IMPLEMENTATION

Food Safety Modernization Act (FSMA): Import Safety

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

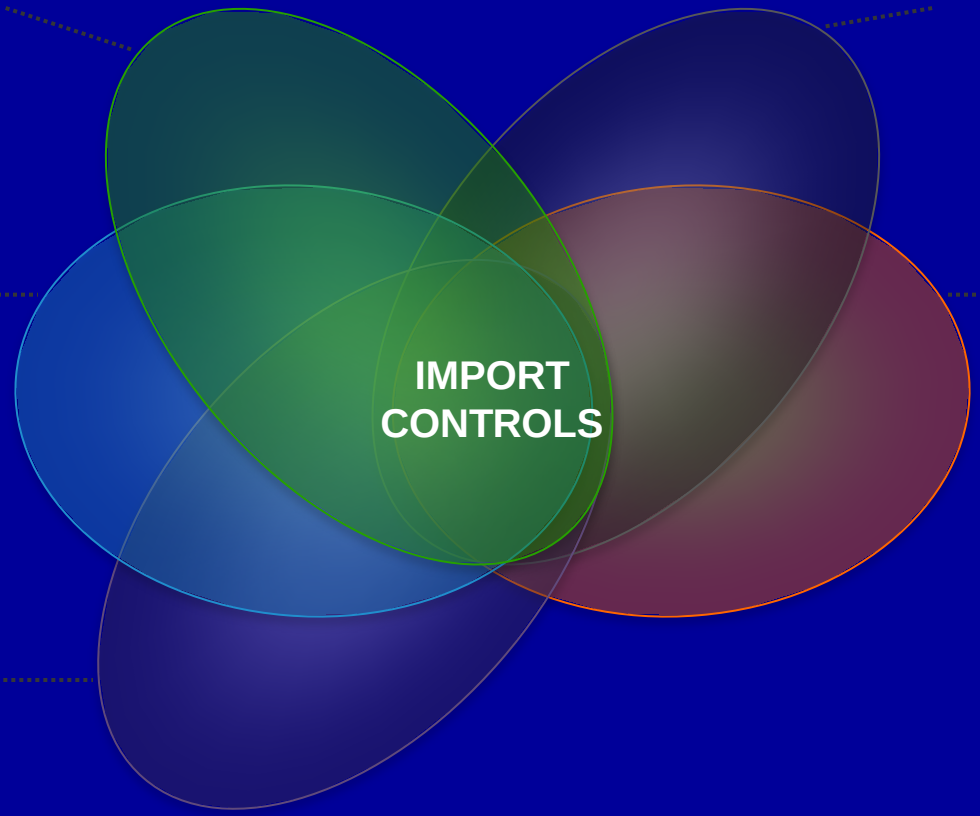
IMPLEMENTATION

Programs Under Import Safety Phase 2 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)



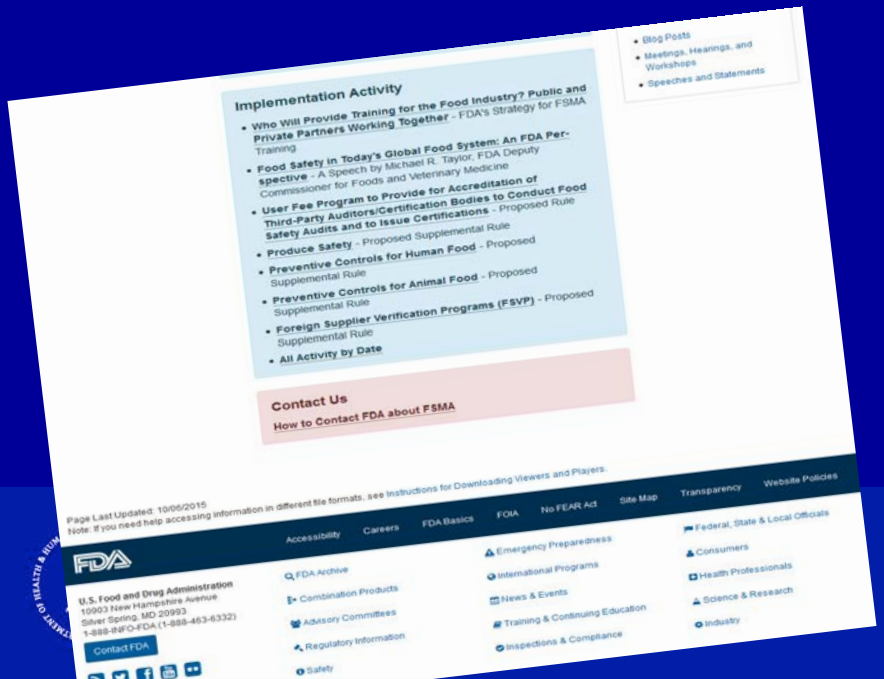
Lab Accreditation
Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

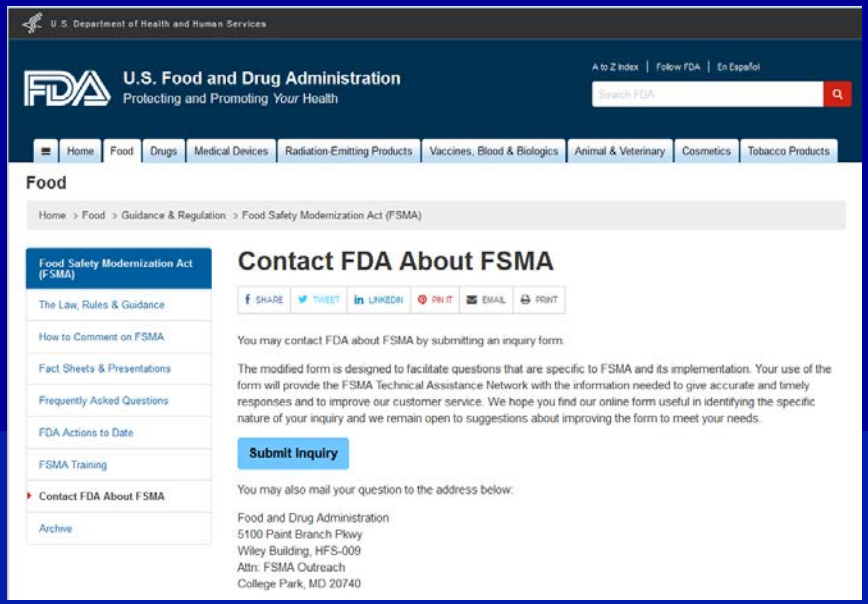
FSVP
Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

IMPLEMENTATION

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





FSVP Final

Final Rule on Foreign Supplier Verification Programs

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

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Background

- FSMA Sec. 301 requires importers to have FSVPs and FDA to issue regulations.
- Final rule published: Nov. 27, 2015
- Food safety → Central role

Key Principles of FSVP Rule

- Establishes explicit responsibility for importers to ensure the safety of imported food
- Risk-based (according to types of hazards, importers, and suppliers)
- Alignment with PC supply-chain provisions
- Flexibility in meeting requirements (assessing activities conducted by others)

Purpose of an FSVP

- To provide adequate assurances that:
  - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
  - Food is not adulterated or misbranded (as it relates to allergen labeling)

Who Must Comply?

- "Importer" is U.S. owner or consignee of a food at time of U.S. entry.

- If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent.

FSVP Exemptions

- Firms subject to juice or seafood HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and alcoholic beverage ingredients

FSVP Exemptions (cont.)

- Food transshipped through U.S.
- Food imported for processing and export
- “U.S. foods returned”
- Meat, poultry, and egg products subject to USDA regulation at time of importation
- Low acid canned food facilities (microbiological hazards only)

Use of Qualified Individuals

- Must use a *qualified individual* to perform required FSVP activities
  - Must have education, training, or experience (or combination thereof) necessary to perform the activity
  - Must be able to read and understand the language of any records reviewed in performing an activity

Standard FSVP Requirements

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- Develop FSVP
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier
- Approval of Foreign Supplier
- Foreign Supplier Verification Activities
- Corrective Actions
- Maintenance of Records

Hazard Analysis: 1.504

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- Known or reasonably foreseeable hazards requiring a control
  - Biological, chemical, radiological, and physical hazards
  - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain

Evaluation for Approval and Verification Activities: 1.505

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- Evaluation of risks posed by a food and performance of foreign supplier
- Evaluation is basis for:
  - Approval of foreign suppliers
  - Determination of verification activities

Foreign Supplier Verification Activities: 1.506

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- Establish and document use of written procedures to ensure the:
  - Use of approved suppliers or unapproved foreign suppliers on a temporary basis
  - Appropriate verification activities are conducted with respect to the imported food

Appropriate Verification Activities

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- Must document determination, performance, conduct, review and assessment of results

- Verification activities include:
  - Onsite audits (qualified auditor), sampling and testing of the food, a review of foreign supplier relevant food safety records, other appropriate activities

Onsite Audits & SAHCODHA

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- Hazard controlled by foreign supplier
- Serious Adverse Health Consequence Or Death to Humans or Animals (SAHCODHA)
- Must conduct or obtain documentation of onsite audit
- Prior to importing food and annually thereafter
- Exception - written determination of other activities

Reliance on Another Entity

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- May rely on another entity to:
  - Conduct hazard analysis
  - Perform evaluation of food and supplier
  - Establish written procedures for the use of approved or unapproved foreign suppliers
  - Determine and conduct verification activities
- Must document review and assessment, including use of a qualified individual

Modified Requirements

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- Certain importers may choose to comply with the modified FSVP requirements
- Only certain verification activities must be conducted
- Applies to sections 1.507, 1.511, 1.512, and 1.513

Hazards Controlled or Controlled after Importation: 1.507

- Foods intended for further manufacturing or processing and hazards will be controlled after importation
- Foods imported in the raw state; cannot be consumed raw
- Not required to conduct an evaluation of the food and supplier or verification activities if hazards requiring a control are identified and any of the circumstances apply

Dietary Supplements: 1.511

- Applies to importers of certain dietary supplements/components intended for further manufacturing, processing, or packaging
- Must establish and comply with certain dietary supplement cGMPs
- “Other importers” → ex. finished dietary supplements
  - Hazard Analysis not required

Very Small Importers: 1.512

- Must meet definition as a very small importer
- Less than $1 million/yr. in human food sales
- Less than $2.5 million/yr. in animal food sales
- Annually documentation of eligibility

Importers of Certain Foods from Certain Small Foreign Suppliers: 1.512

- Small foreign suppliers:
  - Qualified facility
  - Produce from certain small suppliers that are not covered farms
  - Shell egg producers with < 3,000 laying hens

Countries with Comparable or Equivalent Safety Systems: 1.513

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- Importers of certain food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.
- Systems Recognition Countries (SRC)
- Applies to food that is not intended for further manufacturing or processing

Other FSVP Requirements

- Corrective Actions: 1.508 or applicable section
- Importer Identification at Entry: 1.509
- Maintenance of Records: 1.510 or applicable section

Compliance Dates

- The final FSVP rule was published on November 27, 2015
- First compliance date: May 30, 2017
- Last compliance date: July 27, 2020
- Compliance Dates: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm

FSVP Importer Identification

- May 30, 2017 data element input into CBP's Automated Commercial Environment (ACE)

  – The unique firm identifier which is a DUNS#,
  – Firm Name, Firm Address
  – E-Mail address

FDA Supplemental Guidance

- **CBP and Trade Automated Interface Requirements**
-
- FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) Version 2.5
-
- December 28, 2016
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Identification Process

- IF GOVT Agency program code is FOO and processing code is NSF, PRO, ADD, DSU, FEE, THEN the following FSVP-related details will be mandatory for all FDA FOO lines unless Industry Codes 16 or 32 are present in PG02:

  - DUNS#, Firm Name, Firm Address1 are required in PG19;
  - All the elements, except Apt#, are required in PG20 AND
  - Qualifier Code=FSV and eMail address are required in PG21; individual's name and tel# are optional in PG21.

Identification Process-Cont.

- If line item is a food and the above items are not transmitted as above, an exemption must be declared
  - Affirmations of Compliance
    - –FSX (FSVP Exempt) or
    - –RNE (Research and Evaluation).

Identification Process-Cont.

- Rejected by the CBP's ACE system if one of the two codes are not transmitted

- Error message -make the appropriate adjustments and retransmitted.

Resources

- Contact FDA's ACE Support Center for technical questions related to the FDA Supplemental Guide, required data elements, ACE entries,
  - rejects, and errors:

  - ACE_Support@fda.hhs.gov
  - 877-345-1101 (domestic toll-free)
  - 571-620-7320 (local or international)

- Always keep your CBP Client Representative on all ACE-related email traffic.

Guidance and Outreach

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- Webinars and meetings
- FSVP Fact Sheets; FSVP At-a-Glance
- Supplier Evaluation Resources
- Technical Assistance Network (TAN)

Under development:

- FSVP guidance for industry
- Collaboration with FSPCA to develop FSVP training course materials
- “FDA Data Dashboard”

Any Questions?