3rd Party Audits Final

Final Rule Accredited Third-Party Certification

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

What Does This Rule Do?

- It establishes a voluntary program for the accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.

When Are Certifications Needed?

- Importers will not generally be required to obtain certifications.
- Certifications will be used for two purposes:
  1. Facility certifications will be used by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and entry of food.

When Are Certifications Needed?

2. Food or facility certifications will be used for admissibility of a food subject to a risk-based determination by FDA.
   - Requires a specific determination by FDA under section 801(q) of the FD&C Act
   - Factors include consideration of the capability of the regulatory system of the exporting nation to ensure compliance with U.S. safety standards for the food.
   - Exemptions for certain alcoholic beverages and products subject to USDA oversight at import

FDA Third-Party Certification Program

FDA

FDA would recognize accreditation bodies (ABs) based on certain criteria such as competency and impartiality.

Accreditation Bodies

ABs would accredit qualified third-party certification bodies (CBs).

Third-Party Certification Bodies

Third-party CBs would audit and issue certifications for foreign facilities and foods.

Foreign Facilities

Foreign facilities may choose to be audited by an accredited CB.

What Are Accreditation Bodies?

- An accreditation body can be a foreign government/agency or a private third-party.
- An accreditation body may use documentation of its conformance to ISO/IEC 17011, supplemented as necessary, in meeting FDA requirements.

What Must Accreditation Bodies Do?

- FDA requires accreditation bodies to:
  - Assess third-party certification bodies for accreditation
  - Monitor the performance of third-party certification bodies they accredit
  - Assess and correct problems in their own performance
  - Submit reports and other notifications to FDA
  - Maintain and provide FDA access to certain records

What Is Direct Accreditation?

- FSMA allows FDA to directly accredit third-party certification bodies if by two years after the program goes into effect, FDA has not recognized an accreditation body that meets the program needs.
  - Limited circumstances

What Are Certification Bodies?

- An CB can be a foreign government or other third-party entity.
- A CB may use documentation of its conformance with ISO/IEC 17021 or ISO/IEC 17065, supplemented as necessary, in meeting FDA requirements.

What Must Certification Bodies Do?

- Ensure their audit agents are competent and objective
- Verify the effectiveness of facilities' corrective actions to address identified deficiencies
- Assess and correct any problems in their own performance
- Maintain and provide FDA access to certain records

Audit Requirements

- When performing audits under this program, accredited third-party CBs must:
  - Perform facility audits unannounced
  - Notify FDA on discovering a condition that could cause or contribute to a serious risk to public health
  - Submit regulatory audit reports (key data)
  - Maintain consultative audit reports in records, accessed only under section 414

Related FDA Actions

- Voluntary Qualified Importer Program (VQIP) draft guidance (June 2015)
  - Explains how VQIP will work and how importers can qualify for a program that would provide expedited entry of foods
  - In order to participate, importers must import foods from facilities certified by accredited third-party certification bodies participating in the FDA program.

Related FDA Actions

- Model Accreditation Standards draft guidance (July 2015)
  - Contains recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience

Related FDA Actions

- Proposed rule establishing user fees for accreditation and certification bodies (July 2015)
  - 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.

Implementation

- Program will launch after the final user fee rule takes effect.
- Accreditation bodies could begin to apply when the program goes into effect.
  - Third-party certification bodies could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us