

KEY REQUIREMENTS: Final Rule on Accredited Third-Party Certification

The FDA Food Safety Modernization Act (FSMA) rule on the Accredited Third-Party Certification is now final.

This rule, proposed in July 2013, establishes a voluntary program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. These requirements will help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.

Foreign entities may use certifications for two purposes:

- Certifications may be used by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and 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.

Below are the key features of the rule.

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 could directly accredit third-party certification bodies if it has not identified and recognized an accreditation body within two years after establishing this program.

- To promote international consistency and utilize an existing framework that is familiar to industry, accreditation bodies and certification bodies will be allowed to 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 be closely monitoring participants in the program and may revoke an accreditation body's recognition and withdraw a certification body's accreditation if there is cause. 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. In addition to the requirements listed above, the final rule will require 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 public health. In addition to other requirements listed above, the final rule will require 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 facilities
 - 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 draft recommendations on certification body competency are contained in the Model Accreditation Standards draft guidance issued in July 2015. They contain draft recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience. The guidance will be finalized after public comments are considered.

- In June 2015, the FDA published a draft guidance for industry explaining how 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 July 2015 a proposed rule establishing user fees for accreditation bodies and certification bodies. FSMA requires that a user-fee program be established to reimburse the agency for its work in establishing and administering the third-party certification program, which is voluntary.

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
- Meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation.

IMPLEMENTATION

FDA intends to implement this program as soon as possible after publication of the final Model Accreditation Standards guidance, and the final user fee rule, both of which will be published separately.

Accreditation bodies could begin to apply for recognition when the program goes into effect, and third-party certification bodies could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

MORE INFORMATION

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