

FSMA Final Rule on Laboratory Accreditation for Analyses of Foods: “At-a-Glance”

The FDA Food Safety Modernization Act (FSMA) final rule on Laboratory Accreditation for Analyses of Foods (LAAF) establishes a laboratory accreditation program for the testing of food in certain circumstances. Under the LAAF program, the FDA will recognize accreditation bodies that will accredit laboratories to the standards established in the final rule (referred to as LAAF-accredited laboratories).

The final rule specifies eligibility requirements that accreditation bodies and laboratories wishing to participate in the program will need to satisfy, as well as procedures for how the FDA will manage and oversee the program. In certain circumstances, owners and consignees (persons with an ownership or consignment interest in the food product or environment that is the subject of food testing under the final rule) will be required to use a LAAF-accredited laboratory for food testing. The FDA will maintain an online public registry of recognized accredited bodies and LAAF-accredited laboratories.

The LAAF program is intended to improve the accuracy and reliability of certain food testing through the uniformity of standards and enhanced FDA oversight of participating laboratories.

Who is affected by this final rule?

The LAAF final rule applies to accreditation bodies and food testing laboratories that wish to participate in the program. Their participation is voluntary. In certain circumstances explained more fully below, owners and consignees will be required to use LAAF-accredited laboratories to conduct food testing.

Does the LAAF final rule apply to all food testing?

No. Food testing, including environmental testing, is required to be conducted by a LAAF-accredited laboratory only under certain circumstances specified in the rule. For the purposes of this rule, “food” has the same definition as in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that it does not include pesticides (as defined in 7 U.S.C. 136(u)). “Food” includes articles used for food or drink for man or other animals, as well as articles used for components of food, such as raw materials or other ingredients.

What testing is covered under the LAAF final rule?

After the LAAF final rule is fully implemented, owners and consignees will be required to use a LAAF-accredited laboratory for food testing:

- to support removal of a food from an import alert through successful consecutive testing;
- to support admission of an imported food detained at the border because it is or appears to be in violation of the Federal Food, Drug, and Cosmetic Act.
- required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests of shell eggs, sprouts, and bottled drinking water);
- required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow the FDA to require use of a LAAF-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances; and
- conducted in certain administrative processes such as in connection with an appeal of an administrative detention order.

How is sampling covered by the final rule?

Before analyzing a sample, the LAAF-accredited laboratory must develop (if it collected the sample) or obtain the following information to be submitted with the test results: written documentation of the sampler's qualifications, the written sampling plan used to conduct the sampling, and a written sample collection report for each sample collected.

What are the requirements for an accreditation body wishing to participate in the LAAF program?

An accreditation body seeking to participate in the LAAF program must 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(E) with a scope of "Testing: ISO/IEC 17025." The LAAF final rule also includes certain conflict of interest requirements, e.g., generally an 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.

What are the requirements for a testing laboratory wishing to participate in the LAAF program?

A testing laboratory seeking to participate in the LAAF program by becoming LAAF-accredited must be accredited to ISO/IEC 17025:2017(E). In addition, the laboratory must have successfully passed a proficiency test provided by a competent proficiency testing organization within the last 12 months for each method within the scope of LAAF-accreditation (or a comparison program if no proficiency test is available or practicable for a given method). The laboratory must also have procedures in place for monitoring the validity of the results of testing by the use of reference materials or quality control samples with each batch of samples it tests for this program. The LAAF final rule also includes certain impartiality and conflict of interest requirements (e.g., payment of LAAF testing fees must be independent of the outcome of the test results). Finally, LAAF-accredited laboratories will be required to send the results of all tests conducted under the final rule directly to the FDA.

When and how may accreditation bodies and laboratories apply to participate in the LAAF program?

The FDA will announce in early 2022 the launch of a webpage on FDA.gov where accreditation bodies can apply for recognition. After the FDA recognizes a sufficient number of accreditation bodies, the agency will communicate that testing laboratories may apply for LAAF-accreditation directly with one of the recognized accreditation bodies. The FDA will maintain an online public registry listing recognized accredited bodies and LAAF-accredited laboratories.

Updates regarding implementation will be made to the LAAF Final Rule web page at [FSMA Final Rule on Laboratory Accreditation for Analyses of Foods \(LAAF\) | FDA](#).

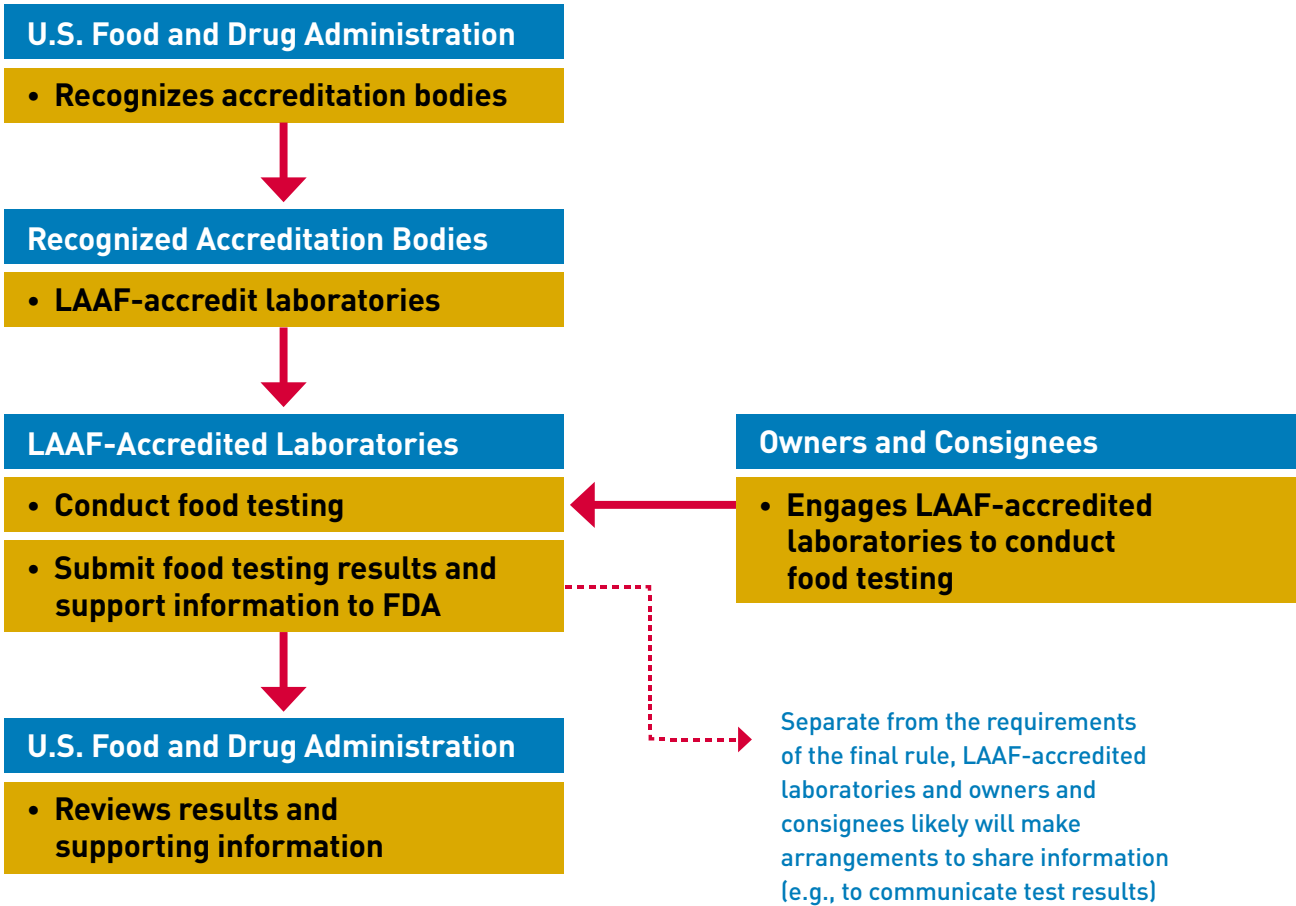
What are the LAAF final rule compliance dates?

Owners and consignees will be required to use a LAAF-accredited laboratory for the testing covered by the final rule only after a sufficient number of laboratories have been LAAF-accredited. FDA will issue a notice in the Federal Register informing owners and consignees that sufficient laboratory capacity has been attained; compliance will be required six months after the notice.

For more information:

- Final Rule: [FSMA Final Rule on Laboratory Accreditation for Analyses of Foods \(LAAF\) | FDA](#)
- Constituent Update: [FDA Issues Final Rule for Laboratory Accreditation for Analyses of Foods | FDA](#)
- Still have a question? Contact the FSMA Technical Assistance Network (TAN) [How to Contact FDA about FSMA](#)

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



For additional information, visit www.fda.gov/fsma