KEY REQUIREMENTS:
Final Rule on Accredited Third-Party Certification

FDA's Accredited Third-Party Certification program is now accepting applications.

The FDA Food Safety Modernization Act (FSMA) rule on Accredited Third-Party Certification was finalized in November 2015. The rule establishes a voluntary program for the accreditation of third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce. These requirements are intended to help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.

FSMA specifies two uses for certifications under this program:

- Certifications may be used by importers to help establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review entry of food.
- To prevent potentially harmful food from reaching U.S. consumers, the FDA can also require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

KEY FEATURES

1. SCOPE

- This rule establishes the framework, procedures and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation.
  - These requirements cover legal authority, competency, capacity, conflict-of-interest safeguards, quality assurance and record procedures.
  - In limited circumstances, the FDA may directly accredit third-party certification bodies. For example, FDA can directly accredit third-party certification bodies if the agency does not identify and recognize an accreditation body to meet the requirements of the program within two years after establishing the program.
- To promote international consistency and utilize an existing framework that is familiar to industry, accreditation bodies and certification bodies can use documentation of their conformance with ISO/IEC standards, supplemented as necessary, in meeting program requirements under this rule. (ISO/IEC stands for the International Organization for Standardization and the International Electrotechnical Commission, which have issued voluntary international consensus standards.)
- The FDA will closely monitor participants in the program and may revoke an accreditation body's recognition or withdraw a certification body's accreditation under certain circumstances. The rule contains FDA procedures relating to monitoring and oversight of participating accreditation bodies and certification bodies.

2. REQUIREMENTS FOR RECOGNIZED ACCREDITATION BODIES

- An accreditation body recognized by FDA under this program could be a foreign government/agency or a private third party. The final rule requires recognized accreditation bodies to:
  - Assess third-party certification bodies for accreditation, including observing a representative sample of the prospective certification body's work
  - Monitor performance of the third-party certification bodies it accredits, including periodically conducting on-site observations, and notifying the FDA of any change in, or withdrawal of, accreditations it has granted
  - Assess and correct any problems in their own performance
  - Submit monitoring and self-assessment reports and other notifications to the FDA
  - Maintain and provide the FDA access to records required to be kept under the program

3. REQUIREMENTS FOR THIRD-PARTY CERTIFICATION BODIES

- Third-party certification bodies accredited under this program are required to perform unannounced facility audits and to notify the FDA upon discovering a condition that could cause or contribute to a serious risk to the public health. The final rule requires these accredited third-party certification bodies to:
  - Ensure their audit agents are competent and objective
  - Verify the effectiveness of corrective actions to address identified deficiencies in audited entities
  - Assess and correct any problems in their own performance
  - Maintain and provide the FDA access to records required to be kept under the program
- There are two kinds of audits that accredited third-party certification bodies can perform as part of the program: consultative and regulatory. In both kinds, auditors will examine compliance with applicable federal food safety requirements.
  - A consultative audit is conducted in preparation for a regulatory audit and is for internal use. In addition to compliance with federal standards, a consultative audit also considers how the facility meets industry standards and practices. Only a regulatory audit can be the basis for certification.
  - An accredited third-party certification body could be a foreign government or other third-party entity or individual.

4. RELATED FDA ACTIONS

- FDA's final recommendations on third-party certification body standards are contained in the Model Accreditation Standards guidance issued in December 2016. They contain recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience.
- In November 2016, the FDA published a final guidance for industry explaining how the Voluntary Qualified Importer Program (VQIP) will work. In order to participate in VQIP, importers must import food from certified facilities.
  - Importers with a robust system of supply-chain management may qualify for expedited review and entry for foods they seek to import.
  - Consumer protections are strengthened by enabling the FDA to focus its resources on food imports that are more likely to present a potential risk to public health.
- The FDA published in December 2016 a final rule to establish a user fee program for the voluntary Accredited Third-Party Certification Program. FSMA required a user-fee program be established to reimburse the agency for its work in establishing and administering this program.

EXEMPTIONS

The Third-Party Certification rule also provides that the mandatory import certification authority under FSMA does not apply to:

- Alcoholic beverages manufactured by foreign facilities under certain circumstances
- Certain meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation.

IMPLEMENTATION

In June 2017 FDA launched a website where organizations can apply to be recognized as an Accreditation Body. The launch of this website will implement the Accredited Third-Party Certification Program.

Third-party certification bodies can seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

MORE INFORMATION

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FDA's Food Safety Modernization Act page at www.fda.gov