it conducts under this program include the use of reference materials or quality control samples with each batch of samples it tests under this program. This requirement reflects a similar requirement in the AOAC 17025 Guidelines (Ref. 9), at section 5.9.1. ISO/IEC 17025:2017 (Ref. 13) section 7.7, which accredited laboratories must comply with under proposed § 1.1146(b), requires that laboratories' procedures for

monitoring the validity of their results "include, where appropriate" use of reference materials or quality control materials. We tentatively agree with the AOAC 17025 Guidelines that it is always appropriate to use of reference materials or quality control samples when conducting food testing. Therefore, to encourage clarity and consistency with respect to the use of reference materials and quality control samples under this program, we have proposed to adopt the AOAC 17025 Guidelines' position on this issue.

4. What Oversight Standards Apply to Sampling? (Proposed § 1.1149)

Because we are not proposing accreditation for sampling, we are not proposing model standards for sampling. However, whether a sample is collected and maintained properly is integral to whether analysis of that sample will produce information that is of regulatory significance. For example, if the analyzed sample(s) is not representative of the food product or environment at issue, the analysis of the sample(s) will not result in information that is meaningful with respect to the food product or environment at issue. Accordingly, we are proposing provisions that would allow us to exercise oversight over the sampling conducted as part of this program. Proposed § 1.1149 would require the accredited laboratory to develop or obtain (depending on whether the accredited laboratory or a different entity collected the sample) and submit to FDA certain information about the sampler and sampling before the accredited laboratory analyzes the collected sample.

Specifically, proposed § 1.1149(a) would require that, before the accredited laboratory analyzes the sample, it must either develop (if it collected the sample) or obtain (if another entity collected the sample) the following documentation:

- Written documentation of the sampler's applicable qualifications by training and experience. If the accredited laboratory collects the sample, the accredited laboratory

would need to develop such documentation the first time the individual collects a sample under this subpart. If another entity collects the sample, the accredited laboratory would need to obtain such documentation the first time it receives a sample collected under this subpart from that sampler. The accredited laboratory must also develop or obtain such documentation if the accredited laboratory learns that the sampler's qualifications have significantly changed since the accredited laboratory last developed or obtained documentation of the sampler's qualifications.

- A written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler 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. This information would help us determine whether the sampling conducted would result in a sample that is representative of the food product or environment in question. Identification of the sampler would allow us to determine whether we have the sampler's qualifications on file already and/or whether their qualifications may now be significantly different.
- A written sample collection report for each sample collected. The written sample collection report must, at a minimum, include:
    - The product code of the food product sampled (if product is being sampled) or the location of and a description of the environment (if environment is being sampled). This information would help us determine whether the correct lot or lots were sampled and whether the sample is otherwise representative of the food product or environment in question.

- The date(s) of the sampling. This information would help us, in part, identify whether certain lots were sampled and help us review the chain of custody of the sample. For example, if the sample was collected a significant amount of time before the analysis, we may evaluate whether the documented chain of custody procedures for the sample would have preserved the sample's integrity.
- The size, identity, and quantity of the sample(s). This information would help us determine whether the sample is representative of the food product or environment in question.
- Documentation of sample collection procedures and any sample preparation techniques. This information would help us determine whether the sampling resulted in a sample that is representative of the food product or environment at issue.
- Documentation of the chain of custody of the sample(s), and of measures taken, to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s). This information would help us determine whether the sample received by the laboratory is the sample that was collected from the product or environment at issue and whether the integrity of the collected sample was compromised between collection of the sample and its analysis. Documentation of the chain of custody should account for the continuous custody of the sample and indicate any gaps in the chain of custody. Documentation of measures taken to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s), might include, for example, documentation of the use of tamper-evident containers, use of secure storage spaces, and any

refrigeration or freezing of the sample. The documentation should indicate at what point in the chain of custody such measures were taken.

Proposed § 1.1149(b) clarifies that we may consider the analysis of a sample to be invalid if the requirements of § 1.1149(a) are not met.

5. What Requirements Apply to Analysis of Samples by an Accredited Laboratory? (Proposed § 1.1150)

Proposed § 1.1150 would establish standards that laboratory analysis conducted under this proposed rule would need to meet, procedures the analysis would need to follow, and other requirements such as the qualifications of the individuals who perform the analysis. Proposed § 1.1150 explicitly states that accredited laboratories must meet the requirements of this section in addition meeting to the requirements in ISO/IEC 17025:2017 relating to analysis that an accredited laboratory is required to meet under § 1.1146(b).

Proposed § 1.1150(a) would require the analysis to be conducted on either the sample(s) received, or, if appropriate for the analysis, on a representative sample of the sample(s) received. Because the sample(s) received may consist of too much material to analyze in its entirety, a laboratory will often take a subsample(s) from the sample(s) received. The laboratory must ensure that it follows appropriate procedures so that the subsample(s) they analyze are representative of the lot. For example, in some circumstances it may be appropriate to homogenize the sample(s) by grinding, sieving, blending, or mixing the original sample(s) and taking a subsample(s) from the resulting mixture.

Proposed § 1.1150(b) would require that the analyst(s) that conducts the analysis be qualified by appropriate education, training, and/or experience to conduct the analysis; to have appropriately demonstrated their ability to conduct the method properly in the specific context of

the food testing to be conducted; and to be in compliance with the conflict of interest requirements of proposed § 1.1146(b) (i.e., the applicable sections of ISO/IEC 17025:2017) and proposed § 1.1147. Of note, under proposed § 1.1152(g)(12) (which we discuss in more detail at section VI.G.8), the laboratory must provide certain information about the analyst's or analysts' qualifications to us at our request.

Proposed § 1.1150(c) clarifies that the method used to conduct the food testing must meet the requirements of proposed § 1.1151 (requirements for methods of analysis, which we discuss at section VI.G.7).

Proposed § 1.1150(d) requires that the accredited laboratory 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. Please see our discussion of proposed § 1.1152(g) for more information about what information full analytical reports must contain.

5. What Requirements Apply to the Methods of Analysis an Accredited Laboratory uses to Conduct Food Testing Under this Subpart? (Proposed § 1.1151)

Food testing subject to section 422(b)(1) of the FD&C Act must be conducted by accredited laboratories that have been accredited for the appropriate analytical testing methodology or methodologies." Proposed § 1.1151 would establish certain requirements with regard to methods of analysis, which would apply in addition to the requirements in ISO/IEC 17025:2017 (Ref. 13) section 7.2 relating to selection, validation, and verification of methods (under proposed § 1.1146(b)).

Proposed § 1.1151(a) would require that analysis under this program be conducted using a method(s) of analysis that: (1) is fit for purpose, (2) is within the accredited laboratory's scope of accreditation, (3) has been appropriately validated for use in such food testing, in accordance

with § 1.1146(b) (i.e., the applicable ISO/IEC 17025:2017 provisions) and paragraph (c) of § 1.1151, and (4) has been appropriately verified by the accredited laboratory for use in such food testing, in accordance with paragraph (d) of § 1.1151.

As we noted above, proposed § 1.1151(a)(1) would state that all methods of analysis used in food testing under this rule would have to be fit for purpose, in that they may only be applied for the food testing to which they are intended to apply and for the purpose for which they are validated. For example, if a method of analysis was developed and validated only for determining the presence and level of chloramphenicol in shrimp, the method may only be used to determine the presence and level of chloramphenicol in shrimp. The concept of fit for purpose is related to the concept of validation, in that successful validation of a method for a purpose for which the method had not yet been validated would typically demonstrate that the method is in fact fit for that purpose. For example, if the method that has been validated only for determining the presence and level of chloramphenicol in shrimp is subsequently validated for determining the presence and level of chloramphenicol in fish, the method could then be applied as fit for the purpose of determining the presence and level of chloramphenicol in fish.

Proposed § 1.1151(a)(2) would require that the method used be included within the accredited laboratory's scope of accreditation. This requirement flows from section 422(a)(6) of the FD&C Act, which requires laboratories to be accredited for the specified testing methods they use for food testing in this program. Note that while some of the food testing that would be covered by this program is static (e.g., the testing of shell eggs described in § 118.4(a)(2)(i)) other testing scenarios covered by this program are dynamic and will change with different circumstances (e.g., testing to support removal from Import Alert). Therefore, we are not proposing a defined inventory of possible scopes; rather, under this program laboratories would

be able to become accredited for a variety of food analytical methods, such as methods listed in the Bacteriological Analytical Manual (BAM) of procedures preferred by FDA for the detection of pathogens and microbial toxins in food (see https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm).

Proposed § 1.1151(a)(3) and (4), respectively, would require that the method must have been appropriately validated for use in the food testing to be conducted and have been appropriately verified by the accredited laboratory for use in such food testing. We have issued procedures for our laboratories on these issues (e.g., "Methods, Method Verification and Validation," ORA Laboratory Manual Vol. II Section 2, document number 5.4.5 (Ref. 18) and "Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition" (Ref. 19)), and we note that many food testing laboratories currently adhere to voluntary consensus standards and procedures issued by organizations, such as ISO and AOAC International, that address how to ensure analytical methods used by the laboratory are fit for purpose and appropriately validated and verified. Depending on the needs of the program as it develops, in the future we may issue guidance on this topic. Note that FDA maintains a website listing of all the FDA regulatory methods currently being used for food and feed safety programs, including links to other online manuals/compendia of methods (at https://www.fda.gov/food/science-research-food/laboratory-methods-food). On that web page we also provide links to the method development, validation, and implementation guidelines of FDA's Office of Food Policy and Response, and a list of methods currently undergoing validation.

Proposed § 1.1151(b) provides that with respect to food testing conducted under proposed § 1.1107(a)(1), the method or methods of analysis (if any) prescribed by the applicable

testing requirement in the FD&C Act or implementing regulations are the only appropriate methods for the food testing to be conducted; and with respect to food testing conducted under proposed § 1.1107(a)(2), the method or methods of analysis (if any) prescribed by the food testing order are the only appropriate methods for the food testing to be conducted. In such cases, the statute, regulation, or food testing order would dictate the appropriate method for the food testing.

Proposed §1151.1(c)(1) would make explicit for this program the validation requirement in ISO/IEC 17025:2017 (Ref. 13) section 7.2.2, which accredited laboratories must follow in accordance with proposed § 1.1146(b). As stated in ISO/IEC 17025:2017 section 7.2.2, accredited laboratories would be required to validate "non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified."

Proposed § 1.1151(c)(2) would require an accredited laboratory validating a method under this subpart to record all the information required by ISO/IEC 17025:2017 (Ref. 13) section 7.2.2.4 as well as the supporting analytical data. In the context of validation studies, supporting analytical data may include information about the detection limit, selectivity of method, linearity, limit of repeatability and/or reproducibility (accuracy and precision), robustness against external influences and/or cross sensitivity against interference from the matrix of sample. We have tentatively determined that this information is necessary for us to assess the validation and determine whether it demonstrates that the accredited laboratory can properly apply the method for the specific intended use.

Proposed § 1.1151(d)(1) provides that before an accredited laboratory conducts food testing under this program 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 program, the accredited laboratory must have verified it can properly perform the method for the specific intended use. We propose to make this requirement explicit for this program; and believe it is consistent with ISO/IEC 17025:2017 (Ref. 13) section 7.2.1 (which accredited laboratories must follow in accordance with proposed § 1.1146(b)), which requires that accredited laboratories verify a method before they introduce the method.

Proposed § 1.1151(d)(2) would require that an 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. We have tentatively determined that this information is necessary for us to determine whether the verification is valid.

Section 422(b)(3) of the FD&C Act provides that FDA may waive requirements of section 422(b) if 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 the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. In accordance with this statutory provision, proposed § 1.1151(e) provides that an accredited laboratory may submit a written request to FDA requesting FDA's permission to use a method or methods outside of its scope of accreditation for food testing. FDA may approve the request if both of the following conditions are satisfied: (1) a new methodology or methodologies have been developed and validated but no reasonably available laboratory has been accredited to perform such methodology or methodologies and (2) the use of such method or methods is necessary to prevent, control, or mitigate a food emergency

or foodborne illness outbreak. We propose to interpret section 422(b)(3)(A) of the FD&C Act to allow waiver of section 422(b)'s requirements when no "reasonably available" laboratory has been accredited to perform such a methodology. If an accredited laboratory exists but is not reasonably available (e.g., due to geographic location, capacity constraints, or other factors), such a laboratory would not be able to address the emergent circumstances in which section 422(b)(3) applies. Therefore, if no "reasonably available" laboratory has been accredited to perform the methodology in question, we believe section 422(b)(3)(A) of the FD&C Act may be interpreted to permit waiver of section 422(b)'s requirements. We have tentatively determined that any laboratory that conducts food testing under the exception of section 422(b)(3) of the FD&C Act must be accredited for at least one method under this program, because such accreditation would ensure that all of the requirements for this program apply to the laboratory and would ensure an important level of general competence and reliability.

7. What Notifications, Results, and Reports Must Accredited Laboratories Submit to FDA? (Proposed § 1.1152)

Proposed § 1.1152 would require that accredited laboratories submit test results, sampling reports, analytical reports, validation and verification studies, and certain other notifications to FDA about food testing they conduct under this program. Proposed § 1.1152 would also establish requirements for such submissions, including requirements about what information the submissions must contain. Under section 422(b)(2) of the FD&C Act, the results of food testing conducted under this program must be submitted directly to FDA. To facilitate our meaningful review of such test results, it is critical that we receive supporting information necessary for us to understand the test results and to assess the validity of the underlying testing conducted in that instance. Section 422 of the FD&C Act acknowledges that other information

may be sent to FDA under this program, specifically requiring that the model standards we establish under this program must ensure that reports of analyses, which laboratories currently routinely submit to us as testimony in the circumstances described by section 422(b)(1)(B) of the FD&C Act, are certified as true and accurate (see section 422(a)(6) of the FD&C Act).

Proposed § 1.1152(a) through (c) address what information (e.g., test results, sample collection reports, and analytical reports) about the food testing conducted under this program must be submitted to FDA. We have proposed in § 1.1152(d) that accredited laboratories that meet certain requirements may submit abridged analytical reports in lieu of full analytical reports, subject to certain exceptions in proposed § 1.1152(e). Proposed § 1.1152(f) would establish what information must be in an abridged analytical report, and proposed § 1.1152(g) would establish what information must be in a full analytical report. Proposed § 1.1152(h) would require an accredited laboratory using a non-standard method to provide FDA with documentation of the method. By "documentation" we mean the method standard operating procedure, or some other document that describes the steps within the method. Proposed § 1.1152(i) would establish requirements for the submission of advance notices of sampling to FDA. Proposed § 1.1152(j) would establish requirements for notifications to FDA of significant changes affecting the accreditation of the accredited laboratory. Proposed § 1.1152(k) would state if FDA does not receive all information required under this section we may consider the related testing to be invalid.

Proposed § 1.1152(a) would require all documentation submitted to us by accredited laboratories under the subpart, which includes test results, sampling reports, analytical reports, validation and verification studies, and certain notifications, to be submitted to us electronically and in English, and to contain certain generally applicable information. More specifically,

proposed § 1.1152(a)(1)(i) would require all such notifications, results, reports, and studies submitted to us to include the legal name and street address of the accredited laboratory submitting the information, and would require the documents to identify an appropriate point-of-contact for the accredited laboratory who FDA may contact with questions or comments regarding the notification, result, report, or study, and to include the email address and telephone number of the point of contact. Identification of the accredited laboratory submitting the report would help us identify which accredited laboratory is responsible for the submissions. The identification of a point-of-contact for the accredited laboratory, and the email address and telephone number of the point-of-contact, would help us efficiently conduct any followup communications, as appropriate, with the accredited laboratory that submitted the information. Proposed § 1.1152(a)(1) would also require all documents submitted to FDA under this section to display an identification unique to each test result, report, notification, or study. Of note, proposed § 1.1152(b)(3) would require the test results to cross reference the unique identifiers of all associated reports, notifications, and studies. These requirements are intended to help us quickly identify which submissions are related to each other as we receive them. This provision also reflects a similar provision in ISO/IEC 17025:2017 (Ref. 13) at section 7.8.2, "Common requirements for reports." The last general requirement for submissions, per proposed § 1.1152(a)(iii), is that each submission must be true, accurate, unambiguous, and objective. This requirement would implement the requirement underlying section 422(a)(6)(A)(i) of the FD&C Act that the model standards established by this program for accredited laboratories must ensure that "reports of analyses are certified as true and accurate," and help ensure that accredited laboratories submissions clearly and correctly communicate the information the submission is based on and is intended to communicate. We have tentatively concluded that it is

appropriate to establish such a requirement for all submissions under this program to FDA from accredited laboratories.

Proposed § 1.1152(a)(2) would clarify that the accredited laboratory that conducts the analysis of the sample under this program is responsible for the submission of all related notifications, results, reports, and studies to FDA as required by this section.

Proposed § 1.1152(a)(3) provides that if the accredited laboratory that is responsible for the submission becomes aware that any aspect of the submission is inaccurate, the accredited laboratory or sampling service must immediately inform FDA and submit a corrected version. Proposed § 1.1152(a)(3) further provides that such corrections to the notification, result, report, or study must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017 (Ref. 13) section 7.8.8 (incorporated by reference, see § 1.1138(a)(2)). This requirement is important so that we may easily determine when and how a submission has been amended and to which prior submissions the amended submission relates.

Proposed § 1.1152(a)(4) would require that any opinions and interpretations in any notification, result, report, or study submitted to FDA must meet the requirements in ISO/IEC 17025:2017 (Ref. 13) section 7.8.7 (which is incorporated by reference, see proposed § 1.1138(a)(2)), 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 section 7.8.6 (incorporated by reference, see proposed § 1.1138(a)(2)). We have tentatively determined that ISO/IEC 17025:2017 section 7.8.7 provides rules that will be effective at ensuring that opinions and interpretations in submissions to FDA are appropriate and clearly identified. Similarly, we have tentatively determined that ISO/IEC 17025:2017 section 7.8.6 provides rules that will be effective at ensuring that

statements of conformity in submissions to FDA under this section are accompanied by appropriate disclosures.

Proposed § 1.1152(b) would establish requirements for submission of test results to FDA. In accordance with section 422(b)(2) of the FD&C Act, proposed § 1.1152(b)(1) provides that the results of all tests conducted under this subpart must be directly submitted to FDA. Proposed § 1.1152(b)(2) specifies that the accredited laboratory that conducted the analysis must submit the results of the food testing to FDA via the website described by § 1.1109, unless FDA has directed a different method of submission in connection with the testing conducted under § 1.1107(a)(2) or (3).

Proposed § 1.1152(b)(3) would require the test results submitted to FDA under this section to be clear, and identify the unique identification of the associated notifications, reports, and studies. These requirements would help us ensure that we can efficiently review the test results and associated submissions as one package.

Proposed § 1.1152(c) would require certain documentation to be submitted with the test results. Specifically, we would require submission to FDA of the following documentation with each test results:

- All sampling plans and sample collection reports related to the food testing conducted, as obtained or developed by the accredited laboratory in accordance with proposed § 1.1149.
- Written documentation of the sampler's qualifications, if proposed § 1.1149(a)(1) requires the accredited laboratory to obtain or develop such documentation.
- The analytical report or reports documenting the analysis related to the food testing. The analytical reports would have to be either abridged or full, depending on whether the

accredited laboratory is permitted under proposed § 1.1152(d) to submit abridged analytical reports to FDA. For more information about our proposed requirements for abridged and full analytical reports, see our discussion of proposed § 1.1152(d) through (g) below.

- For any validation studies required by proposed § 1.1151(c)(1), any documentation required by proposed § 1.1151(c)(2), except when the circumstances of proposed § 1.1152(c)(6) (which we discussed in connection with § 1.1138(a)(1)(a), previously) apply with respect to the validation study.
- For any verification studies required by § 1.151(d)(1), the documentation required by § 1.1151(d)(2), except when the circumstances of proposed § 1.1152(c)(6) (which we discussed in connection with § 1.1138(a)(1)(A), previously) apply with respect to the verification study.
- Proposed § 1.1152(c)(6) would establish an important exception to the above two validation and verification study documentation requirements. Proposed § 1.1152(c)(6) provides that we would not require the accredited laboratory to submit the validation or verification study to FDA if the accredited laboratory submitted the validation or verification study to its recognized accreditation body as required by proposed § 1.1138(a)(1) (which addresses certain requirements a laboratory must meet to become accredited by a recognized accreditation body). We have tentatively determined that it is not appropriate under this program for us to duplicate, on a routine basis, the accreditation efforts of accredited laboratory's recognized accreditation body. If the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1), the accreditation body must instead submit to FDA,

in lieu of the validation or verification study, a statement that the validation or verification study has been submitted to its recognized accreditation body in accordance with § 1.1138(a)(1), and the accredited laboratory must identify the method, analyte, and matrix that were the subject of the validation or verification study. This information would provide us with sufficient information to determine whether the accredited laboratory's invocation of this exception is appropriate. As discussed in relation to proposed § 1.1113(c), we expect recognized accreditation bodies to substantively review the validation and verification studies they receive from laboratories participating in this program.

- A certification from one or more members of the 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 specify the name, title, and signature of the certifier or certifiers. The certification that reports are true and accurate is required by section 422(a)(6)(A)(i) of the FD&C Act, but we propose to require the certification to also extend to the test results and related submissions. We propose to include a certification that the laboratory has submitted all tests conducted under this subpart not only because direct submission of test results to FDA is a statutory directive, but because it is vital to the integrity of this program. We expect this certification to help ensure that appropriate laboratory personnel have confirmed the accuracy of the statement.

  Note that we do not intend for this certification to mean that the laboratory is attesting that the tested product satisfies regulatory requirements as it is FDA's purview (and not the laboratory's) to determine whether the product meets our regulatory

standards. Although the word "certification" has such meaning in conformity assessment terminology, we intend a different meaning here. We are using the word, "certification" to mean that the management of the laboratory acknowledges that the test was conducted and vouches that the test was conducted properly according to laboratory defined procedures, that the report is true and accurate, and that the report represents all the testing conducted by that laboratory of that particular product for this program.

We propose in § 1.1152(d) that accredited laboratories that meet certain requirements may submit abridged analytical reports under this program in lieu of full analytical reports. We would require full analytical reports to document, in full and step-by-step, the analysis conducted by the accredited laboratory, so that we can engage in a meaningful indepth scientific review of the analysis to determine whether, in that instance, the analysis was valid. For example, we propose in § 1.1152(g) that a full analytical report must include all original compilations of raw data, identify and describe negative and positive quality controls, and include all calculations, among other documentation. Abridged analytical reports, in contrast to full analytical reports, would only need to include certain more limited information describing the analysis.

We view the standards we are creating in this program as relatively rigorous. Accreditation to ISO/IEC 17025:2017, along with the quality assurance, conflict of interest, and other additional requirements contained in this proposed rule, enhance our confidence in the laboratories that participate. In addition, the recognized accreditation bodies will serve an ongoing role monitoring the laboratories they have accredited under this program, helping ensure that the required standards are maintained and serving as an additional observer of the laboratories. For those reasons, and contingent on a positive experience with the accredited laboratories' initial reports, we would have adequate assurance in the validity of the test results

to permit abridged analytical reports, and we tentatively conclude that such abridged analytical reports will provide an adequate basis for FDA to make regulatory decisions.

In addition, we believe that allowing the submission of abridged analytical reports under this food testing program may provide advantages to FDA and the public. We should be able to review abridged analytical reports more quickly than we review full analytical reports, and this may enable us to decide more quickly whether a food safety problem has been addressed and whether to admit an article of food into the United States. This may further allow us to allocate our own laboratory and field resources more efficiently. Furthermore, not requiring accredited laboratories to compile and submit a full analytical report every time they conduct food testing under this program may reduce some of the paperwork and administrative costs of food testing conducted under this program.

At the same time, we note that this laboratory accreditation program would not guarantee that testing by participating laboratories will be valid in every instance. Indeed, a single false negative test result submitted to us under this program could lead us to admit violative food into the United States, or to incorrectly determine that a food safety problem has been adequately addressed, thus potentially harming U.S. consumers. Accordingly, we do not propose to automatically or always allow all accredited laboratories to submit abridged analytical reports under this program. Instead, we have proposed that only accredited laboratories that have fulfilled certain conditions may submit abridged analytical reports to us under this program, and that in certain circumstances we may require such accredited laboratories to submit full analytical reports.

Proposed § 1.1152(e)(1) provides that FDA will occasionally require an accredited laboratory permitted to submit abridged analytical reports to submit to FDA, within 48 hours of

the request, the full version of the analytical report. Such a policy will serve the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program. By "occasionally," we tentatively conclude that we would not invoke the exception for more than approximately 10 percent of the abridged analytical reports that any given accredited laboratory submits to us per year. We would invoke this exception at our discretion, sometimes on a random basis and sometimes based on risk. With regard to risk, we may be more likely to invoke this requirement where the analysis conducted is for an analyte that presents a relatively high risk to public health (e.g., *Clostridium botulinum*). We may also invoke the exception where something in the abridged laboratory report appears to be amiss (e.g., the method used does not appear to be appropriate). However, we may also invoke the exception on a random basis and in relatively low-risk situations to ensure consistent laboratory performance across the program. At a minimum, we expect to invoke this exception to require each accredited laboratory permitted to submit abridged analytical reports to us to submit at least one full analytical report to us per year. We also note that this provision (along with proposed § 1.1150(d)) would effectively require that accredited laboratories permitted to submit abridged analytical reports to us must still consistently document their analyses internally to such a degree that the accredited laboratory would be able to complete and submit a full analytical report for the analysis to FDA within forty-eight hours of when FDA requests the full analytical report.

We have proposed an additional exception, in proposed § 1.1152(e)(2), to accredited laboratories' ability to submit abridged analytical reports to us under this program. Proposed § 1.1152(e)(2) provides that FDA may require an accredited laboratory that is permitted to submit abridged analytical reports to submit full analytical reports to FDA under this program if such analytical reports relate to an FDA investigation or FDA enforcement proceeding. We may

invoke this exception, for example, in the case of a food testing order involving a potentially high risk to public health, or as part of evidence for a hearing under section 423(c) of the FD&C Act, in which case we would have determined that not only does a suspected or identified food safety problem exist but that there is also reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals.

Proposed § 1.1152(d)(1) describes the criteria for an accredited laboratory seeking initial permission to submit abridged analytical reports. Accredited laboratories that are not currently disqualified from submitting abridged analytical reports (see our discussion about disqualification under proposed § 1.1152(d)(6) and (7)) and that are not on probation would become permitted to submit abridged analytical reports to FDA under this program on an ongoing basis after FDA has given notice that all four of the following conditions are fulfilled: (1) the accredited laboratory submits 10 consecutive full analytical reports to FDA under this program, (2) the consecutive full analytical reports include at least one full analytical report relating to each major food testing discipline represented by the methods in the accredited laboratory's scope of accreditation for which it seeks to submit abridged analytical reports, (3) none of the consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing, and (4) the consecutive full analytical reports submitted by the accredited laboratory do not contain repeated administrative deficiencies. Accordingly, when laboratories become accredited under the program they must first submit full laboratory analytical reports under § 1.1152(g), along with the test results and the other documentation required under proposed § 1.1152(c), which FDA will assess to determine whether the four conditions are fulfilled. FDA will track whether the accredited laboratory has fulfilled the four conditions.

As we state above, we are proposing to require that the 10 consecutive full analytical reports includes least one full analytical report relating to each major food testing discipline represented by the methods in the accredited laboratory's scope of accreditation for which the accredited laboratory seeks to submit abridged analytical reports. Three examples of the "major food testing disciplines" relevant in this context are microbiology, chemistry, and physical (filth).

Proposed § 1.1152(d)(2) addresses the impact of an accredited laboratory's failure to initially satisfy the four criteria of § 1.1152(d)(1). Under proposed § 1.1152(d)(2)(i), if any analytical report submitted by the accredited laboratory to FDA under this program demonstrates a material substantive shortcoming in the food testing, the accredited laboratory would become disqualified from submitting abridged analytical reports, in accordance with proposed § 1.1152(d)(6)(i). If the 10 full analytical reports submitted by an accredited laboratory are substantively satisfactory but suffer from repeated administrative deficiencies, the accredited laboratory would have another chance to submit consecutive full analytical reports that fulfill the criteria in § 1.1152(d)(1)(i) through (iv). Repeated administrative deficiencies during the second set of 10 full analytical reports would result in disqualification in accordance with proposed § 1.1152(d)(6)(i).

We propose that a single material substantive shortcoming in the food testing in any of the initial 10 full analytical reports would disqualify an accredited lab, for the period described in § 1.1152(d)(6). We would consider a material substantive shortcoming in the food testing to be incompetence or dishonesty resulting in an invalid test result. FDA will be relying on the food testing conducted under this program to make regulatory decisions, which will impact public health. It is critical that the testing be valid. We have a duty to monitor the testing conducted by

an accredited laboratory that submits a full analytical report containing a material substantive shortcoming, so it is appropriate that such a laboratory be disqualified from the privilege of submitting abridged analytical reports (see § 1.1152(d)(6)). Note also that under proposed § 1.1160(a) and (b), if we find a material substantive shortcoming in the food testing, we may consider the analysis to be invalid, and will notify the accredited laboratory, and potentially its recognized accreditation body and the owner or consignee of the food, of the deficiency. For further information on proposed § 1.1160, see section VI.I.3. Note also that under proposed § 1.1146(b), the accredited laboratory would have to treat the feedback as a complaint, in accordance with sections 3.2 and 7.9 of ISO/IEC 17025:2017 (Ref. 13).

Proposed § 1.1152(d)(3) discusses the criteria that laboratories, already submitting abridged analytical reports, must meet in order to begin submitting abridged analytical reports for additional disciplines. Specifically, proposed § 1.1152(d)(3) allows accredited laboratories, not on probation and already permitted to submit abridged analytical reports for at least one major food testing discipline, to submit to abridged analytical reports relating to additional major food testing discipline(s), after FDA has given notice that the following conditions are fulfilled: (1) the accredited laboratory submits to FDA at least one full analytical report for each additional major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports; (2) there is no material substantive shortcoming in the full analytical report(s) for the additional major food testing discipline(s); and (3) the full analytical reports for the additional major food testing discipline(s) do not contain repeated administrative deficiencies.

Proposed § 1.1152(d)(4) addresses the impact of an accredited laboratory's failure to initially satisfy the three criteria of § 1.1152(d)(3). Under proposed § 1.1152(d)(4)(i), if any analytical report submitted by the accredited laboratory to FDA under this program demonstrates

a material substantive shortcoming in the food testing, the accredited laboratory would become disqualified from submitting abridged analytical reports for the food testing discipline that was represented in the analytical report containing the material substantive shortcoming, in accordance with proposed § 1.1152(d)(6)(ii). If any full analytical reports relating to a food testing discipline submitted by an accredited laboratory are substantively satisfactory but suffer from repeated administrative deficiencies, the accredited laboratory would have another chance to submit a full analytical report for that food testing discipline that fulfills the criteria in § 1.1152(d)(3)(i) through (iii). Repeated administrative deficiencies in the second full analytical report would result in disqualification in accordance with proposed § 1.1152(d)(6)(ii).

Proposed § 1.1152(d)(5) provides that if an accredited laboratory, permitted to submit abridged analytical reports for a particular discipline, submits one or more test results, notifications, reports, and/or studies that demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies, the accredited laboratory would be disqualified for that discipline. The period of disqualification should be governed by § 1.1152(d)6)(ii) if the accredited laboratory is permitted to submit abridged analytical reports for other disciplines, and with § 1.1152(d)(6)(i) if not.

For accredited laboratories that currently do not have permission to submit any abridged analytical reports for any disciplines, proposed § 1.1152(d)(6)(i) states that the period of disqualification is either 2 years or until the accredited laboratory submits 20 more satisfactory full analytical reports to FDA under this program, whichever period is longer. During this period of disqualification the accredited laboratory would be ineligible to submit, and to request permission to submit, abridged analytical reports under this program. It is important that this period of disqualification be of sufficient length to establish a meaningful consequence for

accredited laboratories that are seeking permission to submit abridged analytical reports but who demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies. We also propose that shortcomings during the disqualification period under § 1.1152(d)(6)(i) would extend the disqualification. Such a policy would help ensure that disqualified laboratories have every incentive to maintain excellent performance during the disqualification period. We propose that any material substantive shortcoming in testing would extend the disqualification period by 6 months, and repeated administrative deficiencies would extend the disqualification period by 2 months.

For an accredited laboratory that currently is permitted to submit abridged analytical reports for at least one food testing discipline and is subject to disqualification for at least one additional food testing discipline, proposed § 1.1152(d)(6)(ii) states that the period of disqualification is either 2 years or until the accredited laboratory submits two or more satisfactory full analytical reports to FDA under this program, whichever period is longer. During this period of disqualification, the accredited laboratory would be ineligible to submit, and to request permission to submit, abridged analytical reports for the testing discipline(s) that is subject to the disqualification period. We also propose that shortcomings during the disqualification period under § 1.1152(d)(6)(ii) would extend the disqualification. Such a policy would help ensure that disqualified laboratories have every incentive to maintain excellent performance during the disqualification period. We propose that any material substantive shortcoming in testing would extend the disqualification period by 6 months, and repeated administrative deficiencies would extend the disqualification period by 2 months.

While the policy in proposed § 1.1152(d)(1) for becoming permitted to submit abridged analytical reports to FDA under this program would apply to newly accredited laboratories that

have never been disqualified under proposed § 1152(d)(1), the policy and procedures would be somewhat different for accredited laboratories that have been disqualified. Proposed § 1.1152(d)(7) provides that an accredited laboratory that has fulfilled the criteria under § 1.1152(d)(6), as applicable, and is not on probation, may submit a request (via a portal we would establish on our website) to FDA to submit abridged analytical reports under § 1.1152(d)(1) or (3), as applicable. After FDA receives the request, FDA will consider permitting the accredited laboratory to fulfill the conditions of proposed § 1.1152(d)(1) or (3), as applicable. If FDA grants permission, and once the conditions described by proposed § 1.1152(d)(1) and (3), as applicable, are fulfilled, FDA will provide notice that the accredited laboratory is permitted to submit to FDA on an ongoing basis abridged analytical reports relating to the discipline(s) for which the conditions are fulfilled.

As we have noted above, if an accredited laboratory submits one or more test results, notifications, reports, and/or studies that demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies we may also take other appropriate action under this proposed rule, including notifying the accredited laboratory's recognized accreditation body (in accordance with proposed § 1.1160) and/or, in more egregious cases, even putting an accredited laboratory on probation or revoking the accredited laboratory's accreditation, if appropriate under proposed § 1.1161.

We request comment on all aspects of our proposed approach to allowing accredited laboratories to submit abridged analytical reports to FDA, including with respect to the practicality and potential consequences of the approach.

Abridged analytical reports, in contrast to full analytical reports, would have to include only certain limited information describing the analysis. Proposed § 1.1152(f) provides that abridged analytical reports must contain:

- All information described by ISO/IEC 17025:2017 (Ref. 13) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d).
- The justification for any modification or deviation to the method(s) of analysis used, and documentation of the accredited laboratory's authorization for the modification or deviation. Although ISO/IEC 17025:2017 (Ref. 13) section 7.8.2.1 requires disclosure of additions to, deviations, or exclusions from the method, we have tentatively determined that abridged analytical reports should also include the justification and authorization for any modification or deviation to the method. This proposed requirement should help us understand whether the method, although modified, is within the accredited laboratory's scope of accreditation, and otherwise help us determine whether we should require submission of the full analytical report version of the abridged analytical report.

Although the information in abridged analytical reports are not sufficient to allow us to engage in a meaningful indepth scientific review of the analysis, and ISO/IEC 17025:2017 section 7.8 appears to relate more to reports laboratories submit to their customers rather than reports laboratories submit to regulatory authorities, we have tentatively determined that the information in abridged analytical reports, as proposed by § 1.1152(f), would be sufficient information for us to make other meaningful decisions related to the analysis, such as whether the method used is appropriate or whether certain risks are present that warrant the submission of the full analytical report. We request comments on what other information should, or should not be, in an abridged analytical report.

Proposed § 1.1152(g) establishes what information full analytical reports submitted under this program must contain. We developed the proposed requirements for what information full analytical reports must contain based on what information we have found is necessary for us to assess the validity of the analyses that private laboratories currently conduct in support of admission of an article of food under section 801(a) of the FD&C Act and to support removal from an import alert through successful consecutive testing. We have tentatively determined that the information we propose full analytical reports must contain is necessary for us to engage in a meaningful indepth scientific review of the analysis to determine that the analysis is valid. Proposed § 1.1152(g) would require full analytical reports to include the following information:

- All information that must be included in an abridged analytical report. As noted previously, this information consists primarily of administrative items and limited substantive information about the analysis performed. It also includes the justification for any modification or deviation to the method(s) of analysis used and documentation of the accredited laboratory's authorization for the modification or deviation.
- Documentation of references for the method or methods of analysis used. Here we simply mean that the package must include the name (e.g., "Concentration, Extraction, and Detection of Norovirus and Hepatitis A Virus in Molluscan Shellfish") and source (e.g., AOAC, FDA BAM) of the method used.
- Identification of the analyst or analysts who conducted each analytical step, validation step (if applicable), and verification step (if applicable), including the analyst's or analysts' legal name and signature, and the date each analytical step, validation step (if applicable), and verification step (if applicable) was performed. This information is

important because, in accordance with section 422(a)(6)(A)(iv) of the FD&C Act and proposed § 1.1150(b), the analysts must be appropriately qualified.

- Calculations presented in a legible and logical manner. We may need to verify the calculations to verify whether the results of the testing are valid.
- As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and made in a clear order. These items represent objective evidence and raw data supporting the test results. We may need to review such information to understand and verify the validity of the results of the testing.
- 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, date of preparation, expiration date, chemical balance, and solvent used.
- A copy of the label from any immediate container sampled and any additional labeling needed to evaluate the product. Many products are shipped in a variety of different forms, container quantities, and may have varying packaging or labels. The label would likely include important information about the form, unit quantity, or packaging of the food, which we may use to verify that the laboratory analyzed the samples using an appropriate method. The label and labeling would provide additional information which may be helpful to the analysis and our review, such as the ingredient list of the food. For example, if the ingredient list indicates that the food contains an ingredient, additive, or

pesticide at a violative level, we may subject to higher scrutiny test results that indicate the food is free from the ingredient, additive, or pesticide or that indicate the food contains the ingredient, additive, or pesticide at a lower level than the ingredient list indicates.

- All original compilations of raw data secured in the course of the 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, date and time, associated with the test. This information is important for us to understand and to verify the validity of the test results. Furthermore, requiring submission of discarded, unused, or reworked data, along with a justification for discarding, not using, or reworking such data, should discourage testing into compliance.
- 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.
- Identification of any software used, including any certificate or certificates of analysis for standards and software used. This information helps us understand the associated test results and verify that the standards used are valid and that the software used is functioning properly.
- The following information about the qualifications of the analyst or analysts who were involved in the analysis conducted under this program, if the accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the

analyst's qualifications have significantly changed since the accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

- The analyst's curriculum vitae;
- Training records with regards to methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider;
- Any other documentation of analyst's ability to perform the method properly in the specific context of the food testing to be conducted, under § 1.1150(b) (e.g., a certificate of completion of a relevant training and/or documentation that the analyst was the investigator for the relevant validation or verification study); and
- Individual proficiency test worksheets relevant to the analysis being performed.

We invite comment on our proposed requirements for what information full analytical reports must contain. If commenters believe we are proposing to require too much information to be included in full analytical reports, please specifically address in your comments which requirements of § 1.1152(g) we should delete or revise, and why that piece of information is not necessary for us to engage in a meaningful indepth scientific review of the analysis to determine whether the analysis is valid. For commenters who believe we have not proposed sufficient information to be included in full analytical reports, please specify what additional information we should require and why it is critical to our assessment of the analysis and test results.

Proposed § 1.1152(h) would require that if the 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 accredited laboratory must submit documentation of the method to FDA. If the method used has been published in a reputable international or national standard (e.g., in the Official Methods of

Analysis of AOAC International) or the method is otherwise publicly available (readily available, so that a reasonable analyst would be able to easily find the method), we would be able to look up the method ourselves. However, if the method is not published in a reputable international or national standard or otherwise readily publicly available, the accredited laboratory would need to share information about the method with us, if requested, as we may have no other way to access the information. For example, in the case of a method developed by the laboratory, the laboratory would need to submit to us sufficient information about the method for us to understand how the method is applied, such as the method standard operating procedure, or some other document that describes the steps within the method. Such information would be in addition to the validation or verification information that would be required under proposed § 1.1152(c)(4), (5), or (6).

Proposed § 1.1152(i) addresses advance notice of sampling. We are proposing to require advance notice of sampling in certain circumstances as an additional technique to exercise oversight over sampling conducted for food testing in this program. Under proposed § 1.1152(i)(1), if we determine that the sampling conducted by a sampler may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if we determine that the sampling may have been otherwise improper, we may require the accredited laboratory that analyzed the associated sample(s), and other accredited laboratories under this program that have analyzed samples collected by the sampler previously, to request and receive from the sampler, and submit or require the sampler to submit, an advance notice of sampling to the destination specified by the laboratory accreditation program website portal 48 hours before each of the 10 occasions that the sampler will collect a sample that the accredited laboratory will analyze under this program. As we discuss below, we also propose at

§ 1.1152(i)(2)(ii) and (iii) to be able to specify certain timeframes other than 48 hours and to specify a number other than 10 occasions.

We intend advance notice of sampling to encourage the use of sampling techniques that will allow for a meaningful analysis, by facilitating our observation of sampling and collection of audit samples before we receive the test results with the accompanying sample collection report. Audit samples are samples we collect from the lot or environment at issue, which we then analyze, and compare our test results with the test results of the accredited laboratory. We believe it is reasonable to generally require the notice of sampling to be submitted to us 48 hours prior to collection of the sample(s) to allow us time to determine whether to observe the sampling and/or take an audit sample, and assign appropriate personnel to the task. Note that we may take audit samples (as we currently do) even if we have not required advance notice of sampling.

Proposed § 1.1152(i)(2) elaborates that we may, as appropriate (based on the relevant circumstances): specify the type of food product or environment that requires advance notice of sampling under this section; determine that an amount of time other than 48 hours in advance is required, to a minimum of 24 hours and up to 7 business days in advance; determine that a number of occasions other than 10 are required, to a minimum of one occasion and up to a maximum of 20 occasions; and notify affected accredited laboratories that submission of additional notices of sampling are not required. We would typically notify affected accredited laboratories that submission of additional notices of sampling are not required after we have observed and/or audit an amount of sampling conducted by the sampler sufficient for us to determine whether the sampler appears to be conducting sampling properly.

Proposed § 1.1152(i)(3) would require that the advance notice of sampling include the following information:

- A unique identification code for the notice of sampling. This would help us identify, review, and record the notification efficiently and would help us identify associated submissions. The test results would reference the identification numbers of each associated submission.
- The name of the accredited laboratory that will conduct analysis of the sample. This would allow us to, for example, followup with the accredited laboratory that will conduct the analysis, if appropriate, before or during the accredited laboratory's analysis of the samples.
- The name and street address of the sampler that will conduct the sampling. This information will help us organize our review of notices of sampling as they are submitted to us.
- A primary contact (name and phone number) for the sampler. This information would be necessary if we need to contact the sampler. For example, we may need to contact the sampler if we choose to observe or audit the sampling, but the food product or environment at issue is not at the location specified on the notice of sampling.
- The reason(s) why the food product or environment will be sampled. We would want to know, for example, if the sample to be collected will be analyzed by an accredited laboratory with regards to a particular import alert. We expect this information to help us determine whether to observe or audit the sampling.
- 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. This would help

us locate the food product or environment in the case we would want to observe the sampling or take an audit sample.

- As applicable, the U.S. Customs and Border Protection entry and line number(s) and the product code(s) of the food. This would help us identify the food product at issue if we choose to observe or audit the sampling. In the import context, we would want to know the FDA product code. In the domestic context, the U.S. Customs and Border Protection entry and line number(s) would be inapplicable, and we would instead want to know the product code assigned by the manufacturer, packager, labeler, as applicable. In the context of environmental sampling, both items are inapplicable.
- The date and approximate time the sampling will begin. The date must be correct and we would expect the estimated time to be as close to the actual time of the sampling as reasonably possible.

Proposed § 1.1152(j) provides that when any changes occur that affect the accreditation of the accredited laboratory, the accredited laboratory must immediately send FDA, within 48 hours, and the accreditation body that accredited it notice of such changes, a detailed description of such changes, and an explanation of how such changes affect the accreditation of the accredited laboratory. This provision would cover changes in the name or operations of an accredited laboratory, such as the purchase of an accredited laboratory by a company, as well as changes that would cause the accredited laboratory to no longer meet the requirements of this program. We have proposed this requirement in accordance with section 422(a)(1)(C) of the FD&C Act, which requires that, in pertinent part, as a condition of accreditation, as appropriate, accredited laboratories must report to FDA any changes that would affect the accreditation of the laboratory. Proposed § 1.1152(j) would not require accredited laboratories to notify us of

changes covered by proposed § 1.1123(c), which requires recognized accreditation bodies to immediately notify us of certain information related to the accreditation status of laboratories they accredit or that have sought their accreditation (e.g., certain changes initiated by the recognized accreditation body, and findings of fraud).

Proposed § 1.1152(k) provides that if FDA does not receive all information required to be submitted to FDA by proposed § 1.1152(a) through (j), FDA may consider the related food testing to be invalid. For example, if we do not receive a validation study when its submission to FDA is required, we would not be able to determine whether the method is appropriate for the intended use; if we do not receive a full analytical report when we require its submission, we would be unable to conduct the necessary indepth scientific review of the analysis to determine whether, in that instance, the analysis was valid; and if we do not receive all the required information about the sampling, we would not be able to determine whether the sample that was analyzed was representative of the food product or environment at issue.

8. What Other Records Requirements Must an Accredited Laboratory Meet? (Proposed § 1.1153)

This proposed rule would establish requirements for accredited laboratories to establish, control, and retain records relating to their food testing activities under this program. In addition to meeting the ISO/IEC 17025:2017 records requirements (in accordance with proposed § 1.1146(b)), accredited laboratories would have to meet the additional records requirements of this proposed section.

Proposed § 1.1153(a) would require laboratories that have been accredited to maintain electronically, for 5 years after the date of creation, certain records created and received during their period of accreditation that relate to compliance with this proposed rule. Even if no longer accredited, laboratories that used to be accredited would have an obligation under this proposed

rule to maintain records created and received during their period of accreditation. Proposed § 1.1153(a) elaborates that these records include: (1) documents related to the accredited laboratory's grant (and, if applicable, extensions) of accreditation from its accreditation body; (2) documentation of food testing the accredited laboratory conducted under this program, in accordance with proposed § 1.1150(d); (3) all documents that the accredited laboratory was required to submit to FDA under § 1.1152, and associated correspondence by the accredited laboratory (and its officers, employees, and other agents) with the owner or consignee (and its officer, employees, and other agents) of the tested food product or environment; (4) all requests for food testing from an owner or consignee that would be conducted under this proposed rule; (5) documentation of any internal investigations, internal audits, and corrective actions taken to address any problems or deficiencies related to activities under this proposed rule; (6) documentation related to probation or withdrawal from accreditation under this program; and (7) documentation of changes to its management system or food testing activities that may affect its compliance with this proposed rule. We believe it appropriate to require maintenance of these records for purposes of this proposed rule.

Proposed § 1.1153(b) provides that within 30 days of the receipt of proficiency testing results by the accredited laboratory, the accredited laboratory must submit the proficiency testing results to the recognized accreditation body that accredits the accredited laboratory, and, if the accredited laboratory failed the proficiency test, also to FDA, via the destination specified by the website described by § 1.1109. During our conversations with certain laboratories and accreditation bodies, we received feedback that this proposed rule would benefit from a requirement that proficiency testing results be submitted to the recognized accreditation body that accredits the laboratory. See "Record of Outreach Sessions on FDA Proposed Rules,

Conference call between the FSMA Lab Accreditation Workgroup and the Food Laboratory Alliance, July 21, 2015" (Ref. 20), and attached meeting minutes. Our understanding is that there is currently no such requirement, and accredited laboratories may decline to submit proficiency test results to their accreditation body. Proficiency test results would provide accreditation bodies with valuable information about the food testing capabilities and proficiencies of the accredited laboratories they accredit. Furthermore, because proficiency testing providers are typically uninterested third parties, there is little risk that submitting the proficiency test results to the accreditation body and potentially FDA would affect the conduct of the proficiency testing. We also believe we may find proficiency testing results helpful as well, particularly if the proficiency testing was unsuccessful and related to food testing results submitted to us under proposed § 1.1152.

Proposed § 1.1153(c) provides that laboratories that have been accredited must make these records available for inspection and copying upon written request of an authorized officer or employee of FDA. The authorized officer or employee of FDA may request that the laboratory submit such records to FDA electronically or that the laboratory 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 the records be submitted electronically, the records must be submitted electronically not later than 10 business days after the date of the request. However, records related to the immediate notification requirements in § 1.1152(j) must be submitted within 48 hours. If the authorized FDA officer or employee requests records that are maintained in a language other than English, the laboratory must electronically submit an English translation of the records to FDA within a reasonable time. We

are not proposing that the records themselves be maintained in English, as we believe such an approach would be unduly burdensome, particularly for foreign laboratories.

Proposed § 1.1153(d) would require laboratories that have been accredited to ensure that significant amendments to records described by proposed § 1.1153(a) and (b) can be tracked to previous and original versions. Proposed § 1.1153(d) further provides that if such a significant amendment is made, both the original document and amended document must be maintained by the laboratory that has been accredited during the time period that the amended document must be maintained. Further, 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 a more recent version of the document exists. This provision is based on ISO/IEC 17025:2017 (Ref. 13) at section 7.5.2. However, section 7.5.2 of ISO/IEC 17025:2017 applies to "technical records," while proposed § 1.1153 applies to a wider category of records.

We acknowledge that the requirements of proposed § 1.1153 may require revisions to contracts and perhaps other documents establishing the scope of a laboratory's authority with respect to granting records access. We nonetheless have tentatively concluded that the records maintenance and access requirements in proposed § 1.1153 are necessary for us to maintain an appropriate degree of oversight over accredited laboratories (in accordance with proposed § 1.1159) and for recognized accreditation bodies to monitor and assess laboratories they accredit.

H. Proposed Provisions About Procedures for Accreditation of Laboratories (Proposed §§ 1.1158 through 1.1165)

This proposed rule would establish procedures for laboratories to apply for accreditation or relinquish accreditation, and for our oversight of accredited laboratories, including procedures for our review of test results and supporting information, and for probation and revocation of the accreditation of laboratories.

1. How Does a Laboratory Apply for Accreditation or Modification of its Scope of Accreditation by a Recognized Accreditation Body? (Proposed § 1.1158)

Proposed § 1.1158 explains how laboratories must apply for accreditation; reinstatement of accreditation or modification of their scope of accreditation; addresses the duration of accreditation; and describes the effects of a denial of an application for accreditation. Section 422 of the FD&C Act establishes a structure whereby FDA recognizes accreditation bodies, who, in turn, accredit laboratories that meet the applicable requirements of the program. As we indicate in proposed § 1.1109, we will maintain a list of recognized accreditation bodies, who may perform accreditation, along with the contact information of these recognized accreditation bodies, so that laboratories would be able to use our website as a resource to find a recognized accreditation body that can assess whether the laboratory is eligible for accreditation.

Proposed § 1.1158(a) provides that a laboratory seeking accreditation must submit its application for accreditation to a recognized accreditation body identified on the website described in proposed § 1.1109. Proposed § 1.1158(a) further provides that the recognized accreditation body will review and assess the application in accordance with the applicable requirements of this program. Proposed § 1.1158(a) also provides that if the laboratory seeking accreditation had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body, or revoked by FDA the previous time it was accredited under this program, the laboratory

must meet the additional requirements specified by proposed § 1.1165 (which addresses the question of how a laboratory requests reinstatement of accreditation).

Proposed § 1.1158(b) clarifies that a laboratory may use documentation of conformance with ISO/IEC 17025:2017, as applicable and supplemented as necessary, in meeting the applicable requirements of this program. For example, if a laboratory is already accredited to ISO/IEC 17025:2017 by a recognized accreditation body, the recognized accreditation body could accept this accreditation as evidence that the laboratory meets the requirements of ISO/IEC 17025:2017 the laboratory must meet under proposed § 1.1138 to become accredited under this proposed rule.

Proposed § 1.1158(c) clarifies that an accredited laboratory's accreditation continues until withdrawn, revoked, or relinquished under this program. It is our understanding that the current practice by accreditation bodies and laboratories is that the laboratory's intent to remain accredited is generally assumed, and the accreditation body continues to accredit the laboratory and conduct assessments and reassessments under that understanding. We seek comment with regards to whether this is correct.

2. How Will FDA Oversee Accredited Laboratories? (Proposed § 1.1159)

Proposed § 1.1159 would establish certain requirements related to our oversight of accredited laboratories. Although the recognized accreditation bodies have primary oversight responsibility over accredited laboratories, we would also exercise some ability to oversee accredited laboratories, via requesting records and, if appropriate, conducting onsite assessments. We note that in contrast to recognized accreditation bodies, under section 422(b)(2) of the FD&C Act, FDA will routinely receive the results of food testing conducted under section 422(b)(1),

along with supporting information, which will provide us with information on accredited laboratories' compliance with this program.

Proposed § 1.1159(a) provides that we may assess accredited laboratories at any time to determine whether they continue to comply with the applicable requirements of the program and whether there are any deficiencies in the performance of the accredited laboratory that, if not corrected, would warrant probation or revocation of its accreditation.

Proposed § 1.1159(b) clarifies that, in the course of our evaluation of the performance of an accredited laboratory, we may review any of the following: records the accredited laboratory would be required to maintain under this proposed rule; records the recognized accreditation body that accredited the accredited laboratory is required to maintain under this proposed rule; information we obtain during an onsite assessment of the accredited laboratory (conducted under proposed § 1.1159(c)); information we obtain during our assessment of the recognized accreditation body that accredited the laboratory; and any other information we obtain, including during FDA's inspections or investigations of one or more owners or consignees of food subject to food testing under this proposed rule.

Proposed § 1.1159(c) provides that our assessment may include our own onsite assessment of the accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to assess an accredited laboratory. We would exercise this authority as appropriate to followup on potential problems that come to our attention, for which referral to a recognized accreditation body may be inefficient or otherwise inappropriate, and to otherwise verify compliance with the program. Proposed § 1.1159(d) clarifies that we will also report any of our observations and findings of our assessment to the accredited laboratory's recognized accreditation body.

We seek comments regarding this proposed section and how accreditation bodies and FDA should share oversight of accredited laboratories under this proposed program.

3. How Will FDA Review Submitted Test Results and Analytical Reports? (Proposed § 1.1160)

Proposed § 1.1160(a) clarifies that if we find that any test results, analytical report, related documents (for example, the sampling plan, verification studies, and validation studies) or the associated analysis, contains deficiencies or otherwise indicates that any aspect of the food testing is not being conducted in compliance with the program, FDA may consider the analysis to be invalid. We will notify the accredited laboratory that appears to be responsible for the deficiency, and we may also notify the owner or consignee of the food of the deficiency. When we notify the accredited laboratory that appears to be responsible for the deficiency, our notice would be considered a complaint that would be treated in accordance with the laboratory's established procedures for complaints under section 7.9 of ISO/IEC 17025:2017 (Ref. 13). When we notify the laboratory of the deficiency, the laboratory must respond, in writing, to us regarding the deficiency within 30 days or an agreed-upon timeframe, including a statement with respect to how the accredited laboratory intends to address the deficiency, and/or a statement describing the extent to which the laboratory has addressed the deficiency.

Proposed § 1.1160(b) clarifies that we may also report any of our determinations of deficiencies resulting from our review of any test results, reports, and related documents under this rule to the recognized accreditation body that accredits the accredited laboratory.

Proposed § 1.1160(c) clarifies that if the deficiency in the test result, analytical report, and/or the associated analysis demonstrates a material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, FDA will also consider

whether disqualification from being eligible for permission to submit abridged analytical reports under proposed § 1.1152(d), and/or other action under this program, is appropriate.

Proposed § 1.1160(d) reiterates the language of section 422(d) of the FD&C Act, stating that nothing in this rule shall be construed to limit our ability to review and act upon information from food testing, including determining the sufficiency of such information and testing. For example, we would typically consider analysis of a non-representative sample to be invalid.

4. When Will FDA put an Accredited Laboratory on Probation or Revoke the Accreditation of a Laboratory? (Proposed § 1.1161)

This proposed rule would establish the conditions under which we could put an accredited laboratory on probation or revoke a laboratory's accreditation to conduct food testing under this proposed program. Under this proposal, we could put an accredited laboratory on probation or revoke accreditation only in limited circumstances, including where the recognized accreditation body that accredits the accredited laboratory does not withdraw accreditation itself.

Proposed § 1.1161(a) provides that we may revoke the accreditation (in whole or in part) of an accredited laboratory program for good cause, which may include any of the following reasons: (1) demonstrated bias or lack of objectivity when conducting food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory; (2) performance that calls into question the validity or reliability of its food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory; or (3) other failure to substantially comply with this rule where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

Proposed § 1.1161(b) provides that if we determine that an accredited laboratory has demonstrated deficiencies in performing its functions that are less serious and more limited than

would warrant revocation of accreditation, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, we may temporarily put the laboratory on probation and request that the laboratory take appropriate corrective actions.

Proposed § 1.1161(c) further clarifies that when there are grounds for revocation of accreditation, but the deficiencies are associated with or affect only certain methods within the accredited laboratory's scope of accreditation, we may revoke the accredited laboratory's accreditation only for those affected methods.

Proposed § 1.1161(d) clarifies that our probation of a laboratory's accreditation shall remain in effect until the laboratory demonstrates to our satisfaction that the laboratory has successfully implemented appropriate corrective actions, or until we determine that revocation of accreditation is warranted.

If we determine that revocation is warranted, under proposed § 1.1161(e) we would notify the laboratory and its recognized accreditation body of the revocation of its accreditation through the issuance of a revocation notice. The revocation notice would state the grounds for revocation; whether the revocation of accreditation is in-whole or in-part, and if it is in-part, to which methods it applies; state the procedures for requesting a regulatory hearing on the revocation under proposed § 1.1173; and state the procedures for requesting reinstatement of accreditation under proposed § 1.1165.

Similarly, if we determine that probation of an accredited laboratory is warranted, under proposed § 1.1161(f) we would notify the laboratory and its recognized accreditation body of the probation, describe the grounds for the probation, and specify other key details, including all deficiencies that must be corrected for FDA to lift the probation. Furthermore, 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 notice and identify timeframes for completion.

Proposed § 1.1161(g) provides that we may revoke (in-whole or in-part) the accreditation of the laboratory that has been put on probation if we determine that the laboratory is not implementing appropriate corrective actions.

Proposed § 1.1161(h) reiterates the provision of proposed § 1.1109 that we will provide notice on the website described in proposed § 1.1109 of our probation or revocation of the laboratory's accreditation.

5. What Are the Consequences if FDA Puts an Accredited Laboratory on Probation or Revokes the Accreditation of a Laboratory? (Proposed § 1.1162)

Under proposed § 1.1162(a), if we revoke the accreditation in whole of a laboratory, the laboratory would be immediately ineligible to conduct food testing under this rule. Proposed § 1.1162(a) further provides that if we revoke the accreditation of laboratory in-part, the laboratory is immediately ineligible to use the methods that are subject to the revocation to conduct food testing under this subpart. An accredited laboratory that is put on probation by FDA would be permitted to continue to conduct food testing under this proposed program.

Proposed § 1.1162(b) further provides that, with respect to food testing conducted by the laboratory prior to our revocation of accreditation, we may refuse to consider specific food testing results and associated reports of food testing conducted under this program by the accredited laboratory if the basis for our revocation of accreditation of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

Proposed § 1.1162(c) would require that within 10 business days of the date of issuance of the revocation of accreditation, the laboratory must notify us electronically, in English, of the name of the custodian who will maintain the records required by proposed § 1.1153, and the contact information for the custodian, which must include an email address, and the street address where the records will be located.

Proposed § 1.1162(d) would require that within 10 business days of the date of issuance of the probation or revocation the laboratory notify any owners or consignees for whom it is conducting food testing under this proposed rule that it is on probation or its accreditation has been revoked.

6. What if a Laboratory Wants to Voluntarily Relinquish its Accreditation? (Proposed § 1.1163)

This proposed rule would offer accredited laboratories a mechanism for voluntarily relinquishing their accreditation. We are proposing certain procedural requirements, similar to those in the accredited third-party certification regulation, that accredited laboratories must follow to relinquish their accreditation. We believe these procedures are necessary to ensure an orderly accreditation relinquishment process and so that we may exercise appropriate oversight and timely update the website described by proposed § 1.1109.

Proposed § 1.1163(a) would require accredited laboratories to notify us electronically, in English, and notify their recognized accreditation body, at least 60 days before voluntarily relinquishing its accreditation in whole or in part. The notice would need to include the date on which relinquishment will occur. If the relinquishment is of the laboratory's accreditation in-whole, the notification must also include the name and contact information of the custodian who will maintain the records required under proposed § 1.1153 after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by

proposed § 1.1153. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by proposed § 1.1153 will be located.

For food testing that is subject to proposed § 1.1107(a), we would consider food testing conducted by a laboratory that is not accredited at the time of the food testing to be invalid. This position is in accordance with section 422(b)(1) of the FD&C Act, which requires such food testing to be conducted only by accredited laboratories.

Proposed § 1.1163(b) reiterates that we will provide notice on the website described in § 1.1109 of the voluntary relinquishment of accreditation of the laboratory.

7. What is the Effect on Accredited Laboratories if their Accreditation Body Voluntarily or Involuntarily Loses its Recognition? (Proposed § 1.1164)

Section 422(a)(7)(B) of the FD&C Act provides that we must promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act, specifying, as appropriate, any terms and conditions necessary for laboratories accredited by such body to continue to perform food testing under this proposed program. We would establish those terms and conditions in § 1.1164 of this proposed rule. Accordingly, proposed § 1.1164(a) provides that when an accreditation body has its recognition revoked, relinquishes its recognition, allows its recognition to expire, or has its application for renewal of recognition denied, a laboratory accredited by the accreditation body must take the following actions (subject to an exception in paragraph (b), which we discuss below): (1) no later than 30 days after FDA issues the notice to the laboratory under proposed § 1.1129, § 1.1130, or § 1.1131 that its accreditation body is no longer recognized, the laboratory submits to FDA documentation of the accredited laboratory's most recent internal audit, which all

accredited laboratories would be required to maintain under proposed § 1.1153(a)(5), documentation showing compliance with the conflict of interest requirements in proposed § 1.1147, and documentation of the most recent proficiency test for each test method for which the laboratory is accredited under this subpart, to show compliance with proposed § 1.1138(a)(1)(ii); and (2) no later than 1 year after FDA issues the applicable notice under proposed § 1.1129, § 1.1130, or § 1.1131 to the laboratory, the laboratory becomes accredited by a recognized accreditation body.

Our review of accredited laboratories' quality assurance records in accordance with proposed § 1.1164(a)(1) would allow us to ensure that the accredited laboratory is in compliance with this rule while it transitions. We believe a period of one year, in accordance with proposed § 1.1164(a)(2), gives the laboratory sufficient time to find a recognized accreditation body and complete its accreditation process while limiting the time the laboratory conducts food testing without the oversight of a recognized accreditation body. We may be more proactive in our oversight of such accredited laboratories during the period they are not subject to the oversight of a recognized accreditation body.

Proposed § 1.1164(b) would establish an exception to the above-described requirements. Under proposed § 1.1164(b), the accredited laboratory may choose to relinquish its accreditation in lieu of meeting the requirements of proposed § 1.1164(a). In such case, the accredited laboratory would have to initiate relinquishment of its accreditation in-whole under proposed § 1.1163 not later than 15 days after FDA issues the applicable notice to the accredited laboratory under proposed § 1.1129, § 1.1130, or § 1.1131, and the relinquishment would need to occur within 90 days. Of note, proposed § 1.1163(a) would typically require an accredited laboratory to submit the relinquishment notice to its recognized accreditation body and to FDA.

However, for a relinquishment initiated in accordance with proposed § 1.1164(b), the accredited laboratory would submit the relinquishment notice under proposed § 1.1163(a) to FDA only, as the accredited laboratory would have no recognized accreditation body at the time.

Generally, if the accredited laboratory does not meet the requirements of either proposed § 1.1164(a) or (b), the accredited laboratory would no longer be in substantial compliance with this proposed rule and its accreditation would generally be subject to revocation under proposed § 1.1161.

8. How Does a Laboratory Request Reinstatement of Accreditation? (Proposed § 1.1165)

Proposed § 1.1165 describes how a laboratory may obtain reinstatement of its accreditation if we revoked its accreditation, if a recognized accreditation body withdrew its accreditation, or if the laboratory voluntarily relinquished its accreditation.

Proposed § 1.1165(a) addresses how a laboratory may obtain reaccreditation if its accreditation was withdrawn (in whole or in part) by a recognized accreditation body or revoked (in-whole or in-part) by FDA. The laboratory may seek reaccreditation by submitting a new application for accreditation (in-whole or in-part, as applicable) under proposed § 1.1158 to a recognized accreditation body. Proposed § 1.1165(a) further provides that the laboratory must also: (1) notify us, before it submits the new application for accreditation to the recognized accreditation body, that the laboratory will be submitting a new application for accreditation to the recognized accreditation body, including in the notification the legal name of the laboratory, valid contact information for the laboratory, the legal name of the recognized accreditation body the laboratory will be submitting the application to, and the date that the laboratory expects to submit the new application for accreditation; and (2) demonstrate, to the satisfaction of the recognized accreditation body it is submitting the new application to, that the grounds for the

withdrawal of accreditation have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring. If the laboratory's accreditation had been withdrawn by a recognized accreditation body, the requirement to notify us would allow us to check whether the laboratory had been recently denied reaccreditation by a different recognized accreditation body, which could possibly indicate whether the laboratory is successively seeking approval of accreditation without changing its practices. Alternatively, if we revoked the laboratory's accreditation, we may want to contact the recognized accreditation body to which the laboratory is applying, to, for example, explain to the accreditation body why we found it necessary to revoke the laboratory's accreditation.

Proposed § 1.1165(b) addresses how a laboratory may obtain reaccreditation after it voluntarily relinquishes its accreditation. A laboratory that voluntarily relinquished its accreditation may seek reinstatement of accreditation by submitting a new application for accreditation under proposed § 1.1158 to a recognized accreditation body.

I. Proposed Provisions About Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under this Rule (Proposed §§ 1.1171 through 1.1174)

This proposed rule would establish requirements and procedures an accreditation body would have to follow to request that we reconsider our decision to deny its application for recognition, to request we internally review our decision to deny its request to reconsider its application for recognition, and to request a regulatory hearing on our decision to take adverse action with respect to its recognition. This proposed rule would also establish requirements and procedures a laboratory would have to follow to request a regulatory hearing on our decision to take an adverse action with respect to the laboratory's accreditation. Further, this proposed rule would establish requirements and procedures owners and consignees would have to follow to

request a regulatory hearing on a food testing order. Finally, this proposed rule would establish procedures for the conduct of such reconsiderations, internal reviews, and regulatory hearings.

1. How Does an Accreditation Body Request Reconsideration by FDA of a Decision to Deny its Application for Recognition, Renewal, or reinstatement? (Proposed § 1.1171)

This proposed rule would establish procedures for an accreditation body to seek reconsideration of our denial of its application for recognition, renewal of recognition, or reinstatement of recognition.

The procedures described by proposed § 1.1171 require submission of the request for reconsideration within 10 business days of the issuance of such denial. The request for reconsideration must be submitted to us electronically, in English, and in accordance with the procedures described in the notice of denial. The request must also be signed by the accreditation body or by an individual authorized to act on its behalf. Within a reasonable time after we complete our review and evaluation of the request for reconsideration and the supporting information submitted, we would notify the requestor through the issuance of the recognition upon reconsideration or through the issuance of a denial of recognition upon reconsideration. We note that should FDA issue a denial after a request for reconsideration, the accreditation body would be able to request the review of such decision under 21 CFR 10.75.

2. 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? (Proposed § 1.1173)

This proposed rule explains the procedures that would be used for challenges to our revocation of an accreditation body's recognition or our revocation of a laboratory's accreditation.

Under proposed § 1.1173(a), an accreditation body whose recognition was revoked or a laboratory whose accreditation was revoked (or an individual authorized to act on the accreditation body's or laboratory's behalf) may submit a request for a regulatory hearing, under part 16, on the revocation. The request must be submitted within 10 business days of the date of revocation. Written notices of revocation will contain all the elements required by § 16.22 and will thereby constitute the notice of an opportunity for hearing under part 16.

Under proposed § 1.1173(b), the request for a regulatory hearing must be submitted with a written appeal that responds to the bases for our decision described in the written notice of revocation together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted to us electronically, in English, and in accordance with the procedures described in the notice of revocation.

Proposed § 1.1173(c) makes clear that the submission of a request for a regulatory hearing under this rule will not operate to delay or stay the effect of our decision to revoke recognition of an accreditation body or to revoke accreditation of a laboratory unless we determine that delay or a stay is in the public interest.

Under proposed § 1.1173(d) and (e), the presiding officer for a regulatory hearing under this proposed rule will be designated after the request for a regulatory hearing is submitted to us. The presiding officer may deny a request for regulatory hearing under this proposed rule under 21 CFR 16.26(a) when no genuine or substantial issue of fact has been raised.

Proposed § 1.1173(f) states that if a hearing request is granted, 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 requestor and the presiding officer and FDA.

The presiding officer must conduct the hearing under part 16, except that, under § 16.5(b), the procedures for a regulatory hearing described in part 16 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 rule. The following requirements of part 16 are inapplicable to regulatory hearings conducted under this rule: § 16.22 (Initiation of a 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).

Proposed § 1.1173(f)(3) clarifies that a decision by the presiding officer to affirm the revocation of recognition or the revocation of accreditation that served as the basis for the request for a regulatory hearing is considered a final Agency action for purposes of 5 U.S.C. 702.

3. How Does an Owner or Consignee Request a Regulatory Hearing on a Food Testing Order? (Proposed § 1.1174)

This proposed rule explains the procedures that would be used for challenges to our issuance of a food testing order.

Proposed § 1.1174(a) provides that no later than 24 hours after we issue the food testing order, the owner or consignee who is the subject of the food testing order may submit a request for a regulatory hearing, conducted under part 16, on the food testing order. The food testing order will contain all of the elements required by § 16.22(a) and will thereby constitute the notice of an opportunity for hearing under part 16.

Proposed § 1.1174(b) provides that the request for a regulatory hearing must be submitted with a written appeal that responds to the bases for our determinations described in the food testing order, together with any supporting information upon which the requestor is relying. The

request, appeal, and supporting information must be submitted in English to the address specified in such notice and in accordance with the procedures described therein. The request, appeal, and supporting information may be submitted electronically.

Proposed § 1.1174(c) states that the presiding officer for the regulatory hearing will be designated after a request for the regulatory hearing is submitted to FDA. Proposed § 1.1174(c) states that the presiding officer may deny a request for regulatory hearing under this rule under § 16.26(a).

Proposed § 1.1174 provides that if the presiding officer grants a request for a regulatory hearing, the hearing will be held within 2 business days after the date the request was filed or, if applicable, within a time frame agreed upon in writing by requestor and the presiding officer and FDA. Furthermore, the presiding officer may require that a hearing conducted under this proposed rule be completed within one business day, as appropriate. We believe that it is in the interest of both public health and the owner and consignee that regulatory hearings on food testing orders be resolved quickly and efficiently. As noted, however, this proposed rule would allow for flexibility by allowing the requestor, the presiding officer, and FDA to agree on an alternative timeframe for holding the hearing.

Proposed § 1.1174(e)(3) provides that the presiding officer must conduct the hearing in accordance with part 16, except that, consistent with § 16.5(b), the procedures for a regulatory hearing described in part 16 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 proposed rule. Accordingly, the following requirements of part 16 would be inapplicable to regulatory hearings conducted under this proposed rule: the requirements of §§ 16.22 (Initiation of a regulatory hearing); 16.24(e) (timing) and (f) (contents of notice); 16.26(a) (denial of

hearing); 16.40 (Commissioner); 16.42(a) (presiding officer););16.60(a) (public process); 16.95(b) (Administrative decision and record for decision); and 16.120 (Reconsideration and stay of action) of this chapter.

Proposed § 1.1174 clarifies that a decision by the presiding officer to affirm the testing order would be considered a final Agency action under 5 U.S.C. 702.

J. Proposed Provisions About Electronic Records and Public Disclosure Requirements Under this Rule (Proposed §§ 1.1199 through 1.1200)

1. Are Electronic Records Created Under this Rule Subject to the Electronic Records Requirements of Part 11 of this Chapter? (Proposed § 1.1199)

We are proposing to exempt from the requirements of 21 CFR part 11 records that meet the definition of electronic records in § 11.3(b)(6) and are established or maintained to satisfy the requirements of this proposed rule. We believe it would be unnecessarily burdensome to require such records to comply with the requirements in part 11. However, records that are established or maintained to satisfy the requirements of this program but that also are required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter. This is the same approach we took when finalizing our rule on accredited third-party certification.

2. Are the Records Obtained by FDA Under this Rule Subject to Public Disclosure? (Proposed § 1.1200)

We understand that notifications, records, and reports required under this program will often contain commercially sensitive information. Information submitted to the Agency, including reports and notifications submitted under proposed §§ 1.1123 and 1.1152, becomes an Agency record. We are proposing to clarify at proposed § 1.1200 that records under this proposed rule are subject to 21 CFR part 20, which provides protections for trade secrets and

confidential commercial information from public disclosure (see, e.g., § 20.61, "Trade secrets and commercial or financial information which is privileged or confidential"). This is the same approach we took when finalizing our rule on accredited third-party certification.

K. Proposed Revisions to 21 CFR Part 1, Subpart M

On November 27, 2015, FDA published in the *Federal Register* a final rule, "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (accredited third-party certification regulation), to implement section 808 of the FD&C Act on accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered food facilities) and the human and animal food produced by such entities meet applicable FDA food safety requirements (80 FR 74570). The accredited third-party certification regulation, codified at part 1, subpart M, establishes the requirements for how an accredited third-party certification body must conduct a food safety audit--i.e., a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices.

Under the accredited third-party certification regulation, an accredited third-party certification body must use an accredited laboratory when sampling and analysis is conducted for a regulatory audit (§ 1.651(c)(2)). Laboratories may be accredited in accordance with ISO/IEC 17025:2005 or another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of the sampling methodologies, analytical methodologies, and analytical results (§ 1.651(b)(3)). For consistency between the accredited third-party certification regulation and this rulemaking, we propose to revise § 1.651(b)(3) to cite the current version of the ISO/IEC laboratory accreditation standard by striking "ISO/IEC 17025:2005" and

inserting "ISO/IEC 17025:2017." This would mean that a laboratory accredited under this proposed rule, if finalized, would be among the laboratories that a third-party certification body could use to perform analysis.

In addition, we propose to remove the option in § 1.651(b)(3)(ii) for an accredited third-party certification body to use a laboratory accredited under a standard other than ISO/IEC 17025 when sampling and analysis is conducted for a regulatory audit. In developing this proposed rule, we have gathered additional information about the number and capacity of laboratories accredited under ISO/IEC 17025 to conduct food testing. Based on this information and in the interest of consistency, we are proposing to remove the option in § 1.651(b)(3)(ii) for an accredited third-party certification body to use a laboratory accredited under a standard other than ISO/IEC 17025 when sampling and analysis is conducted for a regulatory audit.

Finally, we are proposing clarifying edits to §§ 1.651(b)(3) and 1.651(c)(2) make it clear that the requirement to use a laboratory accredited under ISO/IEC 17025 to conduct food testing applies only to the analysis of the sample and not the collection of the sample itself. As discussed previously in this rule, we are not at this time proposing requirements for the accreditation of samplers.

We solicit comment on the effect, if any, of these proposed changes on an accredited third-party certification body's ability to meet the requirements in §§ 1.651(b)(3) and 1.651 (c)(2) to use an accredited laboratory when analyzing samples collected during a regulatory audit.

L. Proposed Revisions to 21 CFR Part 11

As we discussed in section VI.K.2, we are proposing to exempt from the requirements of part 11 records that meet the definition of electronic records in § 11.3(b)(6) and are established

or maintained to satisfy the requirements of this proposed rule. Consistent with that provision, we are making a conforming change in part 11 by adding a paragraph (p) to § 11.1 to that effect. The new paragraph (p) would also clarify that records that satisfy the requirements of this program but that also are required under other statutory provisions or regulations remain subject to part 11 to the extent that they are not separately exempted.

M. Proposed Revisions to 21 CFR Part 16

As we discussed in section VI.J, at proposed §§ 1.1171 through 1.1174 we have proposed to establish procedures for regulatory hearings for certain actions we may take under this proposed rule. We are proposing a conforming change to part 16, which describes procedures for regulatory hearings, to add revocation of recognition of an accreditation body, revocation of accreditation of a laboratory, and issuance of a food testing order to the list of actions for which a regulation hearing under part 16 may be held. The affected section is § 16.1.

N. Proposed Revisions to 21 CFR Part 129

As noted above at section VI.B.1, where we discuss proposed § 1.1107, the regulations on the processing and bottling of bottled drinking water at part 129 contain an explicit testing requirement that addresses an identified or suspected food safety problem and that therefore would have to be conducted by a laboratory accredited under this proposed rule. Specifically, § 129.35(a)(3)(i) contains a requirement that a source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Section 129.35(a)(3)(i) contains additional routine testing requirements that do not address an identified or suspected food safety problem and are not subject to this proposed rule.

Section 129.35(a)(3)(iii) provides that the analysis of samples taken under § 129.35(a)(3)(i) "may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency and State-certified laboratories)." Section 129.35(a)(3)(iii) has the potential to conflict with this proposed rule because section 422(b)(1)(A)(i) of the FD&C Act requires food testing conducted in response to the explicit testing requirement that "address[es] an identified or suspected food safety problem" in § 129.35(a)(3)(i) to be conducted by a laboratory accredited under this proposed program. A laboratory may qualify as a "competent commercial laboratory" but not be accredited under this proposed program. Accordingly, we are proposing a conforming change to § 129.35(a)(3)(iii) to clarify that the explicit testing requirement in § 129.35(a)(3)(i) that addresses an identified or suspected food safety problem must be conducted under this proposed program, which would require, in pertinent part, the laboratory conducting the testing to be accredited under this proposed program.

VII. Proposed Effective Date and Implementation Steps

The effective date is the date that provisions in the rule affect the current Code of Federal Regulations. We propose that the effective date of this rule would be 60 days after publication of the final rule in the *Federal Register.*

FDA intends to implement this program as expeditiously as practicable. Implementation of this laboratory accreditation program will necessarily need to occur in a stepwise fashion. We would announce when, after the effective date, we are prepared to accept applications for recognition from accreditation bodies. We would announce when we have recognized a sufficient number of accreditation bodies, at which point laboratories could then apply to the recognized accreditation bodies for accreditation. FDA would publish in the *Federal Register*, at

least 6 months in advance, notice that we have attained sufficient laboratory capacity such that owners/consignees in the circumstances described in proposed § 1.1107 will be required to utilize laboratories accredited under this program.

VIII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order (EO) 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). EOs 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). EO 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is not a significant regulatory action as defined by EO 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a significant number of testing laboratories are small businesses and due to initial one-time costs we find that the proposed rule may 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 $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Summary of Costs and Benefits

The proposed rule, if finalized, would require that testing of food in certain circumstances be performed by an accredited laboratory (participating lab) accredited to the proposed standards by a recognized accreditation body (participating accreditation body), and for the results to be submitted to us. The costs of the proposed rule, if finalized, would be incurred primarily by participating accreditation bodies, participating labs, shell-egg producers, sprouts producers, bottled water manufacturers, and owners and consignees of human and animal food offered for import covered by the proposed rule. We would incur costs to establish and maintain the program for recognizing accreditation bodies hoping to participate in our program, assessing participating accreditation bodies and participating labs, and for reviewing associated documents and reports. The present value of the cost of the proposed rule, if finalized, would range from $34 million to $78 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the cost would range from $39 million to $92 million.

The proposed rule, if finalized, would generate some quantified and unquantified benefits. Quantified benefits include cost-savings from the proposed clarifications of the process for compiling, submitting and reviewing analytical reports for human and animal food offered for import covered under the proposed rule, and a reduced burden from the proposed abbreviated reporting requirements. In addition, there would be savings from fewer false positive test results. We anticipate a reduction in the number of foodborne illnesses from fewer false negative test results for human and animal food offered for import covered under the proposed rule and for

shell eggs, sprouts, bottled water, and other food subject to specific testing requirements covered under the proposed rule. Unquantified benefits could include fewer illnesses from deterring unsafe manufacturing practices by all entities affected by the proposed rule. The present value of the quantified benefits of the proposed rule, if finalized, would range from $26 million to $81 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the quantified benefits would range from $32 million to $98 million. We expect that specific test reporting requirements would result in more accurate analytical reports and reporting.[7]

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. In table 1, we provide the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information System accounting information.

Table 1.--Summary of Benefits, Costs and Distributional Effects of Proposed Rule[1]

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$7.56	$3.71	$11.52	2016	7%	10 years	Cost savings
		$7.56	$3.71	$11.52	2016	3%	10 years	Cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative	Reduced risk of food-related illness from improper test reporting practices imported human and animal food covered under the proposed rule, and shell eggs, sprouts and bottled water and other tests subject to specific testing requirements. Reduced risk of food-related						

[7] There are currently no reporting requirements for tests of shell eggs, sprouts, or bottled water.

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
		illness from unsafe food manufacturing practices.						
Costs	Annualized Monetized $millions/year	$6.73	$4.64	$9.27	2016	7%	10 years	
		$6.76	$4.73	$9.28	2016	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						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 labs program described by the proposed rule. Wages: None Growth: None							

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

In line with EO 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon.

Table 2.--EO 13771 Summary Table (in $ Millions 2016 dollars discounted over an infinite time horizon)[1]

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$100.29	$56.49	$144.54	$216.92	$115.07	$319.32
Present Value of Cost Savings	$101.85	$71.15	$134.87	$237.65	$172.25	$307.92
Present Value of Net Costs	-$1.56	-$57.43	$53.51	-$20.73	-$149.76	$110.77
Annualized Costs	$7.02	$3.95	$10.12	$6.51	$3.45	$9.58
Annualized Cost Savings	$7.13	$5.17	$9.24	$7.13	$5.17	$9.24
Annualized Net Costs	-$0.11	-$3.99	$3.84	-$0.62	-$4.49	$3.32

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 21) and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

IX. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded, 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. Therefore, neither an environmental assessment nor an environmental impact statement is required (Ref. 22).

X. Paperwork Reduction Act of 1995

This proposed 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 (PRA) (44 U.S.C. 3501-3520). This analysis provides a description of these provisions and an estimate of the annual reporting and recordkeeping burden associated with the proposed rule. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Laboratory Accreditation for Analyses of Foods

Description: As mandated by section 422 of the FD&C Act, we are establishing of a program for the testing of food by accredited laboratories; establishing a publicly available registry of recognized accreditation bodies and accredited laboratories; and establishing procedures for reporting any changes affecting the recognition of such accreditation bodies or 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 accreditation from recognized accreditation bodies, and accredited laboratories. We estimate the burden of the information collection as follows:

Reporting Burden: Consistent with figures discussed in our Preliminary Regulatory Impact Analysis (PRIA) (see Section II.D, Number of Entities), we estimate a total of 66 respondents. We estimate that five to 80 accreditation bodies would apply for FDA recognition under the rule, with a mean distribution of 17.5 accreditation bodies. For this analysis we round up to 18. Similarly, we estimate of a mean of 48 laboratories will participate in the program, for a total of 66 respondents to the information collection. The reporting burden includes a burden of 8,820 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 2,940 hours. Cumulatively, this results in a total annual reporting burden of 15,049.05 hours, as reflected in table 3.

Table 3.--Estimated Annual Reporting Burden

21 CFR Part 1, Subpart R citation; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§§ 1.1113/1.1128(a); Accreditation bodies (ABs) application for recognition (one-time submission)	18	1	18	20	360
§ 1.1123(b) and (c); ABs--general reporting requirements	18	12	216	.5 (30 mins.)	108
§ 1.1128(b); ABs--application for renewal of recognition	18	1	18	3.6	64.8
§§ 1.1138 and 1.1158; laboratories--submission of application for accreditation (one-time submission)	48	1	48	20	960
§ 1.1152(c)(1) and (2); laboratories--Submission of sampling plan, sample collection report, and sampler qualifications	48	88.48	4,247	1.75	7,432
§ 1.1152(d); laboratories--qualification to submit abridged analytical reports (one-time submission).	48	10	480	2	960
§ 1. 1152(c)(3); laboratories--abridged analytical reports submissions	48	88.48	4,247	1.16	4,927
§ 1.1152(c)(4) and (5); laboratories--validation and verification studies submissions	9	1	9	.25 (15 mins.)	2.25
§ 1.1152(i); laboratories--advance notice of sampling submissions	48	3	144	1.5	216
§ 1.1152(j); laboratories--immediate notification	48	1.5	72	.25	18
§§ 1.1165; 1.1171; 1.1173; and 1.1174; requests in response to FDA action	1	1	1	1	1
Total					15,049.05

Proposed § 1.1128(a) would require accreditation bodies that wish to be recognized to submit an application to FDA that demonstrates their qualifications (those qualifications are specified by proposed § 1.1113) to accredit laboratories under this rule. We estimate this process would take one analyst between 40 and 80 hours to compile all the relevant information, prepare for an assessment, and complete 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 360 hours of burden for initial applications submitted by 18 accreditation bodies (18 applications × 20 hours per application), as reflected in row 1.

Proposed § 1.1123 would require a recognized accreditation body to report information, including significant changes affecting its accreditation program or the accreditation status of laboratories it accredits, and ensure FDA has access to these and other records. We estimate recognized accreditation bodies would incur a burden of 1 hour per month, or 12 hours per year, complying with both the reporting requirements of proposed § 1.1123 and the recordkeeping requirements of proposed § 1.1124. For this analysis, we identify recordkeeping and reporting burdens separately and assume 6 of the 12 hours (i.e., 30 minutes per month) would be spent meeting the reporting requirements of § 1.1123. Annually, this results in 108 hours (18 recognized accreditation bodies × 6 hours per year), as reflected in row 2.

Proposed § 1.1128(b) would require accreditation bodies 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 18 accreditations bodies for a total of 64.8 hours annually for the submission of renewal of applications (18 applications × 3.6 hours per application), as reflected in row 3.

Proposed § 1.1158 would require a laboratory seeking accreditation to submit an application for accreditation to a recognized accreditation body, demonstrating that it meets the requirements for accreditation under the proposed rule (those requirements are specified by proposed § 1.1138). We estimate 48 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 48 laboratories would be 960 hours (48 applications × 20 hours per application), as reflected in row 4.

Proposed § 1.1152(a) through (i) would require accredited laboratories to submit testing results of testing conducted under the program and include supporting documentation. However, 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 4,197, 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 a count of 50 submissions for a total of 4,247.

Proposed § 1.1152(c)(1) would require accredited laboratories to obtain, or develop, and submit a sample collection plan and sample collection report (the contents of which would be prescribed by proposed § 1.1149) with each test result. Under proposed § 1.1152(c)(2), laboratories would also be required to include documentation of the sampler's qualifications the first time the sampler collects a sample, or when the sampler's qualifications have significantly changed. We assume that it would take 30 minutes to 1 hour to compile a sampling plan, 30 minutes to one 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 credentials. 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 of time per test results 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 credential requirements (48 accredited laboratories × 88.48 sampling plans and sample collection reports × 1.75 hours) is 7,432 hours, as reflected in row 5.

Proposed § 1.1152(d) would allow accredited laboratories to qualify to submit abridged analytical reports in lieu of full analytical reports. At this time we expect this would be a one-time burden, but we may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. We assume that each accredited laboratory would submit 10 consecutive full analytical reports to qualify to submit abbreviated reports. We also assume accredited laboratories 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 accredited laboratories to qualify to submit abridged analytical reports of 960 hours (48 laboratories × 10 full analytical reports each × 2 hours per analytical report), as reflected in row 6.

After an accredited laboratory qualifies to submit abridged analytical reports, we assume it would submit abridged analytical reports to us thereafter. We may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. 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 an accredited laboratory 1.74 hours to compile and submit an abridged analytical report (29 percent × 6 hours). This results in an annual total reporting burden for the 48 accredited laboratories to compile and submit abridged analytical reports of approximately 4,927 hours (48 laboratories × 88.48 abridged analytical reports × 1.16 hours per abridged analytical report), as reflected in row 7.

The proposed rule would also require the participating lab to submit verification and validation studies to FDA as part of an analytical report, or to an accreditation body as a prerequisite for participation in the labs program. The ISO/IEC 17025 standard requires the use of validated and verified methods for testing foods. However, the proposed rule, if finalized, would require additional verification studies over and above the requirements of ISO/IEC 17025. 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 laboratories to submit verification studies such as matrix extensions under this proposed rule to be a middle value of approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025 (the PRIA estimates a range of 1 percent to 5 percent). In the PRIA 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.

With regard to validation requirements, we assume that methods used to test shell eggs, sprouts, and bottled water are either already validated or the costs to doing so would be included

in the costs to maintain accreditation to the ISO/IEC 17025 standard. Consequently, we assume that shell eggs, sprouts, and bottled water producers would incur no burden from this requirement beyond the burden of the proposed rule's requirements to meet the validation requirements of ISO/IEC 17025.

We estimate the time required to perform a matrix extension is a middle value of 34 hours (the PRIA 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 proposed rule would be approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO 17025, 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 proposed 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 .17708 matrix extensions per accredited laboratory (8.5 ÷ 48). Because the number of respondents and the annual responses per respondent in a PRA analysis must be whole numbers, we instead estimate that nine accredited laboratories (48 × .17708, rounded to 9 from 8.5) 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 proposed rule is 2.25 hours (9 accredited laboratories × 1 verification studies × .25 hours per study), as reflected in row 8.

Proposed § 1.1152(i) would provide that, under certain circumstances, FDA may require one or more accredited laboratories to 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 accredited laboratory will analyze under this program. We assume that it would take a laboratory analyst between 1 and 2 hours to compile the required information and submit the information, and we assume that between one percent and five percent of all test results submitted annually under this program would be subject to the notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Thus, we estimate that 127.41 test results (4,247 × 3%) would require submission of advance notice of sampling under the proposed rule. For this analysis we assume that each of the estimated 48 accredited laboratories would be required to submit three notices of advance sampling annually under the proposed rule (127.41 ÷ 48 = 2.65; rounded to 3). Thus, the annual reporting burden on accredited laboratories due to the proposed advance notice of sampling requirement would be 216 hours (48 laboratories × 3 advance notices of sampling × 1.5 hours), as reflected in row 9.

Proposed § 1.1152(j) would require accredited laboratories to notify FDA and the accreditation body of any changes that affect the laboratory's accreditation. Note, however, that under § 1.1123(c), recognized accreditation bodies also have a duty to immediately notify FDA of changes in an accredited laboratory's status. Thus, an accredited laboratory is not required to notify FDA of changes that fall under § 1.1123(c). To be conservative we estimate that every lab that participates will have some change about which it must notify its accreditation body, and for half of those changes the accredited laboratory will also need to notify FDA. We estimate it will

take an accredited laboratory 15 minutes per notification. Thus we estimate the burden associated with § 1.1152(j) would be 18 hours (48 accredited laboratories × 1.5 notifications × 0.25 hours per notification), as reflected in row 10.

Proposed §§ 1.1165, 1.1171, 1.1173, and 1.1174 provide for requests to FDA. Specifically, § 1.1165 provides for requests for reinstatement of 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 are estimating a cumulative total of 1 respondent and 1 burden hour, as reflected in row 11, however we invite specific comment in this regard. Upon implementation of any final rule, we will reevaluate our burden estimate in light of overall submissions to the Agency and public comments received.

Recordkeeping Burden: Recordkeeping requirements associated with the proposed rule include a one-time burden of 1,366.05 hours and annual burden of 41,912.74 hours. In this analysis, we annualize the one-time recordkeeping burden using a 3-year period horizon and zero percent discount rate, for an annualized one-time recordkeeping burden of 455.35. Cumulatively, we estimate an annual recordkeeping burden under this proposed rule of 43,278.79 hours, as reflected in table 4.

Table 4.--Estimated Annual Recordkeeping Burden

Proposed 21 CFR part 1, subpart R; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§§ 1.113 and 1.1118; recordkeeping associated with ISO/IEC 17011	18	1	18	1	18
§ 1.1124; ABs--additional recordkeeping requirements	18	1	18	6	108
§ 1.1138; laboratories--becoming accredited to ISO/IEC 17025 (one-time)	5	1	5	91.06	455.35
§ 1.1146; laboratories--maintaining ISO/IEC 17025 accreditation	48	1	48	889.53	42,697.44
Total					43,278.79

Proposed § 1.1113 and § 1.1118 would require accreditation bodies to meet the requirements of ISO/IEC 17011 to be recognized. While ISO/IEC 17011 includes recordkeeping requirements, as noted above we estimate that all of the 18 accreditation bodies that would become recognized under the proposed rule currently adhere to ISO/IEC 17011. 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.

Proposed § 1.1124, however, provides for the maintenance of certain records in addition to those required by ISO/IEC 17011. We estimate recognized accreditation bodies would incur a burden of 12 hours per year to comply with both the recordkeeping requirements of proposed § 1.1124 and the reporting requirements of proposed § 1.1123. For this analysis, we identify the recordkeeping and reporting burdens separately, assuming six of those 12 annual hours would be spent complying with the recordkeeping requirements of proposed § 1.1124. Thus, the annual recordkeeping burden for the 18 recognized accreditation bodies to meet the additional recordkeeping requirements of proposed § 1.1124 would be 108 hours, as reflected in row 2.

Proposed § 1.1138 would require laboratories to meet certain requirements of ISO/IEC 17025, including its recordkeeping requirements, to be accredited under the proposed rule. We estimate that between two to eight laboratories not currently accredited to ISO/IEC 17025 would become accredited. We use a middle estimate of five laboratories and also estimate that it would take a mean of 91.06 hours for the associated recordkeeping activities. This results in an annualized burden of 455.35, as reflected in row 3.

Proposed § 1.1146 would require laboratories to maintain conformance with ISO/IEC 17025, including its recordkeeping requirements. Based on available data, and as discussed in

our PRIA, we estimate a mean of 889.53 hours for this recordkeeping. This results in an annual burden of 42,697.44 hours, as reflected in row 4.

The proposed rule also affects currently approved information collections. Information collection provisions found in part 11 of our regulations are currently approved under OMB Control No. 0910-0303. Information collection provisions found in part 129 of our regulations are currently approved under OMB Control No. 0910-0658. Although no new information collection or no material modification is being introduced by the proposed rule, upon implementation of any final rule we will reevaluate our burden estimates for these collections accordingly. Finally, information collection provisions found in part 16 of our regulations are exempt from OMB review and approval under the PRA, as the information collection occurs during the conduct of an official administrative action (see 5 CFR 1320.4(a)(2)).

To ensure that comments on this information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the PRA, the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. We will publish a notice concerning OMB approval of these requirements in the *Federal Register*.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in EO 13132. We have determined that the proposed rule does not contain policies that have a substantial direct effect on the States, on the relationship between the National Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed 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.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*1. 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.

*2. 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 on June 17, 2019.

*3. "Private Laboratory Guidance," ORA Laboratory Manual, Vol. III, Section 7, document number III-07. FDA. January 30, 2013. https://www.fda.gov/media/81810/download. Accessed on June 17, 2019.

4. "ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories" (withdrawn). International Organization for Standardization/International Electrotechnical Commission. May 2005. 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/39883.html, or may be viewed on the internet through, https://www.surveymonkey.com/r/KFJMZ67

or may be examined at the Dockets Management Staff (Ref. Docket No. FDA-2019-N-3325 and/or RIN 0910-AH31).

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*8. FDA Draft Guidance for Industry, "Submission of Laboratory Packages by Accredited Laboratories" (withdrawn). FDA. January 16, 2009.

9. "Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2005." AOAC International. April 2015. Copies are available from AOAC International, 2275 Research Blvd, ste. 300, Rockville, MD 20850-3250, USA, or on the internet at http://www.aoac.org/aoac_prod_imis/AOAC/AOAC_Member/PUBSCF/ALACCCF/ALACC_M.aspx, or may be examined at the Dockets Management Staff (Ref. Docket No. FDA-2019-N-3325 and/or RIN 0910-AH31).

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12. "ISO/IEC 17011:2017(E), "Conformity Assessment–Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." International Organization for Standardization/International Electrotechnical Commission. November

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*16. "Accreditation Requirements: ISO/IEC 17025 Testing Laboratories (Non-Forensics)." ANSI/ASQ National Accreditation Board. October 9, 2018. https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=8160. Accessed on June 17, 2019.

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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).

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*19. FDA Memorandum, "Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition." FDA Foods and Veterinary Medicine Science and Research Steering Committee. May 19, 2015. https://www.fda.gov/media/81810/download. Accessed on June 17, 2019.

*20. Meeting Record, "FSMA Lab Accreditation/Food Laboratory Alliance Meeting Record August 21, 2015." FDA. July 21, 2015.

*21. FDA. Accreditation of Laboratories to Conduct Food Testing: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2019. https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

*22. FDA Memorandum. "Proposed Rule: Amendment of 21 CFR Parts 1, 11, 16, and 129 to Establish a Program for Laboratory Accreditation for Analyses of Foods as Required by FD&C Act." Leah D. Proffitt, FDA, June 14, 2019.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements, Incorporation by reference.

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, it is proposed that 21 CFR parts 1, 11, 16, and 129 be 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, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

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 Federal Food, Drug, and Cosmetic Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices.

* * * * *

3. Add subpart R, consisting of §§ 1.1102 through 1.1200, to read as follows:

Subpart R--Accreditation of Laboratories to Conduct Food Testing

Sec.

1.1109 How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public?

Recognition of Accreditation Bodies

1.1113 What requirements must an accreditation body meet to be recognized by FDA?

Requirements for Recognized Accreditation Bodies

1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?
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 evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?
1.1121 What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant 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 and notifications must a recognized accreditation body submit to FDA?
1.1124 What records requirements must a recognized accreditation body meet?
1.1125 What internal audit requirements must a recognized accreditation body meet?

Procedures for Recognition of Accreditation Bodies

1.1128 How does an accreditation body apply to FDA for recognition or renewal of recognition?
1.1129 How will FDA review applications for recognition and applications for renewal of recognition?
1.1130 How will FDA oversee recognized accreditation bodies?
1.1131 When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation?
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?
1.1133 How does an accreditation body request reinstatement of recognition?

Accreditation of Laboratories

1.1138 What requirements must a laboratory meet to become accredited by a recognized accreditation body?

Requirements for Accredited Laboratories

1.1146 What are the general requirements for accredited laboratories to remain accredited?
1.1147 What impartiality and conflict of interest requirements must accredited laboratories meet?
1.1148 What quality assurance requirements must accredited laboratories meet?

Procedures for Accreditation of Laboratories

Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under This Subpart

Electronic Records and Public Disclosure Requirements Under This Subpart

Subpart R--Accreditation of Laboratories to Conduct Food Testing

General Provisions

§ 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:

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.

Accredited laboratory means a laboratory that a recognized accreditation body has determined meets the applicable requirements of this subpart and has been accredited to conduct food testing using one or more methods of analysis under this subpart.

Analyst means an individual who analyzes samples.

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.

Food testing order means 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.

Owner or consignee means any person with an ownership or consignment interest in:

(1) The food product or environment that is the subject of food testing conducted under § 1.1107(a)(1);

(2) Food product or environment that is the subject of the order issued under § 1.1107(a)(2);

(3) The food product or environment that is the subject of food testing conducted under § 1.1107(a)(3);

(4) The article of food for which food testing is being conducted under § 1.1107(a)(4); or

(5) The food subject to an import alert for which food testing is conducted under § 1.1107(a)(5).

Recognition means a determination by FDA that an accreditation body meets the applicable requirements of this subpart and is authorized to 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 accredit laboratories under this subpart.

Representative sample means a sample that accurately, to a scientifically acceptable degree, represents the characteristics and qualities of the food product or environment that the sample was collected from.

Sampler means an individual or individuals who perform sampling.

Scope of accreditation refers to the methods of analysis for which the accredited laboratory is accredited. References in this subpart to accreditation "in-whole" refers to all methods in the accredited laboratory's scope of accreditation and references to accreditation "in-part" refers to only certain methods in the accredited laboratory's scope of accreditation.

§ 1.1103 Who is subject to this subpart?

(a) *Accreditation bodies.* An accreditation body is subject to this subpart if it has been recognized by FDA, or is seeking to be recognized by FDA, to accredit laboratories to conduct food testing under this subpart.

(b) *Laboratories.* A laboratory is subject to this subpart if it has been accredited by a recognized accreditation body, or is seeking to be 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 they are required to use an accredited laboratory to conduct food testing under this subpart.

General Requirements of this Subpart

§ 1.1107 Under what circumstances must food testing be conducted under this subpart by an accredited laboratory?

(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.* 21 CFR 112.146(a), (c) and (d);

(ii) *Shell eggs.* 21 CFR 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e); and

(iii) *Bottled drinking water.* 21 CFR 129.35(a)(3)(i) (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 food testing order;

(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 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;

(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 accredited laboratories that are accredited for the appropriate analytical method or methods by a recognized accreditation body.

(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 FDA has determined, and responded in writing to the owner/consignee, that a sample(s) taken prior to arrival is or would be representative sample(s) of such article(s) offered for import into the United States.

§ 1.1108 When and how will FDA issue a food testing order?

(a) FDA may require the owner or consignee of an article of food 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 related to the article of food.

(b) The food testing order will specify the food product or environment to be tested; whether the food testing may be conducted using an 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 food testing 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 food testing order, pursuant to § 1.1174 of this subpart.

§ 1.1109 How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public?

(a) Except as provided by paragraph (b) of this section, FDA will place on its website a list of:

(1) Recognized accreditation bodies, including for each recognized accreditation body: the name, contact information, and duration of recognition of the recognized accreditation body;

(2) Accreditation bodies that have their recognition revoked by FDA or are put on probation, and accreditation bodies that have relinquished their recognition or have allowed their recognition to expire, including for each accreditation body: the name of the accreditation body, whether FDA revoked recognition of the accreditation body or put the recognized accreditation body on probation, or whether the accreditation body relinquished its recognition or allowed its recognition to expire, and the date of the probation, revocation, relinquishment, or expiration;

(3) Laboratories accredited under this subpart, including for each laboratory: the name, contact information, and scope of accreditation of the accredited laboratory, and the name and contact information of the accreditation body that accredits the accredited laboratory; and

(4) Laboratories that have been put on probation or have had their accreditation withdrawn or revoked (in-whole or in-part) by a recognized accreditation body or by FDA, or have relinquished their accreditation (in-whole or in-part), including for each laboratory: the name of the laboratory, whether a recognized accreditation body or FDA put the laboratory on

probation, or withdrew or revoked the accreditation of the laboratory, or whether the laboratory relinquished its accreditation, and the date of the probation, withdrawal, revocation, or relinquishment.

(b) In the interest of national security, FDA, in coordination with the Secretary of Homeland Security, may determine an alternate time, manner, and form in which the list described in paragraph (a) of this section is made publicly available.

Recognition of Accreditation Bodies

§ 1.1113 What requirements must an accreditation body meet to become recognized by FDA?

To become recognized by FDA, an accreditation body seeking recognition by FDA must:

(a) Be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017;

(b) Demonstrate it complies with ISO/International Electrotechnical Commission (IEC) 17011:2017, "Conformity assessment--Requirements for accreditation bodies accrediting conformity assessment bodies," Second edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, https://www.iso.org/home.html. 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 fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations; and

(c) Demonstrate that it possesses sufficient scientific/technical expertise to be able to:

(1) Review the validation and verification studies required by § 1.1138(a)(1), including reviewing the verification studies for fitness for purpose;

(2) Assess an accredited laboratory's determination under § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method of analysis; and

(3) Assess whether the comparison program proposed by the accredited laboratory under § 1.1148(a)(2) would provide the recognized accreditation body with the ability to monitor the quality of the laboratory's performance to a degree comparable to a proficiency test.

(d) Demonstrate it is capable of complying with all requirements under this subpart for recognized accreditation bodies.

Requirements for Recognized Accreditation Bodies

§ 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?

To remain recognized, a recognized accreditation body must:

(a) Be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017;

(b) Meet, with respect to activities under this subpart, the requirements of ISO/IEC 17011:2017, which is incorporated by reference (see § 1.1113(b)); and

(c) Demonstrate that it possesses sufficient scientific/technical expertise to be able to:

(1) Review the validation and verification studies required by § 1.1138(a)(1), including reviewing the verification studies for fitness for purpose;

(2) Assess an accredited laboratory's determination under § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method of analysis; and

(3) Assess whether the comparison program proposed by the accredited laboratory under § 1.1148(a)(2) would provide the recognized accreditation body with the ability to monitor the quality of the laboratory's performance to a degree comparable to a proficiency test.

(d) Comply with all of the additional requirements under this subpart for recognized accreditation bodies.

§ 1.1119 What requirements apply to how a recognized accreditation body must protect against conflicts of interests?

(a) In addition to meeting the impartiality and conflict of interest requirements of § 1.1118(b), the recognized accreditation body must:

(1) Ensure that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it accredits; and

(2) Prohibit, subject to the exceptions in paragraph (b) of this section, officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory they accredit or that is seeking their accreditation that conducts food testing.

(b) The prohibited items of value specified in paragraph (a)(2) of this section do not include:

(1) Money representing payment of fees for accreditation services or reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory; or

(2) Lunch 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 to facilitate the efficient conduct of the assessment or reassessment.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities are considered the financial interests of such officers, employees, and other agents involved in accreditation activities.

§ 1.1120 How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?

(a) A recognized accreditation body must conduct an initial assessment of a laboratory seeking accreditation in accordance with the requirements of § 1.1118(b), 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 accreditation body conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017 to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017, 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)(1) and (c).

(d) A recognized accreditation body must oversee the performance of a laboratory it accredits in accordance with the applicable requirements of § 1.1118(b), except as otherwise provided by this subpart, to determine whether the accredited laboratory continues to meet the applicable requirements of this subpart.

(e) The assessment of the sample of the scope of accreditation of the accredited laboratory, which the recognized accreditation body must conduct at least every 2 years in accordance with § 1.1118(b), must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(f) If the recognized accreditation body conducted the initial assessment of the laboratory remotely in accordance with paragraph (c) of this section, the recognized accreditation body must conduct its first assessment of the sample of the scope of accreditation of the accredited laboratory no later than 2 years after the recognized accreditation body last conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017 to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017.

(g) The reassessment at the end of the accredited laboratory's accreditation cycle, which the recognized accreditation body must conduct in accordance with § 1.1118(b), must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(h) Any assessments conducted by a recognized accreditation body that are in addition to the assessments referred to in paragraphs (a), (e), and (g) of this section may be conducted remotely if it will not aid the assessment to conduct them onsite.

§ 1.1121 What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant accreditation?

A laboratory may appeal a decision by the recognized accreditation body to not grant the accreditation (in-whole or in-part) that the laboratory sought, and the recognized accreditation body must consider the appeal in accordance with the requirements of § 1.1118(b). In addition to meeting the requirements of § 1.1118(b) relating to appeals, the recognized accreditation body must make the appeals procedures publicly available. It must also establish and implement written procedures to use a competent person(s) who may or may not be external to the recognized accreditation body, who is free from bias or prejudice and has not participated in the accreditation decision and is not the subordinate of a person who participated in the accreditation decision, to review and decide appeals.

§ 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?

(a) *Grounds for withdrawal of accreditation.* A recognized accreditation body must withdraw the accreditation of a laboratory it accredits when the accredited laboratory substantially fails to comply with this subpart.

(b) *Grounds for probation.* If a recognized accreditation body determines that an accredited laboratory it accredits demonstrates deficiencies in performing its functions under this subpart that are less serious than those identified in paragraph (a) of this section, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, the recognized accreditation body may temporarily put the accredited laboratory on probation.

(c) *Withdrawal in-part.* When there are grounds for withdrawal of accreditation of an accredited laboratory that the recognized accreditation body accredits, but the deficiencies affect

only certain methods within the accredited laboratory's scope of accreditation, the recognized accreditation body may withdraw the accredited laboratory's accreditation for only for those affected methods.

(d) *Records request associated with withdrawal of accreditation or probation.* To assist the recognized accreditation body in determining whether a withdrawal of accreditation (in-whole or in-part) or probation is warranted under paragraph (a), (b), or (c) of this section, the recognized accreditation body may require from a laboratory that it accredits the submission of records that the accredited laboratory is required to maintain under § 1.1153.

(e) *Notification of withdrawal of accreditation.* The recognized accreditation body must notify the laboratory of the withdrawal (in-whole or in-part) of the laboratory's accreditation, and such notification must:

(1) Specify whether the withdrawal of accreditation is in-whole or in-part, and if it is in-part, to which method or methods it applies;

(2) Describe the grounds for withdrawal; and

(3) State the procedures for appealing the withdrawal.

(f) *Notification of probation.* The recognized accreditation body must notify the laboratory of the laboratory's probation, and such notification must:

(1) Describe the grounds for the probation;

(2) Identify all deficiencies that the laboratory must correct for the recognized accreditation body to lift the probation; and either

(i) Inform the laboratory that it has a specific timeframe to take particular corrective actions with respect to the deficiencies identified by the recognized accreditation body, or

(ii) Require the laboratory to submit a plan to the recognized accreditation body for approval that identifies the appropriate corrective actions the laboratory will take to resolve the deficiencies identified by the recognized accreditation body, and identify appropriate timeframes for resolution; and

(g) *Consequences of probation or withdrawal of accreditation, in-whole or in-part.* If the recognized accreditation body withdraws the accreditation of a laboratory in-whole, the laboratory is immediately ineligible to conduct food testing under this subpart. If the recognized accreditation body withdraws the accreditation of a laboratory in-part, the laboratory is immediately ineligible to conduct food testing under this subpart with respect to only the specific method or methods for which accreditation was withdrawn. An accredited laboratory that is put on probation by an accreditation body is permitted to continue to conduct food testing under this subpart.

(h) *Appeals procedures.* A laboratory may appeal a decision by the recognized accreditation body to withdraw the accreditation (in-whole or in-part) of the laboratory, and the recognized accreditation body must consider the appeal in accordance with § 1.1118(b). In addition to meeting the requirements of § 1.1118(b) related to appeals, the recognized accreditation body must establish and implement written procedures to:

(1) Make the appeals procedures publicly available; and

(2) Use a competent person or persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not participated in the withdrawal decision, and are not the subordinate of a person who participated in the withdrawal decision, to review and decide appeals.

§ 1.1123 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *General requirements.* All reports and notifications required by this section to be submitted to FDA must be submitted to FDA electronically and in English, and include:

(1) The name, street address, telephone number, and email address of the accreditation body associated with the report or notification, and the name of an appropriate point-of-contact for the accreditation body, and

(2) If there is a laboratory associated with the report or notification, the name, street address, telephone number, and email address of the laboratory associated with the report or notification, and the name of an appropriate point-of-contact for the laboratory.

(b) *Reporting results of recognized accreditation body internal audits.* A recognized accreditation body must submit to FDA a report of the results of the internal audit it is required to conduct pursuant to § 1.1118(b), including results of the audit of its compliance with the requirements of § 1.1118(c) and (d), conducted pursuant to § 1.1125, no later than 45 days after completing such internal audit, and the report must include:

(1) A description of the internal audit conducted;

(2) A description of any identified deficiencies;

(3) A description of any corrective actions taken and any corrective action the recognized accreditation body will take, including the timeline for such corrective actions; 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) *Immediate notification to FDA.* A recognized accreditation body must immediately, within 48 hours, notify FDA when the recognized accreditation body:

(1) Is aware of a change that would affect the recognition of such accreditation body, and the notification must include:

(i) A description of the change, and

(ii) If the change is one made by the recognized accreditation body, an explanation of the purpose of the change;

(2) Grants accreditation of a laboratory, and the notification must include:

(i) The scope of accreditation requested by the laboratory,

(ii) The scope of accreditation granted, and

(iii) The date on which accreditation was granted;

(3) Denies accreditation (in-whole or in-part) of a laboratory, and the notification must include:

(i) The scope of accreditation requested by the laboratory,

(ii) The scope of accreditation denied, and

(iii) The grounds for the denial;

(4) Receives notice that an accredited laboratory it accredited intends to relinquish its accreditation (in-whole or in-part), and the notification must include:

(i) The scope of accreditation to which the relinquishment applies, as applicable, and

(ii) The effective date of the relinquishment;

(5) Withdraws (in-whole or in-part) the accreditation of a laboratory; and the notification must include:

(i) The scope of accreditation to which the withdrawal applies, and

(ii) The grounds for the withdrawal;

(6) Puts an accredited laboratory on probation, and the notification must include:

(i) The grounds for the probation, and

(ii) Any date by which the recognized accreditation body has determined the accredited laboratory must take appropriate corrective action; and

(7) Knows that an accredited laboratory it accredits has committed fraud or submitted material false statements to FDA, and the notification must include:

(i) A description of the basis for the accreditation body's knowledge of the fraud or material false statements,

(ii) A description of the alleged fraud or material false statements, and

(iii) The actions taken by the recognized accreditation body with respect to such laboratory.

§ 1.1124 What records requirements must a recognized accreditation body meet?

(a) In addition to meeting the requirements of § 1.1118(b) related to records, a recognized accreditation body must maintain electronically, 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 accreditation;

(2) Assessments, reassessments, and decisions to grant, renew, deny, withdraw, expand, or reduce the scope of an accreditation or place an accredited laboratory on probation;

(3) Appeals of probation and denials and withdrawals of accreditation, final decisions on such appeals, and the bases for such final decisions;

(4) Its oversight of accredited laboratories it 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; and

(7) Records of fee payments and reimbursement of direct costs.

(b) An accreditation body that has been recognized must make records it is required to maintain under paragraph (a) of this section available to FDA for inspection and copying promptly upon written request by an authorized FDA officer or employee at the place of business of the accreditation body or at a reasonably accessible location. If the records required by paragraph (a) of this section are requested by FDA electronically, the records must be submitted to FDA electronically not later than 10 business days after the date of the request. Additionally, if the requested records are maintained in a language other than English, the accreditation body must electronically submit an English translation within a reasonable time.

(c) A recognized accreditation body must not prevent or interfere with FDA's access to the records the accredited laboratories it accredits are required to maintain under § 1.1153.

§ 1.1125 What internal audit requirements must a recognized accreditation body meet?

As part of the internal audit a recognized accreditation body is required to conduct pursuant to § 1.1118(b), the recognized accreditation body must audit its compliance with the requirements of § 1.1118(c) and (d).

Procedures for Recognition of Accreditation Bodies

§ 1.1128 How does an accreditation body apply to FDA for recognition or renewal of recognition?

(a) *Applicant for recognition.* An accreditation body seeking recognition must submit an application to FDA demonstrating that it meets the eligibility requirements in § 1.1113.

(b) *Applicant for renewal of recognition.* An accreditation body seeking renewal of its recognition must submit a renewal application demonstrating that it continues to meet the requirements of this subpart.

(c) *Documentation of conformance with requirements.* The accreditation body must submit documentation of conformance with ISO/IEC 17011:2017 and separate documentation of ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017, in meeting the requirements of § 1.1113(a) and (b) or § 1.1118(a) and (b), as applicable. The accreditation body also must submit documentation of its compliance with § 1.1113(c) and (d) or § 1.1118(c) and (d), as applicable.

(d) *Submission.* An accreditation body must submit recognition and renewal applications and any documents provided as part of the application process to FDA electronically, in English. The 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.

(e) *Signature.* An accreditation body must sign the recognition and renewal applications in the manner designated by FDA. Recognition and renewal application must be signed by the applicant or by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.1129 How will FDA review applications for recognition and applications for renewal of recognition?

(a) *Review of application for recognition or renewal of recognition.* FDA will examine an accreditation body's application for recognition or renewal of recognition for completeness and notify the applicant of any deficiencies. FDA will review an accreditation body's application for recognition or renewal of recognition on a first in, first out basis according to the date on which

the completed application was submitted; 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 any submitted application for recognition or renewal of recognition to determine whether the applicant meets the requirements for recognition. Such evaluation may include an onsite assessment of the accreditation body. FDA will notify the applicant, in writing, regarding whether the application has been approved or denied. FDA may make such notification electronically. If FDA does not reach a final decision on a renewal application before an accreditation body's recognition terminates by expiration, FDA may extend the existing term of recognition for a specified period of time or until FDA reaches a final decision on the renewal application.

(c) *Issuance of recognition.* FDA will notify the applicant that its application for recognition or renewal of recognition has been approved through issuance of recognition that will list 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) *Issuance of denial of application for recognition or renewal of recognition.* If FDA denies an applicant's application for recognition or renewal of recognition, FDA will notify the applicant, through an issuance of a notification of denial of recognition or denial of renewal of recognition. The notification of denial of recognition or denial of renewal of recognition 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.* An applicant whose application for renewal of recognition was denied by FDA must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.1124 and make them available to FDA as required by § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1124 will be located.

(g) *FDA notice to accredited laboratories.* FDA will promptly issue a notice of the denial of the application for renewal of recognition of the accreditation body to all laboratories accredited by the accreditation body whose application for renewal of recognition was denied.

(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 a renewal application and will include the date of the issuance of the denial of a renewal application.

§ 1.1130 How will FDA oversee recognized accreditation bodies?

(a) FDA will assess each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment will occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. An FDA assessment of a recognized accreditation body may include review of records, an onsite assessment of the accreditation body, and onsite assessments of one or more accredited laboratories the recognized accreditation body accredits, with or without the recognized accreditation body present.

(b) FDA may conduct additional assessments of a recognized accreditation body at any time to determine the recognized accreditation body's compliance with the applicable requirements of this subpart.

§ 1.1131 When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body if it fails to meet the requirements of this subpart, or where FDA determines the accreditation body has committed fraud or submitted material false statements to FDA.

(b) *Issuance of revocation.* (1) FDA will notify the accreditation body that its recognition has been revoked through the issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under § 1.1173 on the revocation, and the procedures for requesting reinstatement of recognition under § 1.1133.

(2) Within 10 business days of the date of issuance of revocation, the accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain records and make them available to FDA as required by § 1.1124. The contact information for the custodian must provide, at a minimum, an email address and the street address where the records will be located.

(c) *Grounds for probation.* If FDA determines that a recognized accreditation body has demonstrated deficiencies in performing its functions that are less serious and more limited than those identified in paragraph (a) of this section, and it is reasonably likely that the accreditation body will be able to correct such deficiencies within a reasonable period of time, FDA may temporarily put the recognized accreditation body on probation and request that the accreditation body take appropriate corrective actions.

(d) *Length of probation.* FDA's probation of an accreditation body's recognition shall remain in effect until the accreditation body demonstrates to FDA's satisfaction that the accreditation body has successfully implemented appropriate corrective actions to address the deficiencies specified by FDA within the time period identified by FDA, or until FDA revokes the recognition of the accreditation body.

(e) *Notification of probation.* FDA will notify the accreditation body of its probation and such notification will:

(1) Describe the grounds for the probation;

(2) Identify all deficiencies that must be corrected for FDA to lift the probation and identify a specified period of time to take corrective actions to address the deficiencies specified by FDA.

(f) *Effect of revocation of recognition or probation on the accreditation body.* (1) An accreditation body that has had its recognition revoked by FDA may not accredit laboratories under this subpart or continue to oversee the laboratories it has previously accredited.

(2) A recognized accreditation body that is put on probation by FDA will be expected to continue to oversee laboratories that it has accredited under this subpart and is permitted to continue to accredit laboratories under § 1.1120 of this subpart.

(g) *FDA notice to the accredited laboratories.* FDA will issue a notice of the probation or revocation of recognition to all laboratories accredited by the recognized accreditation body that was put on probation or the accreditation body whose recognition was revoked.

(h) Public notice of probation or revocation of recognition. FDA will provide notice on the website described in § 1.1109 of the issuance of the probation or revocation of recognition of an accreditation body.

§ 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?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* A recognized accreditation body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal. The recognized accreditation body must provide the name and contact information of the custodian who will maintain the records required under § 1.1124 after the date of relinquishment or the date recognition expires, as applicable, and make them available to FDA as required by § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1124 will be located.

(b) *Notice to accredited laboratories of intent to relinquish or not to renew recognition.* At least 60 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 accredited 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.

§ 1.1133 How does an accreditation body request reinstatement of recognition?

(a) *Application following revocation of recognition.* An accreditation body that has had its recognition revoked by FDA may seek reinstatement by submitting a new application for recognition under § 1.1128. The accreditation body must also submit evidence to FDA with its application that the grounds for revocation have been resolved, including evidence addressing

the cause(s) or condition(s) that were the grounds for revocation and must identify measures that have been implemented to help ensure that such cause(s) or condition(s) are 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 may seek recognition by submitting a new application for recognition under § 1.1128.

Accreditation of Laboratories

§ 1.1138 What requirements must a laboratory meet to become accredited by a recognized accreditation body?

(a) To become accredited by a recognized accreditation body, an accredited laboratory must:

(1) Demonstrate it is capable of conducting each method of food testing for which it seeks to be accredited, by:

(i) Submitting information to demonstrate appropriate verification or validation of the method(s), including the information required by § 1.1151(c)(2) and (d)(2), and a statement by the laboratory based on the verification or validation results of whether the laboratory is able to properly apply the method; and

(ii) Passing, or having passed within the past year, a proficiency test for the method, subject to the exception that if the laboratory determines there is no proficiency testing program available that addresses the method, or that proficiency testing for the method is otherwise impracticable, the accredited laboratory may instead subject, or have subjected in the past year, the method to an appropriate comparison program. The laboratory's determination must be reviewed by, and approved or denied (as appropriate) by, the recognized accreditation body from which the laboratory is seeking accreditation.

(2) Except as provided in paragraph (b) of this section, demonstrate it complies with ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories," Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, https://www.iso.org/home.html. 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 fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.

(b) For purposes of this program the laboratory is not required to satisfy the following provisions of ISO/IEC 17025:2017:

(1) 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;

(2) In section 7: 7.3; or

(3) In section 7: 7.8.

(c) Demonstrate it is capable of meeting and operating in conformance with all of this subpart's additional requirements for accredited laboratories.

Requirements for Accredited Laboratories

§ 1.1146 What are the general requirements for accredited laboratories to remain accredited?

To remain accredited, the accredited laboratory must:

(a) Be capable of conducting the methods of analysis for the testing of food for which it is accredited;

(b) Maintain conformance with the provisions of ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories," Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, https://www.iso.org/home.html. 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 fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations. This requirement is subject to the exceptions in § 1.1138(b); and

(c) Operate in conformance with the additional requirements of this subpart.

§ 1.1147 What impartiality and conflict of interest requirements must accredited laboratories meet?

(a) In addition to the requirements relating to impartiality and conflict of interest an accredited laboratory is required to meet under § 1.1146(b), the accredited laboratory must, subject to the exceptions in paragraph (b) of this section, prohibit the accredited laboratory's employees, contractors, and agents involved in food testing 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 accredited laboratory.

(b) The prohibited items of value specified in paragraph (a) of this section do not include:

(1) Payment of fees for food testing services;

(2) Reimbursement of direct costs associated with the food testing by the accredited laboratory; and

(3) With respect to accredited laboratories that are owned by the owner or consignee of the food that is tested or to be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

(c) The owner or consignee's payment to the accredited laboratory of fees for food testing services and/or reimbursement of direct costs associated with food testing must be independent of whether the test results indicate that food is or appears to be violative.

§ 1.1148 What quality assurance requirements must accredited laboratories meet?

In addition to the requirements relating to quality assurance an accredited laboratory is required to meet by § 1.1146(b), accredited labs must:

(a) Meet the following proficiency testing requirements:

(1) Accredited laboratories must participate in a proficiency testing program or programs provided by a competent proficiency testing organization, except as provided in paragraph (a)(2) of this section. The accredited laboratory must ensure such proficiency testing is conducted at least once per year for each method within the accredited laboratory's scope of accreditation.

(2) If the accredited laboratory determines there is no proficiency testing program available that addresses a particular method of analysis in the accredited laboratory's scope of accreditation, or that participating in a proficiency testing program for the particular method of analysis is otherwise impracticable, the accredited laboratory may subject that method of analysis to an appropriate comparison program. The determination must be reviewed, and

approved or denied (as appropriate), by the recognized accreditation body that accredits the accredited laboratory.

(b) Ensure 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.

§ 1.1149 What oversight standards apply to sampling?

(a) Before analyzing a sample, the accredited laboratory must develop (if it collected the sample) or obtain (if another entity collected the sample):

(1) Written documentation of the sampler's applicable qualifications by training and experience. An accredited laboratory only needs to develop or obtain documentation of a sampler's qualifications the first time that individual collects a sample under this subpart, unless the accredited laboratory learns that the sampler's qualifications have significantly changed since the accredited laboratory last obtained documentation of the sampler's qualifications;

(2) A written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler 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, at a minimum, include:

(i) The product code of the food product sampled (if product is being sampled) or the location of and a description of the environment (if environment is being sampled);

(ii) The date(s) of the sampling;

(iii) The size, identity, and quantity of the sample(s);

(iv) Documentation of sample collection procedures and any sample preparation techniques; and

(v) Documentation of the chain of custody of the sample(s), and of measures taken, to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s).

(b) If any of the requirements in paragraph (a) of this section are not met, FDA may consider the analysis of the sample to be invalid.

§ 1.1150 What requirements apply to analysis of samples by an accredited laboratory?

In addition to meeting the requirements of § 1.1146(b):

(a) The analysis must be conducted on either the sample(s) received from the sampler or, if appropriate, on a representative sample of the sample(s) received from the sampler.

(b) The analyst(s) that conducts the analysis 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 §§ 1.1146(b) and 1.1147.

(c) The method used to conduct the food testing must meet the requirements of § 1.1151.

(d) The 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(g)).

§ 1.1151 What requirements apply to the methods of analysis an accredited laboratory uses to conduct food testing under this subpart?

In addition to meeting the requirements of § 1.1146(b), an accredited laboratory must meet the following requirements:

(a) Analysis under this subpart must be conducted using a method of analysis that:

(1) Is fit for purpose;

(2) Is within the accredited laboratory's scope of accreditation;

(3) Has been appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and

(4) Has been appropriately verified by the accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.

(b) With respect to food testing conducted under:

(1) Section 1.1107(a)(1), if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribes a test method, that is the only appropriate method that may be conducted for such food testing;

(2) Section 1.1107(a)(2), if the food testing order prescribes a test method, that is the only appropriate method that may be conducted for such food testing.

(c)(1) An accredited laboratory must validate methods in accordance with the requirements of § 1.1146(b).

(2) An accredited laboratory performing validation of a method under this subpart must record the information required by the requirements of § 1.1146(b), and the supporting analytical data.

(d)(1) Before an 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 accredited laboratory must have verified it can properly perform the method for the specific intended use.

(2) An 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.

(e) An accredited laboratory may submit a written request to FDA requesting FDA's permission to use a method or methods outside of its scope of accreditation for food testing. FDA may approve the request if both following conditions are satisfied:

(1) A new methodology or methodologies have been developed and validated but no reasonably available laboratory has been accredited to perform such methodology or methodologies, and

(2) The use of such method or methods is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

§ 1.1152 What notifications, results, and reports must accredited laboratories submit to FDA?

(a) *General requirements.* (1) All notifications, results, reports, and studies required to be submitted to FDA by accredited laboratories under this subpart must be submitted to FDA electronically and in English, and:

(i) Include the legal name and street address of the accredited laboratory, identify a point-of-contact for the accredited laboratory that FDA may contact with questions or comments

regarding the notification, result, report, or study, and include the email address and telephone number of the point-of-contact;

(ii) Display an identification unique to the test results, report, notification, or study; and

(iii) Be true, accurate, unambiguous, and objective.

(2) The 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 accredited laboratory that is responsible for the submission of same becomes aware that any aspect of the submitted material is inaccurate, the 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 section 7.8.8. ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories," Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, https://www.iso.org/home.html. 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 fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations

(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 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 section 7.8.6.

(b) *Test results.* (1) The results of any and all tests conducted by an accredited laboratory under this subpart must be submitted directly to FDA.

(2) The accredited laboratory must submit the results of testing conducted under this subpart directly to FDA via the destination specified by the website described by § 1.1109, unless directed to use a different method of submission by FDA regarding testing conducted under § 1.1107(a)(2) or (3).

(3) The test results must be clear and identify 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 submitted to FDA with each test result 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 accredited laboratory in accordance with § 1.1149;

(2) Written documentation of the sampler's qualifications, if § 1.1149(a)(1) requires the accredited laboratory to obtain such documentation;

(3) The full analytical report required by paragraph (g) of this section, documenting the analysis related to the food testing, except that if the accredited laboratory is permitted in accordance with paragraph (d) of this section to submit abridged analytical reports, the accredited laboratory may instead submit an abridged analytical report, which must contain the information required by paragraph (f) of this section;

(4) For any validation studies required by § 1.1151(c)(1), the documentation required by § 1.1151(c)(2), except when the circumstances of paragraph (c)(6) of this section apply with respect to the validation study.

(5) For any verification studies required by § 1.1151(d)(1), the documentation required by § 1.1151(d)(2), except when the circumstances of paragraph (c)(6) of this section apply with respect to the verification study.

(6) Paragraphs (c)(4) and (5) of this section do not require the accredited laboratory to submit the validation or verification study to FDA if the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1)(i). If the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1)(i), the accredited laboratory must instead submit to FDA, in lieu of the validation or verification study, a statement that the validation or verification study has been submitted to its recognized accreditation body in accordance with § 1.1138(a)(1)(i), and the accredited laboratory must identify the method, analyte, and matrix that were the subject of the validation or verification study;

(7) A certification from one or more members of the 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 the certifier(s).

(d) *Permission to submit abridged analytical reports.* (1) Accredited laboratories that are not disqualified under paragraphs (d)(6)(i) and (d)(7) of this section or on probation are permitted to submit to FDA on an ongoing basis abridged analytical reports relating to a specific

major food testing discipline(s) that is represented in the reports described in paragraph (d)(1)(ii) of this section, after FDA has given notice that the following conditions are fulfilled:

(i) The accredited laboratory submits 10 consecutive full analytical reports to FDA under this subpart;

(ii) The consecutive full analytical reports include at least one full analytical report relating to each major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports;

(iii) None of the consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing; and

(iv) The consecutive full analytical reports do not contain repeated administrative deficiencies.

(2)(i) Accredited laboratories that fail to satisfy the condition in paragraph (d)(1)(iii) of this section are subject to the disqualification period described in paragraph (d)(6)(i) of this section.

(ii) Accredited laboratories that fail to satisfy the condition in paragraph (d)(1)(iv) of this section have a second attempt to satisfy the conditions in paragraphs (d)(1)(i) to (iv) of this section with 10 subsequent consecutive full analytic reports. If one of those subsequent consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing, or the subsequent consecutive full analytical reports contain repeated administrative deficiencies, the accredited laboratory is subject to the disqualification period described in paragraph (d)(6)(i) of this section.

(3) Accredited laboratories that are not on probation and are currently permitted to submit abridged analytical reports for at least one major food testing discipline under this paragraph are

permitted to submit to FDA on an ongoing basis abridged analytical reports relating to any additional major food testing disciplines that were not represented in the reports described in paragraph (d)(1)(ii) of this section, after FDA has given notice that the following conditions are fulfilled:

(i) The accredited laboratory submits to FDA at least one full analytical report for each additional major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports;

(ii) None of the full analytical reports for each additional major food testing discipline demonstrate any material substantive shortcoming in the food testing; and

(iii) None of the full analytical reports for each additional major food testing discipline contain repeated administrative deficiencies.

(4)(i) Accredited laboratories that fail to satisfy the condition in paragraph (d)(3)(ii) of this section for an additional major food testing discipline(s) are subject to the disqualification period described in paragraph (d)(6)(ii) of this section for such additional major food testing discipline(s).

(ii) Accredited laboratories that fail to satisfy the condition in paragraph (d)(3)(iii) of this section for an additional major food testing discipline(s) have a second attempt to satisfy the conditions in paragraphs (d)(3)(i) to (iii) of this section with at least one full analytic report for each additional major food testing discipline for which the accredited laboratory is seeking to submit abridged analytical reports. If that subsequent full analytical report(s) demonstrates any material substantive shortcoming in the food testing, or the subsequent full analytical report(s) contains repeated administrative deficiencies, the accredited laboratory is subject to the disqualification period described in paragraph (d)(6)(ii) of this section for the major food testing

discipline that was the subject of the full analytical report containing the shortcoming or deficiencies.

(5) If one or more test results, notifications, reports, and/or studies relating to a specific major food testing discipline submitted to FDA under this subpart by an accredited laboratory that is permitted to submit abridged analytical reports for that major food testing discipline demonstrates any material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, the accredited laboratory is disqualified to submit abridged reports for that specific major food testing discipline in accordance with either paragraph (d)(6)(ii) of this section (if the accredited laboratory is permitted to submit abridged analytical reports for another discipline) or paragraph (d)(6)(i) of this section (if the accredited laboratory is not permitted to submit abridged analytical reports for any another discipline).

(6)(i) The period of disqualification is either 2 years or until the accredited laboratory submits 20 more full analytical reports to FDA under this subpart, whichever period of time is longer, after which time the accredited laboratory may request permission under paragraph (d)(7) of this section to fulfill the eligibility conditions under paragraph (d)(1) of this section.

(ii) The period of disqualification is either 2 years or until the accredited laboratory submits two more full analytical reports to FDA under this subpart, whichever period of time is longer, after which time the accredited laboratory may request permission under paragraph (d)(7) of this section to fulfill the eligibility conditions under paragraph (d)(3) of this section.

(iii) Whenever, during the period of disqualification described under paragraph (d)(6)(i) or (ii) of this section, a full analytical report submitted by an accredited laboratory demonstrates any material substantive shortcoming in the food testing, that accredited laboratory's disqualification period is extended by 6 months.

(iv) Whenever, during the period of disqualification described under paragraph (d)(6)(i) or (ii) of this section, the full analytical reports submitted by an accredited laboratory contain repeated administrative deficiencies, that accredited laboratory's disqualification period is extended by 2 months.

(7) An accredited laboratory that has fulfilled the conditions of paragraph (d)(6)(i) or (ii) of this section, as applicable, and that is not on probation, may submit a request to FDA via the destination specified by the website described by § 1.1109 to attempt to fulfill the conditions as described in paragraphs (d)(1) and (3) of this section, as applicable. FDA will consider permitting the accredited laboratory to again try and fulfill the conditions of paragraph (d)(1) or (3) of this section, as applicable. If FDA grants permission and upon fulfillment of those conditions, FDA will provide notice that the accredited laboratory is permitted to submit to FDA on an ongoing basis abridged analytical reports relating to the disciplines for which the conditions are fulfilled.

(e) *Exceptions to permission to submit abridged analytical reports.* (1) 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 that an accredited laboratory that is permitted to submit abridged analytical reports additionally submit to FDA the full analytical report within 48 hours of FDA's notice.

(2) FDA may require an accredited laboratory that is permitted to submit abridged analytical reports under this subpart to submit full analytical reports if such analytical reports relate to an FDA investigation or FDA enforcement proceeding.

(f) *Abridged analytical report contents.* Abridged analytical reports must contain:

(1) All information described by ISO/IEC 17025:2017 sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d). ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories," Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, https://www.iso.org/home.html. 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 fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations; and

(2) The justification for any modification or deviation to the method(s) of analysis used and documentation of the accredited laboratory's authorization for the modification or deviation.

(g) *Full analytical report contents.* Full analytical reports must contain:

(1) All information described by paragraphs (f)(1) and (2) of this section;

(2) Documentation of references for the method or methods of analysis used;

(3) Identification of the analyst or analysts who conducted each analytical step, validation step (if applicable), and verification step (if applicable), including the analyst's or analysts' legal name and signature, and the date each analytical step, validation step (if applicable), and verification step (if applicable) 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 made 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 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 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 or certificates of analysis for standards and software; and

(12) The following information about the qualifications of the analyst or analysts who were involved in the analysis conducted under this subpart, if the accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's

qualifications have significantly changed since the accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

(i) The analyst's curriculum vitae;

(ii) Training records with regards to methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider;

(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); and

(iv) Individual proficiency test worksheets relevant to the analysis being performed.

(h) *Additional information about non-standard methods.* If the 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 accredited laboratory must submit documentation of the method to FDA.

(i) *Advance notice of sampling.* (1) If FDA determines that the sampling conducted by a sampler may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if FDA determines that the sampling may have been otherwise improper, FDA may require the accredited laboratory that analyzed the associated sample(s), and other accredited laboratories that have analyzed samples collected by the sampler previously, to request and receive from the sampler, and submit or require the sampler to submit, an advance notice of sampling to FDA 48 hours before each of the next 10 occasions that the sampler will collect a sample that the accredited laboratory will analyze under this subpart.

(2) FDA may, as appropriate:

(i) Specify the type of food product or environment that requires advance notice of sampling under this subpart,

(ii) Determine that an amount of time other than 48 hours in advance is required, to a minimum of 24 hours and up to 7 business days in advance, and

(iii) Determine that a number of occasions other than 10 are required, to a minimum of 1 occasion and up to a maximum of 20 occasions.

(iv) Notify affected accredited laboratories that submission of additional notices of sampling are not required.

(3) The advance notice of sampling must contain:

(i) A unique identification code for the advance notice of sampling;

(ii) The name of the accredited laboratory that will conduct analysis of the sample;

(iii) The name and street address of the sampler that will conduct the sampling;

(iv) A primary contact (name and phone number) for the sampler;

(v) The reason(s) 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(s) and the FDA product code(s) of the food; and

(viii) The date and approximate time the sampling will begin.

(j) *Immediate notification of significant changes.* When any changes occur that affect the accreditation of the accredited laboratory, the accredited laboratory must immediately, within 48 hours, send FDA and the accreditation body that accredited it notice of such changes, a detailed description of such changes, and an explanation of how such changes affect the accreditation of the accredited laboratory. Accredited laboratories are not required to notify FDA of changes that recognized accreditation bodies must provide notification of under § 1.1123(c).

(k) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA by paragraphs (a) through (j) of this section, FDA may consider the related food testing to be invalid.

§ 1.1153 What other records requirements must an accredited laboratory meet?

In addition to meeting the requirements of § 1.1146(b) related to records, laboratories that have been accredited must meet the following requirements:

(a) Maintain electronically, for 5 years after the date of creation, records created and received while they are accredited that relate to compliance with this subpart, including:

(1) Documents related to the accredited laboratory's grant (and, if applicable, expansions and reductions) of accreditation from its recognized accreditation body;

(2) Documentation of food testing the accredited laboratory conducted under this subpart, in accordance with § 1.1150(d);

(3) All documents that the accredited laboratory was required to submit to FDA under § 1.1152, and associated correspondence by the accredited laboratory (and its officers, employees, and other agents) with the owner or consignee (and its officer, employees, and other agents) of the tested food product or environment;

(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 actions taken to address any problems or deficiencies related to activities under this subpart;

(6) Any and all documentation related to probation or withdrawal from accreditation 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) Within 30 days of the receipt of proficiency testing results, submit the results:

(1) To the recognized accreditation body that accredits the accredited laboratory; and

(2) If the accredited laboratory failed the proficiency test, to FDA, via the destination specified by the website described by § 1.1109.

(c) Make the records required by paragraphs (a) and (b) of this section available for inspection and copying upon written request of an authorized officer or employee of FDA. The authorized officer or employee of FDA may request that the laboratory that has been accredited submit such records to FDA electronically or that the laboratory 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 the records be submitted electronically, the records must be submitted electronically not later than 10 business days after the date of the request, except that records related to the immediate notification provision in § 1.1152(j) must be submitted within 48 hours. Additionally, if the authorized FDA officer or employee requests records that are maintained in a language other than English, the laboratory that has been accredited must electronically submit an English translation of the records to FDA within a reasonable time.

(d) Ensure that significant amendments to records described by paragraphs (a) and (b) of 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 laboratory that has been accredited during the time period that 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 a more recent version of the document exists.

Procedures for Accreditation of Laboratories

§ 1.1158 How does a laboratory apply for accreditation or modification of its scope of accreditation by a recognized accreditation body?

(a) *Submission of application for accreditation to a recognized accreditation body.* A laboratory seeking accreditation must submit its application for 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 accreditation had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body or revoked by FDA the previous time it was accredited under this subpart, the laboratory must meet the additional requirements specified by § 1.1165.

(b) *Documentation of conformance with ISO/IEC 17025:2017.* The laboratory may use documentation of conformance with ISO/IEC 17025:2017, as applicable and supplemented as necessary, in meeting the applicable requirements of this subpart.

(c) *Duration of accreditation.* If an accredited laboratory maintains compliance with all requirements of this subpart including maintaining accreditation to ISO/IEC 17025:2017, the laboratory's accreditation does not end until withdrawn, revoked, or relinquished under this subpart.

§ 1.1159 How will FDA oversee accredited laboratories?

(a) FDA may assess accredited laboratories at any time to determine whether the accredited laboratory continues to comply with the applicable requirements of this subpart and

whether there are deficiencies in the performance of the accredited laboratory that, if not corrected, would warrant probation or revocation of its accreditation under § 1.1161.

(b) In evaluating the performance of an accredited laboratory under paragraph (a) of this section, FDA may review any of the following:

(1) Records the accredited laboratory is required to maintain under this subpart;

(2) Records the accreditation body that accredited the accredited laboratory is required to maintain under this subpart;

(3) Information obtained by FDA during an onsite assessment by FDA of the accredited laboratory conducted pursuant to paragraph (c) of this section;

(4) Information obtained by FDA during an assessment of the recognized accreditation body that accredited the laboratory; and

(5) Any other information obtained by FDA, including during FDA's inspections or investigations of one or more owners or consignees of food subject to food testing under this subpart.

(c) FDA may conduct an onsite assessment of an accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to assess an accredited laboratory.

(d) FDA will report any of its observations and findings of its assessment to the accredited laboratory's recognized accreditation body.

§ 1.1160 How will FDA review submitted 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:

(1) May consider the analysis to be invalid; and/or

(2) Will notify the accredited laboratory that appears to be responsible for the deficiency and may also notify the owner or consignee of the food of the deficiency. When we notify the accredited laboratory that appears to be responsible for the deficiency, the accredited laboratory must respond, in writing, to FDA regarding the deficiency within 30 days or an agreed-upon timeframe, including a statement with respect to how the accredited laboratory intends to address the deficiency, and/or a statement describing the extent to which the laboratory has addressed the deficiency.

(b) FDA may report FDA's determinations of any deficiencies resulting from its review of any test results, reports, and related documents under this subpart to the recognized accreditation body that accredits the accredited laboratory.

(c) If the deficiency in the test result, analytical report, and/or associated analysis demonstrates a material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, FDA will also consider whether disqualification from being eligible for permission to submit abridged analytic reports under § 1.1152(d), and/or other action under this subpart, is appropriate.

(d) Nothing in this subpart shall be construed to limit the ability of FDA to review and act upon information received about food testing, including determining the sufficiency of such information and testing.

§ 1.1161 When will FDA put an accredited laboratory on probation or revoke the accreditation of a laboratory?

(a) *Grounds for revocation of accreditation.* FDA may revoke the accreditation (in-whole or in-part) of an accredited laboratory to conduct food testing under this subpart for good cause, which may include any of the following reasons:

(1) Demonstrated bias or lack of objectivity when conducting food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(2) Performance that calls into question the validity or reliability of its food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(3) Other failure to substantially comply with this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(b) *Grounds for probation.* If FDA determines that an accredited laboratory has demonstrated deficiencies in performing its functions that are less serious and more limited than those identified in paragraph (a) of this section, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, FDA may temporarily put the accredited laboratory on probation and request that the laboratory take appropriate corrective actions.

(c) *Revocation in-part.* When there are grounds for revocation of accreditation of a laboratory, but the deficiencies affect only certain methods within the accredited laboratory's scope of accreditation, FDA may revoke the accredited laboratory's accreditation only for those affected methods.

(d) *Length of probation.* FDA's probation of a laboratory's accreditation shall remain in effect until the laboratory demonstrates to FDA's satisfaction that the laboratory has successfully

implemented appropriate corrective actions, or until FDA determines that revocation of accreditation is warranted.

(e) *Notice to the accredited laboratory of revocation of accreditation.* FDA will notify a laboratory and its accreditation body of the revocation of its accreditation through issuance of a revocation notice that will state:

(1) The grounds for revocation;

(2) Whether the revocation of accreditation is in-whole or in-part, and if it is in-part, to which method or methods it applies;

(3) The procedures for requesting a regulatory hearing under § 1.1173 on the revocation; and

(4) The procedures for requesting reinstatement of accreditation under § 1.1165.

(f) *Notification of probation.* FDA will notify a laboratory and its accreditation body of the probation and such notification will:

(1) Describe the grounds for the probation; and

(2) Identify all deficiencies that must be corrected for FDA to lift the probation; and will either:

(i) Inform the laboratory that the laboratory has a specified time period to take corrective actions specified by FDA; or

(ii) 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 notice and identify timeframes for completion.

(g) *Revocation following probation.* FDA may revoke (in-whole or in-part) the accreditation of a laboratory that has been put on probation if FDA determines that the laboratory is not implementing appropriate corrective actions.

(h) *Public notice of probation or revocation of accreditation.* FDA will provide notice on the website described in § 1.1109 of probation or revocation of accreditation of a laboratory.

§ 1.1162 What are the consequences if FDA puts an accredited laboratory on probation or revokes the accreditation of a laboratory?

(a) If FDA revokes the accreditation of a laboratory in-whole, the laboratory is immediately ineligible to conduct food testing under this subpart. If FDA revokes the accreditation of a laboratory in-part, the laboratory is immediately ineligible to use the methods that are subject to the revocation to conduct food testing under this subpart. An accredited laboratory that is put on probation by FDA is permitted to continue to conduct food testing under this subpart.

(b) With respect to food testing conducted by the laboratory prior to the revocation of accreditation, FDA may refuse to consider specific food testing results and associated reports of food testing conducted under this subpart by the laboratory if the basis for the revocation of accreditation of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

(c) Within 10 business days of the date of issuance of revocation, the laboratory must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by § 1.1153, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(d) Within 10 business days of the date of issuance of probation or revocation, the laboratory must notify any owners or consignees that it is conducting food testing on behalf of under this subpart that it is on probation or its accreditation has been revoked.

§ 1.1163 What if a laboratory wants to voluntarily relinquish its accreditation?

(a) *Notice to FDA and the recognized accreditation body of intent to relinquish.* An accredited laboratory must notify FDA electronically, in English, and must notify its recognized accreditation body at least 60 days before voluntarily relinquishing accreditation (in-whole or in-part). The notice must include the date on which relinquishment will occur. If the relinquishment is of the laboratory's accreditation in-whole, the notification must also include the name and contact information of the custodian who will maintain the records required under § 1.1153 after the date of relinquishment, and the laboratory must make such records available to FDA as required by § 1.1153. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1153 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 accreditation of a laboratory.

§ 1.1164 What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition?

(a) If an accreditation body has its recognition revoked, relinquishes its recognition, allows its recognition to expire, or has its application for renewal of recognition denied, the laboratory accredited by the accreditation body must take the following actions (subject to the exception in paragraph (b) of this section):

(1) No later than 30 days after FDA issues the notice to the accredited laboratory under § 1.1129, § 1.1130, or § 1.1131 that the accreditation body that accredits the laboratory has had its recognition revoked, has relinquished its recognition, has allowed its recognition to expire, or has had its application for renewal of recognition denied, the accredited laboratory submits to FDA documentation of the accredited laboratory's most recent internal audit, which all accredited laboratories are required to maintain under § 1.1153(a)(5), documentation showing compliance with the conflict of interest requirements in § 1.1147, and documentation of the most recent proficiency test for each test method for which the laboratory is accredited under this subpart, to show compliance with § 1.1138(a)(1)(ii); and

(2) No later than 1 year after FDA issues the applicable notice under § 1.1129, § 1.1130, or § 1.1131 to the accredited laboratory, the laboratory becomes accredited under this subpart by a recognized accreditation body.

(b) The accredited laboratory does not have to comply with paragraph (a) of this section if, no later than 15 days after FDA issues the applicable notice to the accredited laboratory under § 1.1129, § 1.1130, or § 1.1131, the accredited laboratory initiates relinquishment of its accreditation in-whole under § 1.1163, with the relinquishment to occur within no more than 90 days.

§ 1.1165 How does a laboratory request reinstatement of accreditation?

(a) *Application following withdrawal of accreditation by a recognized accreditation body or revocation of accreditation by FDA.* A laboratory that had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body or revoked by FDA may seek reinstatement of accreditation by submitting a new application for accreditation (in-whole or in-part, as applicable) to a recognized accreditation body under § 1.1158, and the laboratory must also:

(1) Notify FDA, before it submits the new application for accreditation to the recognized accreditation body, that the laboratory will be submitting a new application for accreditation to the recognized accreditation body, including in the notification the legal name of the laboratory, valid contact information for the laboratory, the legal name of the recognized accreditation body the laboratory will be submitting the application to, and the date that the laboratory expects to submit the new application for accreditation; and

(2) Demonstrate, to the satisfaction of the recognized accreditation body it is submitting the new application to, that the grounds for the withdrawal of accreditation have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring.

(b) *Application following voluntary relinquishment of accreditation.* A laboratory that voluntarily relinquished its accreditation (in-whole or in-part), pursuant to § 1.1163, may seek reaccreditation by submitting a new application for accreditation to a recognized accreditation body under § 1.1158.

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?

(a) *Timing of request.* An accreditation body may seek reconsideration of FDA's decision to deny its application for recognition, renewal of recognition, or reinstatement of recognition 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 to FDA

electronically, in English, and 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 recognition upon reconsideration 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 recognized accreditation body's recognition or revoke the accredited laboratory's accreditation?

(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 revocation of accreditation of a laboratory pursuant to § 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. The notice of revocation issued under § 1.1131 or § 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, together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted to FDA electronically, in English, in accordance with the procedures described in the notice of revocation.

(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 recognition of an accreditation body or revoke the accreditation of 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, 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 a 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 revocation of accreditation 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 food testing order?

(a) *Request for hearing.* No later than 24 hours after the time at which FDA issued the food testing order, an owner or consignee may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the food testing order. The food testing 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 food testing order, together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the destination specified in such notice and in accordance with the procedures described therein. The request, appeal, and supporting information may be submitted electronically.

(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 a 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 food testing order is considered a final agency action under 5 U.S.C. 702.

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?

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 the following entries 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 revocation of accreditation 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 food testing order by FDA pursuant to § 1.1107(a)(2).

* * * * *

PART 129--PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

8. The authority citation for part 129 is revised to read as follows:

Authority: 21 U.S.C. 342, 348, 350k, 371, 374, 42 U.S.C. 264.

9. Amend § 129.35 by revising paragraph (a)(3)(iii) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories), except that the analysis of the five samples from the same sampling site that originally tested positive for *E. coli*, as required by paragraph (a)(3) of this section, must be conducted under part 1, subpart R of this chapter.

* * * * *

Dated: September 30, 2019.

_____,

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: October 25, 2019.

_____,

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.

[FR Doc. 2019-23870 Filed: 11/1/2019 8:45 am; Publication Date: 11/4/2019]