

FMI Foundation Retail Food Safety Forum

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<http://www.fda.gov/fsma>

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW



Background



Challenges Presented by Globalization

- Increasing volume of imported products
- Greater complexity in imported products
- More foreign facilities supplying the U.S.
- Greater complexity in supply chains
- Imports coming from countries with less sophisticated regulatory systems
- Greater opportunities for economic fraud
- Food security concerns

Statistics

- 15 percent of U.S. food supply is imported.
 - 75 percent of seafood
 - 20 percent of vegetables
 - 50 percent of fruit
- About 11 million line entries of food in FY14
- More than 105,000 foreign food facilities are registered with FDA.
- More than 200 countries/areas export food to the U.S.

Traditional Import Paradigm

- Border focused
- Virtually all of the information used to assess admissibility came from the import submission.
- FDA made a decision about the compliance status of the product at the time of entry with limited time, resources, and information.

Paradigm Shift

- The border can no longer be our primary line of defense. It should only serve as a final checkpoint on other controls.
- FSMA creates a multilayered safety net.
 - Role of manufacturer
 - Role of importers
 - Role of third parties
 - Role of foreign regulatory bodies
 - Role of FDA

FSMA Import Provisions

- Sec. 201. Inspection Frequency
- Sec. 301. Foreign Supplier Verification Program (FSVP)
- Sec. 302. Voluntary Qualified Importer Program (VQIP)
- Sec. 303. Certification for Food Imports
- Sec. 304. Prior Notice of Imported Food Shipments
- Sec. 305. Capacity Building
- Sec. 306. Inspection of Foreign Food Facilities
- Sec. 307. Accreditation of Third-Party Auditors
- Sec. 308. Foreign Offices of the FDA
- Sec. 309. Smuggled Food
- Sec. 404. Compliance with International Agreements

FSMA Implementation as a Continuum

- Phase 1: Set Standards
 - Regulations, guidance, policy
- Phase 2: Planning/Implementation
 - Design strategies and begin implementation to gain/maintain industry compliance with FSMA rules
- Phase 3: Implementation, Monitor, Evaluate, Refresh

FSMA Implementation: Phase 1



FSVP Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards.
- The requirements will provide flexibility based on the risk of the food.
- Under FSMA section 404, requirements must be consistent with WTO, other agreements.

Who Is Covered by FSVP?

- All importers must establish and follow an FSVP, unless otherwise exempted.
- U.S. importer is the person who has purchased the food offered for import.
 - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee.
 - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent/representative of the foreign owner/consignee.

Who Is Exempt from FSVP?

- Importers of juice and seafood whose suppliers are in compliance with the HACCP program (part 120 or 123)
- Small quantities of food imported for research and evaluation purposes
- Food imported for personal consumption
- Facilities subject to FDA's low acid canned food requirements (microbiological hazards only)
- Alcoholic beverages
- Food that is trans-shipped or that is imported for future export and not consumed or distributed in the U.S.

Overview of FSVP Proposed Rule

- Importers' FSVPs must ensure that:
 - The supplier uses procedures that provide the same level of protection as those required under the preventive controls or produce safety regulations (if applicable)
 - The food is not adulterated or misbranded regarding allergen labeling

Overview of FSVP Proposed Rule

- The requirements are risk-based and vary based on:
 - Type of food product
 - Category of importer, such as very small
 - Nature of the hazard identified in the food
 - Who is to control the hazard

FSVP Proposed Rule

- Importers would generally be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- In general, importers would need to provide:
 - Hazard Analysis
 - Risk evaluation
 - Supplier verification activities
 - Complaints, investigations, and corrective actions (if necessary)
 - Periodic reassessment of the FSVP (every 3 years)
 - Importer identification at entry
 - Recordkeeping

Modified FSVP Requirements

- Importation of a dietary supplement or dietary supplement component
- Importation of food by very small importer or from very small foreign supplier
- Importation of food from a foreign supplier in good compliance standing with a food safety system FDA has officially recognized as comparable to U.S. system



Proposed FSVP Compliance Dates

- Generally 18 months (1.5 years)
OR
- 6 months after the foreign supplier is required to comply with preventive controls or produce safety regulations

What Is VQIP?

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers 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 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 (con'd)

- 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

Draft Elements of a QAP

- Corporate Quality Policy Statement
- Organizational structure and individual responsibilities
- Policies and procedures to ensure food safety from source to entry (e.g., temperature and storage controls), including procedures regarding:
 - Compliance with supplier verification procedures in the FSVP or HACCP rules, if applicable, maintaining current facility certifications under FDA's Accredited Third-Party Certification Program,
 - Communication of information about potential health hazards to FDA and others
 - Corrective actions to address food and foreign supplier non-compliances that post a risk to public health



Draft Elements of a QAP (con'd)

- Food defense system to protect against intentional adulteration
- Experience and training requirements for employees responsible for implementing the QAP
- Written procedures for establishing and maintaining records relating to the structure and implementation of the QAP

Draft Benefits of VQIP

- Expedited entry into the U.S. for all foods included in an approved VQIP application
- Examination and/or sampling generally limited to “for cause” situations in which there is a potential threat to public health
- Any sampling or examination done at destination or another location chosen by the importer

Draft Benefits of VQIP (con'd)

- Expedited laboratory analysis of any samples
- VQIP Importers Help Desk
- Public posting on the FDA's VQIP web page of approved VQIP importers, if desired

Other Elements of the Draft Guidance

- Application Process (e.g., elements, timing, FDA review)
- Revocation Process
- Reinstatement Process
- FDA Oversight
- User Fees

Status of VQIP

- Notice of Availability published in Federal Register 6/5/15
 - Draft Guidance Document
 - Guidelines in Consideration of the Burden of the VQIP Fee on Small Business
 - 75 Day Comment Period

Accreditation of Third-Party Auditors

- Directs FDA to establish a voluntary system for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and, where appropriate, to issue certifications.
- Allows FDA to directly accredit third-party auditors under certain circumstances
- Directs FDA to establish model accreditation standards to qualify third party auditors for accreditation
- Directs FDA to issue implementing regulations that include protections against conflicts of interest
- Authorizes FDA to establish a fee to recoup the costs of this program.

Accredited Third Party Structure

- FDA maintains oversight over the program.
 - FDA recognizes accreditation bodies (ABs).
 - Recognized ABs (or, in some circumstances, FDA itself) accredit third-party auditors (aka certification bodies).
 - Accredited third party auditors conduct consultative and regulatory audits of eligible entities (e.g., registered foreign food facilities) and their foods.
 - Certificates can be issued for foods or facilities only after conducting a regulatory audit.

Accredited Third Party Structure

FDA

FDA would recognize accreditation bodies based on certain criteria, such as competency and impartiality.



Accreditation Bodies

Accreditation bodies would in turn accredit qualified third-party auditors.



Third-Party Auditors or Certification Bodies

Third-party auditors/certification bodies would audit and issue certifications for foreign facilities and foods.



Foreign Facility

Foreign facilities may choose to be audited by an accredited auditor/certification body.

Role of Third Party Certification

- VQIP: Necessary for participation in the program to expedite movement of food through the import process (sec. 302)
- Import Certification: May be required by FDA as a condition of entry based upon the risk of the food. (sec. 303)

Status of Accredited Third Party Certification

- Final Rule: October 31, 2015
- Model Accreditation Standards
- Fee Rule

FSMA Implementation Phase 2

Programs Under Import Controls

Phase II Workgroup

VQIP

Sec. 302: Allows for expedited review and entry; facility certification required (Sec. 806 of FD&C Act)

Accredited Third Party

Sec. 307: Accreditation of Third-Party Auditors / Certification Bodies to conduct food safety audits and to issue certifications (Sec. 808 of FD&C Act)

Import Certification

Sec. 303: Certification for high-risk food imports (Sec. 801(q) of FD&C Act)

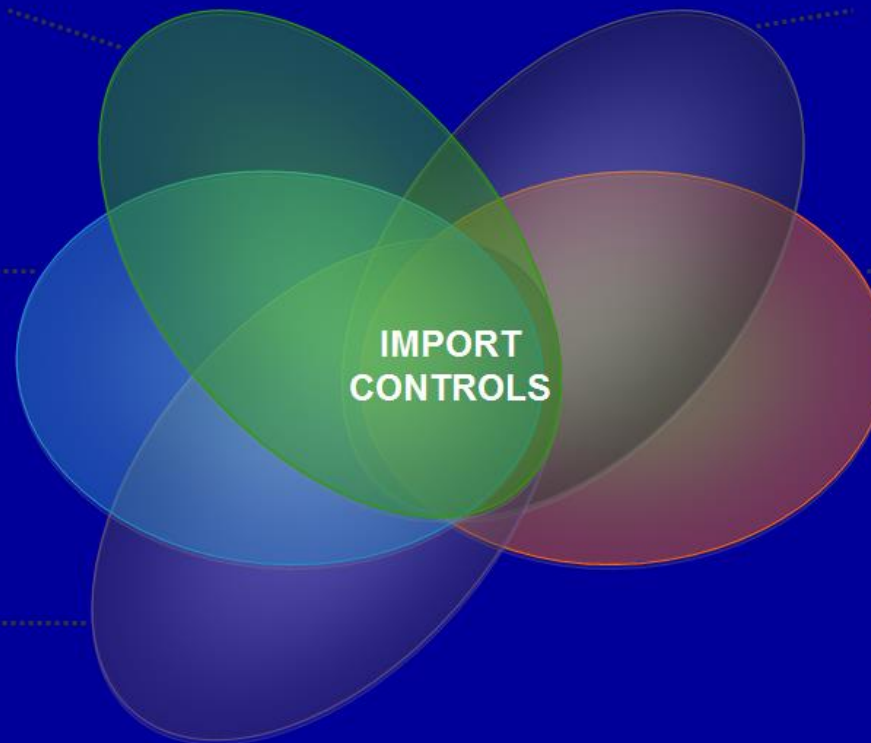
Lab Accreditation

Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

FSVP

Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

*Systems Recognition



Critical Operational Considerations

- Work planning/staffing for industry oversight to help ensure compliance, i.e. inspections, audits, sample collections and import program data integration to target resources
- Industry/stakeholder education, outreach, and technical assistance
- Regulator training and technical support
- IT, integration of domestic and import systems
- International trade context
- Requested \$25.5 M in FY16 for modernized import system

Questions

- For more information, visit our website:
<http://www.fda.gov/fsma>