

3<sup>rd</sup> 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).



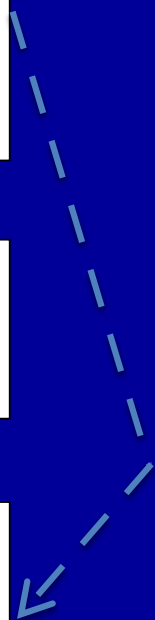
## Third-Party Certification Bodies

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](http://www.fda.gov/fsma)
- Subscription feature available
- To submit a question about FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to [Contact Us](#)

