

Proposed Rules to Help Ensure the Safety of Imported Food

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

**FDA FOOD SAFETY
MODERNIZATION ACT**



Why Are These Proposed Rules Important?

- About 15 percent of the U.S. food supply is imported – including nearly 50 percent of fresh fruit and 20 percent of fresh vegetables.
- Consumers expect that food imported into the U.S. should meet the same level of public health protection as food produced domestically.

Proposed Rules Implement Preventive Framework

- Safety standards established by FDA
 - Standards for produce safety
 - Preventive controls for human food
- Industry must verify standards are met
 - Foreign supplier verification program
 - Accreditation of third-party auditors
- Additional rules and guidance coming

Proposed Regulations for Foreign Supplier Verification Programs (FSVPs)

Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards
- The requirements provide flexibility based on the risk of the food

Overview of FSVP

- Importers would be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- The requirements 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

Who Is Covered?

- An importer is a person in the U.S. who has purchased the food being 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 or representative of the foreign owner or consignee.

What Is Exempt?

- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Food imported for research and evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages

What Is Exempt? (cont.)

- Food that is transshipped or that is imported for future export and not consumed or distributed in the U.S.
- Products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only)

FSVP Requirements

- In general, importers would need to conduct the following activities as part of their FSVPs:
 - Compliance status review of foods and suppliers
 - Hazard analysis
 - Supplier verification activities
 - Corrective actions (if necessary)
 - Periodic reassessment of the FSVP
 - Importer identification at entry
 - Recordkeeping

Control of Hazards

- The proposed requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur.

Importer or Customer Controls Hazard

- If the importer will be responsible for controlling a hazard identified as reasonably likely to occur, the importer would be required to document, at least annually, that it has established and is following procedures that adequately control the hazard.

Importer or Customer Controls Hazard (cont.)

- If the importer's customer will be controlling a hazard, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures that adequately control the hazard.

Hazard Controlled by Foreign Supplier or Its Supplier

- FDA is proposing two options for supplier verification activities when:
 - The foreign supplier is to control a hazard or
 - The foreign supplier verifies that its raw material or ingredient supplier is controlling a hazard
- The options differ based on approach to hazards that can cause serious adverse health consequences or death to humans or animals (SAHCODHA)

Modified FSVP Requirements

- Dietary supplements and dietary supplement components
- Food imported by a very small importer or from a very small foreign supplier
- Food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent

Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule
- Compliance dates
 - Generally 18 months after publication; or
 - Six months after the importer's foreign supplier is required to comply with the new preventive controls or produce safety regulations.

Proposed Rule Accreditation of Third-Party Auditors

Overview

- FDA must establish voluntary program for accrediting third-party auditors to conduct food safety audits of foreign facilities and their foods
- FDA will recognize accreditation bodies, which will in turn accredit third-party auditors under the program
 - FDA can directly accredit third-party auditors in limited circumstances

Key Principles

- A credible third-party program will allow the agency to leverage industry audits
- A credible third-party program will help to facilitate entry of certain imported food
- A comprehensive third-party program will create a new path for working with foreign governments

Are Third-Party Audits Required?

- Importers will not generally be required to obtain certifications
- In certain circumstances FDA would use certifications in determining:
 - Whether to admit certain imported food into the U.S. that FDA has determined, based on FSMA criteria, poses a food safety risk, or
 - Whether an importer is eligible to participate in the Voluntary Qualified Importer Program (VQIP)

How it Would Work

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 auditor s/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.

Eligibility for Recognition of Accreditation Bodies (ABs)

- Foreign government agencies or private organizations
- Must meet requirements on authority, competency, capacity, impartiality, quality assurance, and records

Requirements for Accredited Auditors

- Audit agent competency
- Audit protocols
- Notifications
- Audit reports
 - Consultative audit
 - Regulatory audits (these are not FDA inspections)

Use of Certifications Issued by Accredited Third- Party Auditors

- In meeting eligibility requirements for VQIP for expedited review and entry of food
- In providing certification or other assurances of compliance as a condition of entry for food determined by FDA to pose a safety risk under FSMA criteria

How to Comment on the Proposed Rules

- Go to www.regulations.gov or www.fda.gov/fsma
- Published July 29, 2013; comments due Nov. 26, 2013 (120 days)
- Comment period on produce and preventive controls rules extended to Nov. 15 to enable comment on how the rules can best work together

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

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Guidance & Regulation

Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

How to Comment on FSMA

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FDA Actions to Date

FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.



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Spotlight

FDA Answers Farmers' Questions on the Proposed Rule for Produce Safety
Q&A with Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine

What's New

Strengthening the Oversight of Imported Foods

FDA issues two proposed rules under the Food Safety Modernization Act (FSMA) aimed at strengthening assurances that imported food meets the same safety standards as food produced domestically.

- [Proposed Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals](#)
- [Proposed Rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications](#)

Most Popular

- [FSMA Information by Topic](#)
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For Consumers

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- [FDA Strengthening Our Food Safety Foundation](#)
- [Foreign Exporters Study Food Safety Law](#)
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