

Proposed Rules to Help Ensure the Safety of Imported Food

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**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 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)

Option 1

- If the foreign supplier controls the hazard at its establishment and it is a SAHCODHA hazard, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier.
- Onsite auditing would also be required for microbiological hazards in certain raw agricultural commodities.

Option 1 (cont'd)

- For non-SAHCODHA hazards and all hazards for which the foreign supplier verifies control by its raw material or ingredient supplier, importer would be required to choose a verification activity:
 - Onsite auditing
 - Sampling and testing
 - Review of supplier food safety records
 - Some other appropriate procedure

Option 2

- For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among:
 - Onsite auditing
 - Sampling and testing
 - Review of supplier food safety records, or some other appropriate procedure.

Option 2 (cont.)

- In determining which verification activities are needed and how often they should be conducted, the importer would need to consider:
 - The risk presented by the hazard
 - The probability that exposure to the hazard would result in serious harm
 - The food and foreign supplier's compliance status.

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

FSMA's Import Tool Kit

- New authorities, mandates work together to create integrated import safety system
 - Foreign supplier verification programs (sec. 301)
 - Voluntary qualified importer program (sec. 302)
 - Mandatory certification (sec. 303)
 - Enhancements to prior notice (sec. 304)
 - Building capacity of foreign governments (sec. 305)
 - Improved enforcement authorities (sec. 306)
 - Accreditation of third-party auditors (sec. 307)
 - Foreign offices (sec. 308)

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

Fact Sheets

Frequently Asked Questions

Speeches, Videos, & Webinars

FDA Actions to Date

Resources for You

- [FSMA Blog](#)
- [The Rulemaking Process \(a video tutorial\)](#)
- [FSMA 101 \(a video tutorial\)](#)
- [Translations of Key FSMA Resources](#)
- [Foodborne Illness Outbreaks](#)

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](#)

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