Contains Nonbinding Recommendations

Laboratory Accreditation for Analyses of Foods: What You Need to Know About the FDA Regulation: Guidance for Industry

Small Entity Compliance Guide

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
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This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

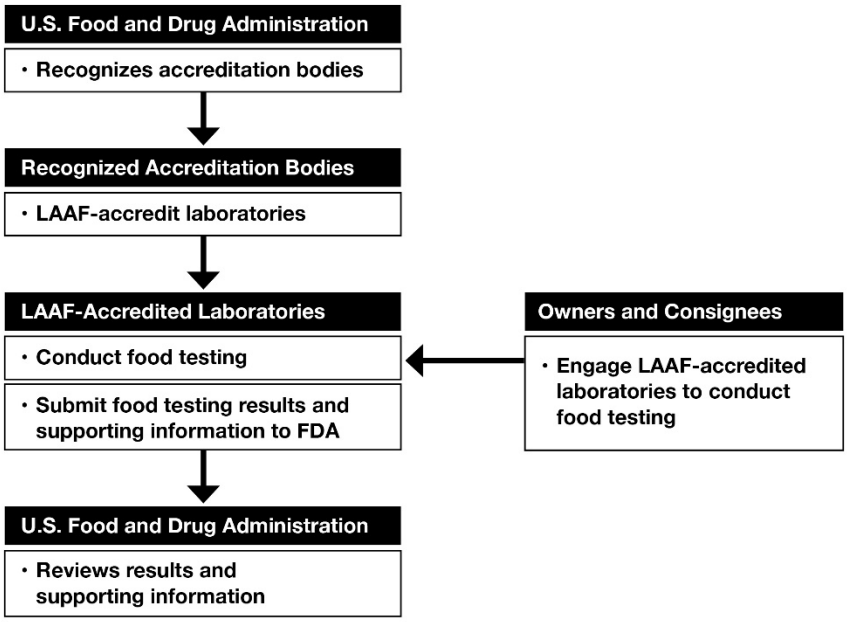
I. Introduction

The FDA Food Safety Modernization Act (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. Section 202(a) of FSMA created section 422 of the Federal Food, Drug, and Cosmetic (FD&C) Act, which directs FDA to establish a laboratory accreditation program for the analyses of foods in certain circumstances. More specifically, section 422 of the FD&C Act directs FDA to recognize accreditation bodies that will accredit laboratories to standards established by the Agency. FDA is to maintain a list of accreditation bodies and laboratories participating in the program. In certain circumstances related to food safety and as described in section 422 of the FD&C Act, testing may only be conducted by a laboratory participating in the program. Section 422 of the FD&C Act further provides that the results of tests conducted under the program must generally be sent by the participating laboratory directly to FDA.

On December 3, 2021, FDA issued a final rule, "Laboratory Accreditation for Analyses of Food" (86 FR 68728) (the LAAF rule or the rule) to implement section 422 of the FD&C Act. The LAAF rule establishes the Laboratory Accreditation for Analyses of Foods (LAAF) program through regulations at 21 CFR part 1, subpart R (1.1101 through 1.1201). The regulations describe applicable requirements and processes by which accreditation bodies and laboratories may participate in the LAAF program, how FDA will oversee those entities and manage the program, and which food safety-related testing must be conducted by a participating laboratory.

The structure of the LAAF program is illustrated by the following diagram:

Structure of the Laboratory Accreditation for Analyses of Foods (LAAF) Program



Implementation of the LAAF program will occur in a stepwise fashion. Once FDA has recognized a sufficient number of accreditation bodies, the Agency will announce that laboratories may apply to the recognized accreditation bodies for LAAF-accreditation. When there is sufficient LAAF-accredited laboratory capacity for a category of food testing covered by the rule, we will publish a document in the *Federal Register* giving owners and consignees six months' notice that they will be required to use a LAAF-accredited laboratory for such food testing.

We have prepared this Small Entity Compliance Guide (SECG) in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to help small entities participate in or comply with the LAAF rule. The regulations are binding and have the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Questions and Answers

A. Who is Subject to the LAAF Rule?

There are three entities primarily affected by the LAAF rule:

- *Accreditation bodies*. An accreditation body is subject to the LAAF rule if it wishes to participate, or is participating, in the LAAF program. Participation is voluntary for accreditation bodies. Accreditation bodies that successfully apply to FDA and meet the requirements of the LAAF rule will be recognized by FDA and thereby authorized to assess laboratories against the standards in the LAAF rule.
- *Laboratories*. A laboratory is subject to the LAAF rule if it wishes to participate, or is participating, in the LAAF program. Participation is voluntary for laboratories. A laboratory that wishes to participate in the LAAF program must apply to a recognized accreditation body; if successful, the laboratory will be considered "LAAF-accredited." Only LAAF-accredited laboratories may conduct testing covered by the LAAF rule.
- *Owners and consignees*. An owner or consignee is any person with an ownership or consignment interest in a food product or environment that is the subject of testing covered by the LAAF rule. When there is sufficient LAAF-accredited laboratory capacity for a category of food testing covered by the rule, FDA will publish a document in the *Federal Register* giving owners and consignees six months' notice that they will be required to use a LAAF-accredited laboratory for such food testing. After that six-month period, owners and consignees must use a LAAF-accredited laboratory to conduct the category of testing covered by the LAAF rule as described in the *Federal Register* document.

(21 CFR 1.1103)

B. What Happens When Testing is Covered by the LAAF Rule?

Testing covered by the LAAF rule must be conducted by a LAAF-accredited laboratory, and the laboratory must submit the results directly to FDA.

(21 CFR 1.1107, 1.1152(b))

C. What Sort of Food Testing is Covered by the LAAF Rule?

Not all food testing is covered by the LAAF rule, nor is all food testing required by FDA food safety regulations covered by the LAAF rule. The LAAF rule applies only to food testing in defined circumstances of heightened food safety concern, as described below in question-and-answer D.

Under the LAAF rule, "food testing" and "testing of food" include the analysis of human or animal food, as well as testing of the food growing or manufacturing environment (i.e., "environmental testing").

(21 CFR 1.1102, 1.1107)

D. What Testing is Covered by the LAAF Rule?

There are certain situations where testing is covered by the LAAF rule, as well as certain testing

requirements for specific food products that are covered by the LAAF rule. These situations and testing requirements are discussed further below.

1. What Import Testing is Covered by the LAAF Rule?

The LAAF rule covers owner/consignee testing to support admission of an article of imported food that FDA has detained at the border under section 801(a) of the FD&C Act. Section 801(a) of the FD&C Act authorizes FDA to detain an imported food article if the article is or appears to be violative of the FD&C Act or our regulations implementing the Act. For example, FDA sometimes detains a food article at the border because it is or appears to be adulterated. Often an owner/consignee will choose to test the article to demonstrate to FDA that the article is actually not violative; such testing is covered by the LAAF rule.

The Detention Without Physical Examination (DWPE) procedure allows FDA to detain an imported product without first physically examining the item. We use the DWPE procedure when there is 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 when certain conditions exist 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 test, or hire a private laboratory to test, a food product in an attempt to overcome the appearance of the violation and facilitate release of the food from detention. Such testing is covered by the LAAF rule.

(21 CFR 1.1107(a)(4) and (5))

2. What Commodity-Specific Testing is Covered by the LAAF Rule?

Section 422 of the FD&C Act provides that the LAAF program will cover testing conducted "in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem."[1] Through the LAAF rulemaking, FDA determined that there are nine testing requirements in existing FDA food safety regulations that are "specific testing requirement[s]… applied to address an identified or suspected food safety problem." Those testing requirements appear in the FDA food safety regulations for sprouts, shell eggs, and bottled drinking water.

a) Sprouts

Sprouts are generally subject to the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety) regulation at 21 CFR part 112. Section 112.146 of the Produce Safety regulation requires sprout operations to take certain actions if *Listeria* species or *L. monocytogenes* is detected in the growing, harvesting, packing, or holding environment. In such circumstances, 21 CFR 112.146(a) requires sprout operations to conduct additional testing of surfaces and areas surrounding the area 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. After the sprout operation cleans and sanitizes the affected surfaces and surrounding areas, 21 CFR 112.146(c) requires additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated. Section 112.146(d) requires sprout operations in these

[1] FD&C Act section 422(b)(1)(A)(i).

circumstances to also conduct finished product testing when appropriate.

The three testing circumstances described in 21 CFR 112.146(a), (c), and (d) are covered by the LAAF rule.

(21 CFR 1.1107(a)(1)(i))

b) Shell Eggs

As is relevant to the LAAF rule, FDA's Production, Storage, and Transportation of Shell Eggs regulations at 21 CFR part 118 require preventive measures during the production of eggs in poultry houses. At several points during the life of a flock, part 118 requires testing of the poultry house environment for *Salmonella* enteritidis. If the result is positive the producer must begin testing the shell eggs (unless the producer instead decides to divert the eggs to treatment). That shell egg testing is covered by the LAAF rule (see 21 CFR 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), and 118.6(e)).

(21 CFR 1.1107(a)(1)(ii))

c) Bottled Drinking Water

FDA's Processing and Bottling of Bottled Drinking Water regulations at 21 CFR part 129 address, among other things, the need for sanitary facilities within a bottled drinking water plant. Section 129.35(a)(3)(i) requires that source water obtained from other than a public water system is to be tested for total coliforms at least once each week. If any coliform organisms are detected, the bottled water firm must test to determine whether any of the coliform organisms are *Escherichia coli.* A source previously found to contain *E. coli* will be considered negative for *E. coli* only 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 (see 21 CFR 129.35(a)(3)(i)). The testing of the five samples collected over a 24-hour period is covered by the LAAF rule.

(21 CFR 1.1107(a)(1)(iii))

3. What is a Directed Food Laboratory Order and is that Testing Covered by the LAAF Rule?

A directed food laboratory order is a precise new tool that allows FDA to require that food testing be conducted under the LAAF rule in certain circumstances. The legal standard for issuing a directed food laboratory order is, "as required by the [FDA], as the [FDA] deems appropriate, to address an identified or suspected food safety problem."[2] Notably, there are two prongs to the standard, both of which must be satisfied for FDA to consider use of a directed food laboratory order. First, FDA interprets "as the [FDA] deems appropriate," to mean that a directed food laboratory order would generally only be appropriate if FDA has reason to question a firm's past or present test results. Second, an "identified or suspected food safety problem" must also exist.

An "identified food safety problem" could be present when a specific article of food violates a food safety provision of the FD&C Act or implementing regulations (e.g., when an article of food is adulterated). A "suspected food safety problem" would not be satisfied by the common or usual characteristics of a food or the manner in which the food is typically produced. Rather, a

[2] FD&C Act section 422(b)(1)(A)(ii).

"suspected food safety problem" typically would have a basis in fact about a particular article of food (e.g., a lot or batch) or food production environment (e.g., a specific facility). A variety of circumstances may generate suspicion of a food safety problem. FDA will consider all applicable regulations and relevant circumstances in determining whether an identified or suspected food safety problem exists.

One example of a situation in which a directed food laboratory order may be useful and appropriate is where FDA is investigating an outbreak of illnesses related to a firm, and FDA subsequently learns the firm has a history of falsifying food testing records.

We note that the purpose of routine product and environmental testing under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulations (21 CFR part 117)) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals regulations (21 CFR part 507) is to verify that preventive controls are consistently implemented and are effective (21 CFR 117.165(a) and 507.49(a)). Accordingly, such routine testing does not address an identified or suspected food safety problem and would not by itself be a sufficient basis for a directed food laboratory order.

A directed food laboratory order will specify the food product or environment to be tested and one or more validated test methods (21 CFR 1.1108(b)). Only certain FDA officials have the authority to issue a directed food laboratory order (e.g., the Associate and Deputy Associate Commissioners for Regulatory Affairs); see Staff Manual Guide 1410.310.[3]

(21 CFR 1.1107(a)(2); 1.1108)

4. What Other Testing is Covered by the LAAF Rule?

Testing conducted in connection with three FDA administrative processes related to enforcement proceedings is covered by the LAAF rule:

- Food testing presented to FDA as part of evidence for a hearing prior to the issuance of a mandatory recall order (see section 423(c) of the FD&C Act);
- Food testing presented to FDA as part of a corrective action plan submitted after an order suspending the registration of a food facility (see section 415(b)(3)(A) of the FD&C Act); and
- Food testing presented to FDA as part of evidence submitted for an appeal of an administrative detention order (see section 304(h)(4)(A) of the FD&C Act).

(21 CFR 1.1107(a)(3))

E. Will FDA Maintain a Public Listing of Recognized Accreditation Bodies and LAAF-Accredited Laboratories?

FDA will maintain on its website a registry of all recognized accreditation bodies and LAAF-accredited laboratories. For each recognized accreditation body, the registry will include the name, contact information, and duration of recognition. For each LAAF-accredited laboratory, the registry will include the name, contact information, and scope of LAAF-accreditation, and the name and contact information of the recognized accreditation body that has LAAF-accredited the laboratory. The registry will also note changes in recognition and LAAF-accreditation. The

[3] www.fda.gov/media/156710/download.

registry may be accessed via the FDA Data Dashboard.[4]

(21 CFR 1.1109)

F. What are the Applicable Requirements and Processes for Accreditation Bodies that Wish to be Recognized under the LAAF Program?

An accreditation body that wishes to be recognized under the LAAF program must demonstrate competence to ISO/IEC 17011:2017(E)[5] with a scope of "Testing: ISO/IEC 17025," be a full member of the International Laboratory Accreditation Cooperative (ILAC), and be a signatory to the ILAC Mutual Recognition Arrangement (MRA).

The accreditation body must also satisfy conflict of interest requirements, and for conflict-of-interest purposes, these requirements apply to the accreditation body's officers, employees, or other agents involved in LAAF-accreditation activities. Further, the financial interests of any children younger than 18 years of age or a spouse of a recognized accreditation body's officers, employees, and other agents involved in LAAF-accreditation activities are considered the financial interests of such officers, employees, and other agents involved in LAAF-accreditation activities.

Subject to two exceptions, the accreditation body may not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it LAAF-accredits. The first exception is that the accreditation body may have an interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund if the accreditation body does not exercise control or have the ability to exercise control over the financial interests held in the fund. The second exception is that a contract assessor acting as agent for the accreditation body may own or have a financial interest in, manage, or otherwise control a LAAF-accredited laboratory if all of the following four circumstances apply:

- The contract assessor's primary occupation is owning or having a financial interest in, managing, or otherwise controlling a LAAF-accredited laboratory;
- The assessor contracts with the recognized accreditation body to provide assessment services on an intermittent or part-time basis;
- The contract assessor does not assess the LAAF-accredited laboratory that the assessor owns or has a financial interest in, manages, or otherwise controls; and
- The contract assessor and the recognized accreditation body inform any laboratory that the contract assessor may assess or reassess for LAAF-accreditation that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory. The laboratory seeking LAAF-accreditation assessment or reassessment must acknowledge that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory and be provided the option to be assessed by a different representative of the recognized accreditation body.

[4] https://datadashboard.fda.gov/ora/fd/laaf.htm

[5] ISO/IEC 17011:2017(E) is available for purchase from the International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, +41 22 749 01 11, central@iso.org (https://www.iso.org/ store.html) or from any other source from which the user is assured that the copy to be received is an accurate version of the standard. The standard may be examined at FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. In addition, the American National Standards Institute maintains a portal whereby a view-only copy of voluntary consensus standards incorporated by reference into federal regulations may be accessed, at https://ibr.ansi.org/Standards/iso6.aspx.

In addition, the accreditation body must prohibit its officers, employees, or other agents involved in LAAF-accreditation activities from accepting any money, gift, gratuity, or other item of value from any laboratory the recognized accreditation body LAAF-accredits or assesses for LAAF-accreditation. The only exceptions to this prohibition are for money representing payment of fees for LAAF-accreditation services or reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory, and a meal of de minimis value provided during an assessment or reassessment and on the premises where the assessment or reassessment is conducted, if necessary for the efficient conduct of the assessment or reassessment.

The accreditation body must also comply with all additional requirements for accreditation bodies under the rule (e.g., frequency and method of laboratory assessments, laboratory oversight, reporting and recordkeeping).

An accreditation body may submit to FDA an application for recognition through the online Application for Recognition Portal.[6] There are no user fees associated with the LAAF program.

(21 CFR 1.1113, 1.1114, 1.1119)

G. What Report, Notification, Documentation, and Additional Recordkeeping Requirements Apply to Recognized Accreditation Bodies?

A recognized accreditation body has 48 hours to notify FDA, and submit to FDA an updated certificate reflecting the scope of accreditation, when any of the following occurs with respect to a laboratory it LAAF-accredits:

- Grant or extension of LAAF-accreditation;
- Denial of LAAF-accreditation;
- Receipt of notice that a LAAF-accredited laboratory intends to relinquish its LAAF-accreditation (where the laboratory has not separately notified FDA 60 days prior to relinquishment);
- Reduction of scope or withdrawal of LAAF-accreditation;
- Suspension or lifting the suspension of a LAAF-accredited laboratory.

A recognized accreditation body is also required to notify FDA within 48 hours if it knows that a laboratory it LAAF-accredits has committed fraud or submitted material false statements to FDA.

A recognized accreditation body also must submit to FDA the results of the internal audit conducted by the recognized accreditation body pursuant to ISO/IEC 17011:2017(E), within 45 days of completing the audit.

A recognized accreditation body is required to maintain certain LAAF program records for five years, such as applications for LAAF-accreditation, assessments of laboratories seeking LAAF-accreditation, its oversight of laboratories it has LAAF-accredited, and any required reports or notifications. Any records a recognized accreditation body is required to maintain must be made available to FDA upon written request.

[6] www.access.fda.gov/?utm_medium=email&utm_source=govdelivery.

(21 CFR 1.1123, 1.1124)

H. How Will FDA Oversee Recognized Accreditation Bodies?

Recognition will be granted or renewed for a maximum of five years. FDA will evaluate each recognized accreditation body to determine whether it is in compliance with the LAAF program requirements no later than year 4 of a 5-year recognition period, or, for a shorter recognition period, at the midpoint of that period. FDA's evaluation may include review of records, an onsite evaluation of the accreditation body, and onsite reviews of one or more LAAF-accredited laboratories the recognized accreditation body LAAF-accredits, with or without the recognized accreditation body present. Certain evaluation activities may be conducted remotely if it will not aid in the evaluation to conduct them onsite.

FDA may conduct additional evaluations at any time.

(21 CFR 1.1115, 1.1130)

I. What are the Applicable Requirements and Processes for Laboratories that Wish to Become LAAF-Accredited?

For each method of food testing for which a laboratory wishes to be LAAF-accredited, the laboratory must be accredited to ISO/IEC 17025:2017(E)[7] by an accreditation body that has been recognized under the LAAF program, and have successfully passed within the last 12 months a proficiency test provided by a competent proficiency testing organization. If the laboratory determines, and the recognized accreditation body agrees, that a proficiency testing program is not available or practicable for a method, the laboratory may demonstrate competency through a comparison program. The laboratory must submit all proficiency test and comparison program results, regardless of outcome, to the recognized accreditation body within 30 calendar days of receipt. In addition, the laboratory must use reference materials or quality control samples with each batch of samples it tests under the LAAF program. The laboratory must also comply with all additional requirements for laboratories under the rule (e.g., tests conducted by qualified analysts, test methods fit for purpose, recordkeeping).

The LAAF rule also contains impartiality and conflict of interest requirements for laboratories. First, the laboratory must require the owner's or consignee's payment of fees for food testing services under the LAAF rule (LAAF food testing) and reimbursement of direct costs for LAAF food testing to be independent of the outcome of the results. Second, subject to limited exceptions, a LAAF-accredited laboratory's employees, contractors, and agents involved in LAAF food testing and related activities may not accept any money, gift, gratuity, or other item of value from the owner or consignee for which LAAF food testing is conducted. The exceptions are that the laboratory may accept payment of fees for LAAF food testing and related services; reimbursement of direct costs associated with the LAAF food testing; and, with respect to a LAAF-accredited

[7] ISO/IEC 17025:2017(E) is available for purchase from the International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, +41 22 749 01 11, central@iso.org (https://www.iso.org/ store.html) or from any other source from which the user is assured that the copy to be received is an accurate version of the standard. The standard may be examined at FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. In addition, the American National Standards Institute has been maintaining a portal whereby a view-only copy of voluntary consensus standards incorporated by reference into federal regulations may be accessed, at https://ibr.ansi.org/Standards/iso6.aspx.

laboratory that is owned by the owner or consignee of the food that is or will be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

Laboratories interested in becoming LAAF-accredited for one or more methods must apply with a recognized accreditation body. FDA does not directly LAAF-accredit laboratories. There are no user fees associated with the LAAF program.

LAAF-accreditation is not granted for a specified period of time; as long as a laboratory continues to satisfy LAAF program requirements for particular methods, it may remain LAAF-accredited for those methods. In contrast, ISO/IEC 17025:2017(E) accreditation is generally conferred for a period of two years. ISO/IEC 17025:2017(E) accreditation is a foundational requirement for LAAF-accreditation. Therefore, if a laboratory temporarily or permanently loses its ISO/IEC 17025:2017(E) accreditation for one or more methods, the laboratory would not be eligible for LAAF-accreditation for those methods.

(21 CFR 1.1138, 1.1139, 1.1147)

J. How Will Recognized Accreditation Bodies and FDA Oversee LAAF-Accredited Laboratories?

A recognized accreditation body is required to reassess laboratories it LAAF-accredits at least every two years. Those reassessments must be conducted at least in part onsite; some reassessment activities may be conducted remotely. A recognized accreditation body is also required to oversee the performance of any laboratory it LAAF-accredits, to ensure the laboratory continues to satisfy program requirements.

Should an accreditation body identify a LAAF-accredited laboratory deficiency, it may require corrective action. If the LAAF-accredited laboratory fails to address the deficiency, the recognized accreditation body may temporarily suspend the laboratory's LAAF-accreditation for one or more methods. If the LAAF-accredited laboratory still fails to adequately address the deficiency, the recognized accreditation body may (after providing notice) reduce the scope of or withdraw LAAF-accreditation. Suspension, reduction in scope, and withdrawal will be noted on the public registry.

FDA may review the performance of LAAF-accredited laboratories at any time to determine whether the laboratory continues to satisfy LAAF requirements; such review encompasses routine review of laboratory analytical reports. FDA may also conduct an onsite review of a LAAF-accredited laboratory at any reasonable time.

Should FDA identify a LAAF-accredited laboratory deficiency, FDA may require corrective action. If the LAAF-accredited laboratory fails to address the deficiency, FDA may place the laboratory on probation for one or more methods. If the LAAF-accredited laboratory still fails to adequately address the deficiency, FDA may (after providing notice) disqualify a LAAF-accredited laboratory from submitting analytical reports under the LAAF program.[8] Probation and disqualification will be noted on the public registry.

[8] FDA may disqualify a LAAF-accredited laboratory from submitting analytical reports under the LAAF rule without first providing an opportunity for corrective action or placing the laboratory on probation in certain circumstances, such as if the laboratory deliberately falsified analytical reports, testing results, or other records submitted to FDA. See 21 CFR 1.1161(c).

A LAAF-accredited laboratory that FDA has placed on probation for one or more methods may continue to conduct food testing under the LAAF rule, but may not submit abridged analytical reports for the major food testing discipline of which the probationary methods are a part. A LAAF-accredited laboratory that FDA has disqualified is ineligible to use the disqualified methods to conduct food testing under the LAAF rule.

(21 CFR 1.1120, 1.1121, 1.1159, 1.1160, 1.1161, 1.1162)

K. May a Recognized Accreditation Body or a LAAF-Accredited Laboratory Voluntarily Depart from the LAAF Program?

Yes. An accreditation body may voluntarily relinquish its recognition, or choose not to renew its recognition, by notifying FDA of its intention to leave the program at least 60 days ahead of time. The accreditation body must also provide FDA with the name and contact information of the custodian who will maintain certain LAAF program records for the retention period of five years after creation. The accreditation body must also notify the laboratories it LAAF-accredits of its intention to leave the program at least 60 days ahead of time.

A laboratory wishing to depart from the LAAF program for one or more methods may do so by providing at least 60 days' notice to FDA and its recognized accreditation body. A laboratory voluntarily relinquishing all methods within its scope of LAAF-accreditation must also provide both FDA and the accreditation body with the name and contact information of the custodian who will maintain certain LAAF program records for the retention period of five years after creation.

(21 CFR 1.1116, 1.1124, 1.1140, 1.1154)

L. What Oversight Standards Apply to Sampling?

Proper sampling procedures are essential to meaningful test results. FDA will exercise oversight over the sampling that occurs under the LAAF rule by reviewing three sampling documents: documentation of the sampler's qualifications by training and experience; a written sampling plan that, among other things, describes how a representative sample will be ensured; and a written sample collection report. LAAF-accredited laboratories are required to develop or obtain these documents prior to analyzing a sample under the LAAF program, and submit them to FDA as part of the (full or abridged) laboratory analytical report.

If FDA determines that the sampling conducted may materially differ from the sampling documented in the sampling plan or sample collection report, or may otherwise have been improper, FDA may require advance notice of sampling at least 48 hours before each of the next 10 occasions that the associated sampling firm will collect a sample for testing under the LAAF program. Such advance notice of sampling will provide FDA an opportunity to audit future sampling activities.

(21 CFR 1.1149, 1.1152(c)(1) and (2))

M. Are There Requirements Pertaining to the Methods of Analysis a LAAF-Accredited Laboratory Uses to Conduct Food Testing Under the LAAF Rule?

The method of analysis used to conduct food testing under the LAAF rule must be fit for purpose

and appropriately validated and verified. The method must also be within the scope of the laboratory's LAAF-accreditation.

If the FD&C Act or FDA regulations prescribe a specific method for the commodity-specific follow-up testing covered by the LAAF rule, then such method must be used for that testing. Similarly, if a directed food laboratory order specifies a method, then such method must be used for testing covered by the order.

(21 CFR 1.1151)

N. What Information is a LAAF-Accredited Laboratory Required to Submit to FDA in Every Laboratory Analytical Report, Whether Full or Abridged?

All laboratory analytical reports submitted to FDA by a LAAF-accredited laboratory under the LAAF rule must include, among other things:

- The name and street address of the LAAF-accredited laboratory;
- A point of contact for the LAAF-accredited laboratory, including email and telephone number, whom FDA may contact with questions or comments;
- An identification unique to the test results, report, notification, or study;
- The test results, which must identify the name and street address of the owner or consignee for which the testing was conducted; and if appropriate, the U.S. Customs and Border Protection entry and line number(s);
- The sampling plan(s), sample collection report(s), and written documentation of the sampler's qualifications;
- Any necessary validation and verification studies and supporting documentation.
- The justification for any modification to or deviation from the method(s) of analysis used and documentation of the LAAF-accredited laboratory's authorization for the modification or deviation; and
- A certification from one or more members of the LAAF-accredited laboratory's management certifying that the test results and associated documentation are true and accurate, and that the documentation includes the results of all tests conducted under the LAAF rule. The certification must include the name, title, and signature of any certifiers.

(21 CFR 1.1152(a), (b), and (c))

O. What Information is Required to be Submitted to FDA in a Full Laboratory Analytical Report?

In addition to the documentation required to be submitted with all test results (see question-and-answer N), a full analytical report must include:

- All information described by ISO/IEC 17025:2017(E) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d);
- Documentation of references for the method of analysis used;
- Name and signature of the analyst who conducted each analytical step, including any applicable validation and verification steps, and the date each step was performed;
- Calculations, presented in a legible and logical manner;
- As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and presented in a clear order;

- 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);
- A copy of the label from any immediate container sampled, if available, and any additional labeling needed to evaluate the product;
- All original compilations of raw data secured in the course of the analysis, including discarded, unused, or re-worked data, with the justification for discarding or re-working such data, corresponding supporting data, and quality control results (including the expected result and whether it is acceptable), all identified with unique sample identification, date, and time, associated with the test;
- 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;
- Any certificate of analysis for standards and software; and
- The following information about the qualifications of each analyst involved in the analysis conducted under the LAAF rule, if the LAAF-accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly changed since the LAAF-accredited laboratory last submitted documentation of the analyst's qualifications to FDA:
    - The analyst's curriculum vitae;
    - Training records for the applicable methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider; and
    - 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 21 CFR 1.1150(b).[9]

(21 CFR 1.1152(d))

P. What Information is Required to be Submitted to FDA in an Abridged Analytical Report?

In addition to the documentation required to be submitted with all test results (see question-and-answer N), an abridged analytical report must include:

- All information described by ISO/IEC 17025:2017(E) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d); and
- Quality control results (including the expected result and whether it is acceptable).

(21 CFR 1.1153(c))

[9] 21 CFR 1.1150(b) requires that the analyst must be qualified by appropriate education, training, and/or experience to conduct the analysis; have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and be in compliance with the conflict of interest requirements applicable to a LAAF-accredited laboratory.

Q. How Does a LAAF-Accredited Laboratory Gain Permission from FDA to Submit Abridged Analytical Reports?

A LAAF-accredited laboratory may request permission to submit abridged analytical reports for each major food testing discipline: Biological, chemical, and physical. FDA will grant permission to submit abridged analytical reports for a single major food testing discipline if all of the following conditions are met:

- The LAAF-accredited laboratory is not on suspension or probation for any method within the major food testing discipline that is the subject of its request (see 21 CFR 1.1121(b) or 1.1161(b));
- The LAAF-accredited laboratory has successfully implemented any required corrective action under 21 CFR 1.1121(a) or 1.1161(a); and
- The last five full analytical reports for the major food testing discipline contain no shortcomings that call into question the validity of the test results or repeated administrative errors.

FDA will notify the LAAF-accredited laboratory if permission is granted or denied.

(21 CFR 1.1153(a))

R. Beyond Test Results and Laboratory Analytical Reports, Are There Additional Notification and Recordkeeping Requirements for LAAF-Accredited Laboratories?

A LAAF-accredited laboratory must notify its recognized accreditation body and FDA within 48 hours of any changes that affect LAAF-accreditation (e.g., a change in the laboratory's name or operations). In terms of recordkeeping, a LAAF-accredited laboratory must maintain, for five years after the date of creation, records created and received related to compliance with the LAAF program, including documents related to its grant of LAAF-accreditation, documentation of food testing conducted under the LAAF rule, all documents that the laboratory was required to submit as part of a laboratory analytical report, and all requests from an owner or consignee for food testing that would be conducted under the LAAF rule. Any records a LAAF-accredited laboratory is required to maintain must be made available to FDA upon written request.

(21 CFR 1.1152(f), 1.1154)

S. For Which Actions May an Entity Subject to the LAAF Rule Request a Regulatory Hearing of FDA?

There are three circumstances under which an entity may request an FDA regulatory hearing under the LAAF rule. First, an accreditation body may request a regulatory hearing within 10 days of receiving from FDA a notice that FDA will revoke the accreditation body's LAAF recognition. Second, a LAAF-accredited laboratory may request a regulatory hearing within 10 days of receiving from FDA a notice that FDA will disqualify the laboratory from submitting analytical reports (for one or more methods) under the LAAF rule. Finally, an owner or consignee may request a regulatory hearing within 3 business days of FDA issuing a directed food laboratory order.

(21 CFR 1.1173, 1.1174)

III. Definitions

Analyst means an individual who analyzes samples.

Corrective action means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.

Directed food laboratory order means an order issued by FDA under 21 CFR 1.1108 requiring food testing to be conducted under the LAAF rule by or on behalf of an owner or consignee.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food testing and *testing of food* means the analysis of food product samples or environmental samples.

LAAF-accreditation means a determination by a recognized accreditation body that a laboratory meets the applicable requirements of the LAAF rule to conduct LAAF food testing using one or more methods of analysis.

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

Owner or consignee means any person with an ownership or consignment interest in the food product or environment that is the subject of food testing conducted under 21 CFR 1.1107(a).

Recognition means a determination by FDA that an accreditation body meets the applicable requirements of the LAAF rule and is authorized to LAAF-accredit laboratories under the LAAF program.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of the LAAF rule and is authorized to LAAF-accredit laboratories under the LAAF program.

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

Sampler means an individual who collects samples.

Sampling firm means an entity that provides sampling services.

Scope of LAAF-accreditation refers to the methods of analysis for which the laboratory is LAAF-accredited.

Street address means the full physical address, including the country. For purposes of this rule, a post office box number alone is insufficient; however, a post office box number may be provided in addition to the street address.

(21 CFR 1.1102)

IV. Resources

LAAF Final Rule website: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-laboratory-accreditation-analyses-foods-laaf

LAAF Final Rule Fact Sheet: https://www.fda.gov/media/155663/download

LAAF Citations: The LAAF final rule (86 FR 68728 (Dec. 3, 2021))[10] creates LAAF regulations at 21 CFR part 1, subpart R (21 CFR 1.1101 - 1.1201)[11]

LAAF Program Contact: FDALAAFINQUIRY@fda.hhs.gov

Registry of Recognized Accreditation Bodies and LAAF-accredited Laboratories: https://datadashboard.fda.gov/ora/fd/laaf.htm

[10] www.govinfo.gov/content/pkg/FR-2021-12-03/pdf/2021-25716.pdf.
[11] www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-R?toc=1