SMALL ENTITY COMPLIANCE GUIDE

Small Entity Compliance Guide: Laboratory Accreditation for Analyses of Foods – What You Need to Know

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Final

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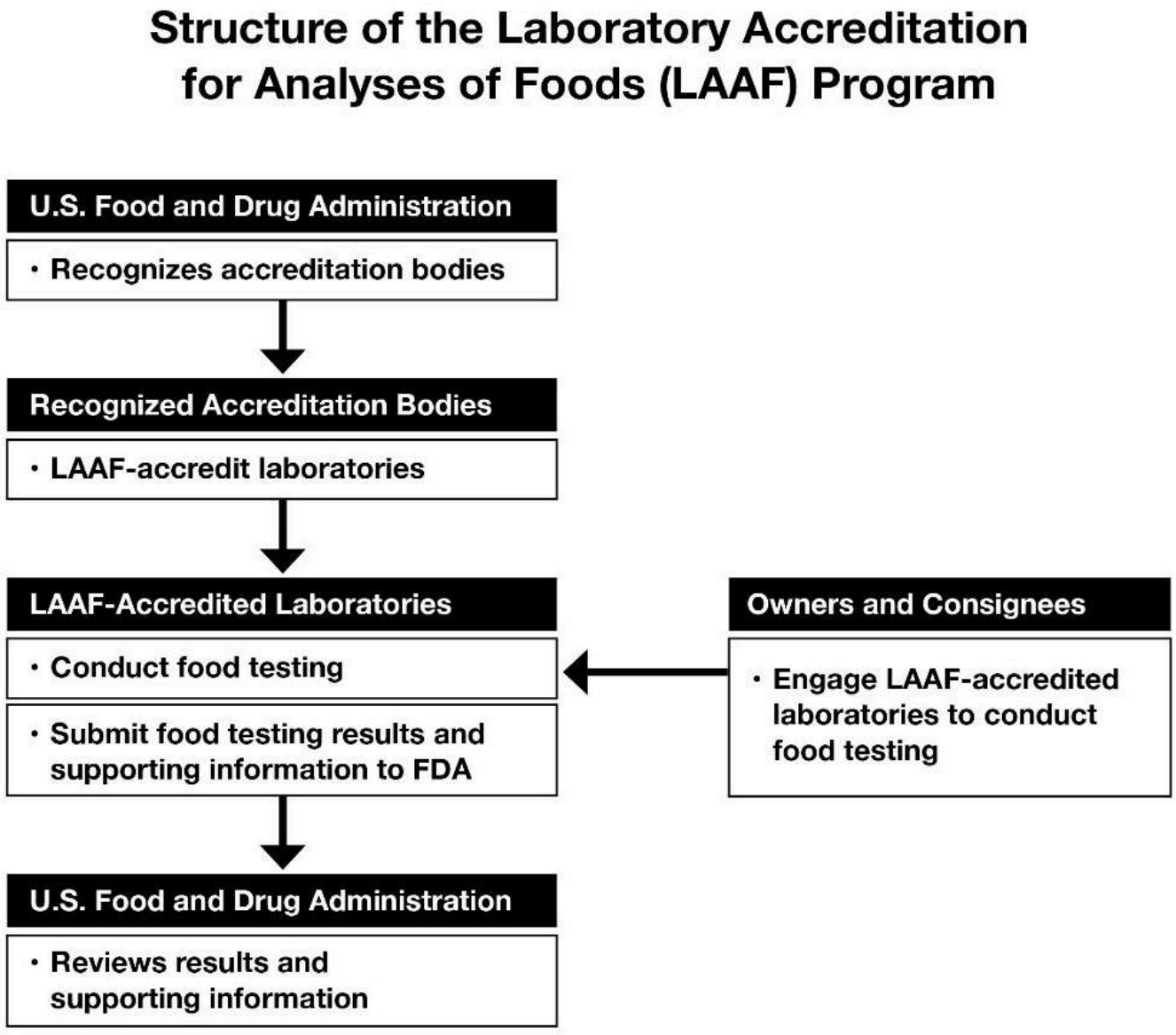
Human Foods Program
Center for Veterinary Medicine
Office of Inspections and Investigations

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:



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.

Download the Guidance (/media/162315/download?attachment)

Related Resources

- FSMA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF) (/food/food-safety-modernization-act-fsma/laboratory-accreditation-analyses-foods-laaf-program-final-rule)
- FSMA Rules & Guidance for Industry (/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry)

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