

Voluntary Qualified Importer Program (VQIP)

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**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW



Voluntary Qualified Importer Program (VQIP)

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Participation is limited to importers who meet all eligibility criteria, including offering food from a facility certified under FDA's accredited third party program.

Definition of VQIP Importer

- Section 806(g) defines “importer” as “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”
 - Can include manufacturers, consignees and importers of record for food for humans and animals
 - May or may not be the FSVP importer

Draft Benefits of VQIP

- Expedited entry into the U.S.
- Examination and/or sampling generally limited to “for cause” situations
- Any sampling or examination done at location chosen by the importer
- Expedited laboratory analysis if sampled
- VQIP Importers Help Desk
- FDA will post approved VQIP importers, if desired
- Work with CBP to allow products to be exported from port of entry of your choice



Draft VQIP Guidance Eligibility Criteria

- Quality Assurance Program (QAP)
- Assurance of compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations
- Current facility certification, including farms, issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food in VQIP

Draft VQIP Guidance

Eligibility Criteria (cont.)

- 3+ year history of importing food to the United States
- No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of non-compliance with food safety regulations by the importer, other entities in the supply chain (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers), or food

Timing of VQIP Program

- Anticipate Final Guidance Summer 2016
- A formal Fee will be published no later than August 1, 2018
- Anticipate first applications January 1, 2018
- Anticipate first benefit period to begin October 1, 2018

Inspections, Compliance, and Enforcement

- Progress on development of procedures
 - Drafting internal operational procedures for application review, field investigations, prioritization of sample analysis, & Help Desk
 - Procedures will detail revocation process, reinstatement, and collaboration with other Federal agencies.

Regulator Training

- Developing training material content for FDA staff working with VQIP
- Developing training material content for the VQIP applicant inspections
- Finalizing a guide to be used during the inspection
- Will develop education for our Customs and Border Patrol counterparts.

Information Technology

- Significant progress in building an integrated IT system to receive and review VQIP Applications
- Developing IT tools for use by FDA staff during VQIP Inspections
- Developed screening criteria for PREDICT to expedite release of VQIP food

VQIP User Fees

- Reviewing comments
- Exploring user fee structure options
 - Will consider any burden on small business

Final Rule Accredited Third-Party Certification

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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).



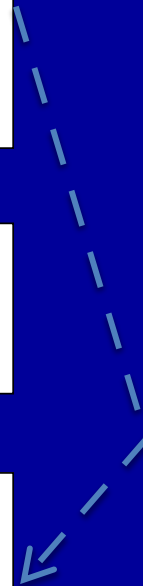
Third-Party Certification Bodies

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

- 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.

Oversight, Compliance and Enforcement

- Developing internal operational procedures for application review and oversight activities
- Working with other FSMA programs and existing FDA programs to establish procedures where programs intersect

Regulator Training

- Developing training program that has components from both external and internal materials and courses
- Developing guides to be used for internal reviews and audits

Information Technology

- Significant progress in building a new and integrated IT system for the program
- Automating all processes
- Integration of old and new systems

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](#)

