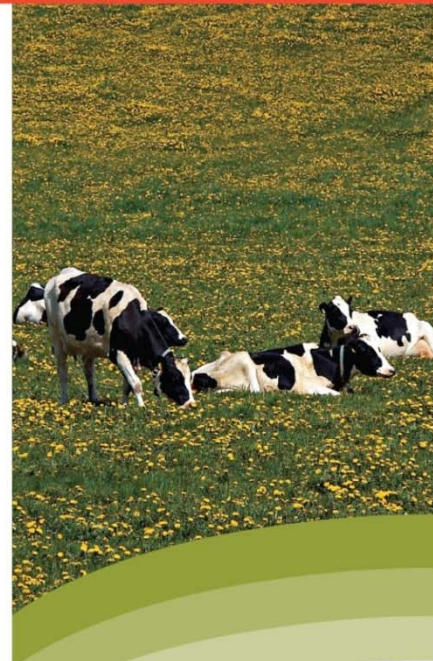
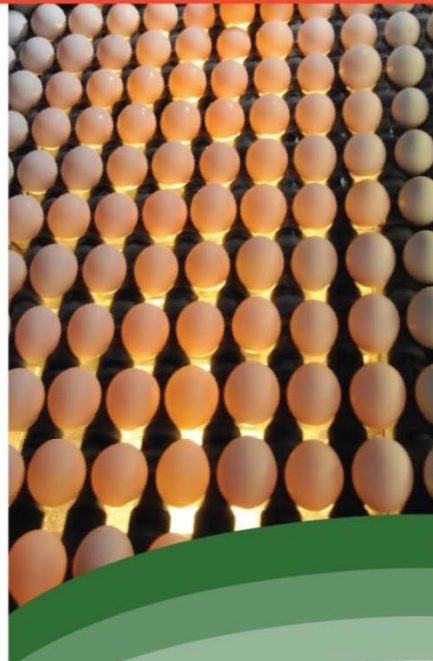




United States Department of Agriculture

Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses



Report on the United States Food Safety Modernization Act (FSMA)

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INTRODUCTION

Question: What is the U.S. Food Safety Modernization Act commonly (FSMA)?

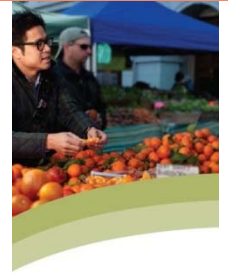
Response: FSMA is the most sweeping reform of United States food safety laws in more than 70 years. It was signed into law by President Obama on January 4, 2011.

FSMA'S Goal: To ensure the U.S. food supply is safe by shifting the focus from responding to contamination to prevention. The food system is viewed as a whole, therefore safety throughout the entire food system domestically and internationally is the responsibility of all participants.

Lead Agency: The United States Food and Drug Administration is responsible for implementing FSMA.

FSMA Central Principles

- Move the food safety system from reaction to prevention
- High rates of compliance critical to success
- Domestic and import parity
- Educate before and while regulating
- Risk based approach to inspection and work planning
- Critical role of partnerships
 - Other federal agencies
 - Integrated food safety system
 - Foreign partnerships



Food Facility Registration



Under FSMA, all facilities (domestic and foreign) that manufacture, hold or pack food for U.S. humans and/or for animals consumption must register with the U.S food and Drug Administration (FDA).
{Section 415 of the Bioterrorism Act}

Renewal of FDA Food Facility Registration is done on every even numbered year between October 1st and December 31st.

Failure to register by the deadline will invalidate the Food Facility Registration number preventing importation into the US.

Farms and Business Descriptions

	Farms	Businesses for Human food	Businesses for Animal Food
	Annual Sales	Annual sales &/or number of employees	Annual sales &/or number of employees
Size			
Large	More than \$500,000.00	More than \$1 million (adjusted for inflation) per year, during the three-year period preceding the applicable calendar year in sales AND that has more than 500 full-time equivalent employees fewer than 500 full-time equivalent employees.	More than \$2.5 million adjusted for inflation per year, during the three-year period preceding the applicable calendar year in sales of animal food AND that has at least 500 full-time equivalent employees.
Small	\$250,001.00 to \$500,000.00	Employing fewer than 500 full-time equivalent employees.	Employing fewer than 500 full-time equivalent employees.
Very Small	\$25,000.00 to 250,000.00	Less than \$1 million (adjusted for inflation) per year during the three-year period preceding the applicable calendar year	Averages less than \$2.5 million (adjusted for inflation) per year during the three-year period preceding the applicable calendar year in sales of animal food plus market value of animal food manufactured, processed, packed or held without sale
Several FSMA rules have provisions in which the value is adjusted for inflation and averaged over 3 years			

Food Facility Registration & Reregistration

Requires food facilities to write and implement a food defense plan that contain:

- Identification of actionable process steps
- Focused mitigation strategies
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

Effects on Exporters



Resulting from this increased accountability required of U.S. importers, they would require the same from their suppliers/exporters.

U.S. importers are accountable for **verifying that imported food and feed products entering the U.S. are produced in accordance with US laws and regulations.**

All facilities that manufacture, hold or pack food for U.S. humans and/or for animals consumption must register and maintain registration with the FDA.

Prohibition on food imports by nonresident importers/consignees.

Effect on Exporters Cont.



- There is a possibility of increased number of (third party) audits to ensure that food is produced in accordance with US laws and regulations
- Record keeping by exporters
- All exporters must have a licensed U.S. importer /agent with a physical address and telephone number so that they can be reached in a timely manner in case of emergency recall or non-conformity.
- Food Facility Registration & Reregistration
- Adherence to the Produce Safety Rule (both domestic and foreign)
 - Establishes minimum standards for safe growing, harvesting, packing and storage of produce.
 - Contains several exemptions

Effect on Exporters Cont.

Produce Safety Rule

Sets food safety standards on:

- Worker training, health and hygiene
- Agricultural water
- Biological soil adjustments
- Domesticated and wild animals
- Equipment, tools and buildings
- Sprouts

Compliance:- Jan 2018 for the largest farms,
Jan 2017 for the largest sprout operations

Egregious violations may result in criminal penalties, however the FDA is considering a more measured approach leading with education and technical assistance to gain compliance.

Effect on Exporters Cont.

Increased Enforcement and Scrutiny of Food Imports – increased inspection of domestic and foreign food facilities throughout the production/distribution chain.

Mandatory Recall Authority – FDA can now mandate recalls of a product if the facility does not do it voluntarily.

A Lower Threshold For Administrative Retention – FDA now has the legal authority to retain goods with only “a reason to believe” they are noncompliant. Previously “credible evidence” was needed.

Administrative retention allows FDA to detain food shipments for a limited period of time, during which the agency undertakes legal action to formally seize the product.

New Fees – Fees for the inspection and re-inspection of domestic and foreign facilities after violations are identified and corrections made.

Prohibition on food imports by nonresident importers/consignees

Effect on Exporters Cont.

Third Party Audits:

- The FDA is contemplating what role reliable, third-party audits, whether conducted by a government agency or a private concern may play.”
- The use of in-site audits is one option when conducting supplier verification activities under the FSVP and PC rules, however, the responsibility for assuring the correct evaluations, document review from the process is the U.S. food importer
- Accepted third party audits: “The auditor must be a “Qualified Auditor” and must consider applicable FDA food safety standards.”

Foreign Supplier Verification Program Highlights

Effective May 30, 2017

It is a program that importers covered by the rule must have in place a system to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

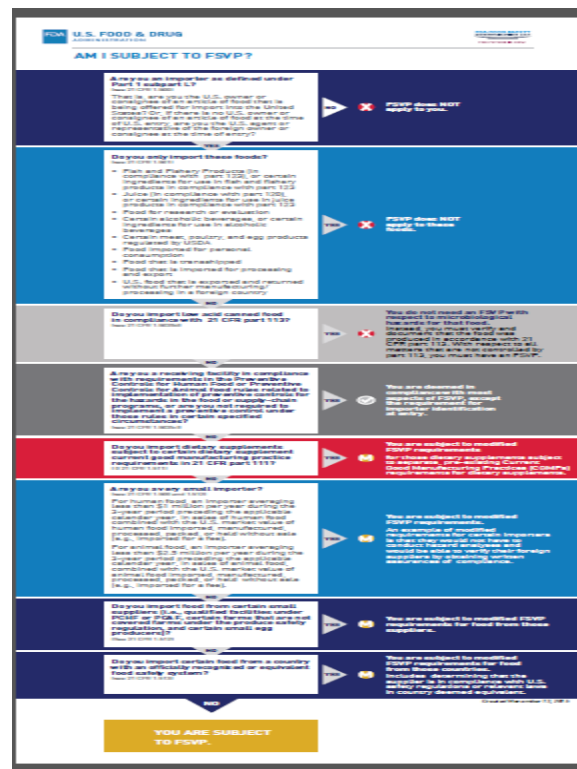
Importer are responsible for actions that include:

- Determining known or reasonably foreseeable hazards with each food
- Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
- Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
- Conducting supplier verification activities
- Conducting corrective actions

FDA FSVP Decision Tree

Am I subject to FSVP?

<https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf>





FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

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- [Key Requirements](#)
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Introduction

The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates begin **May 30, 2017**.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

About the Final Rule

- [Federal Register Notice](#)
- Docket Folder [FDA-2011-N-0143](#)
- [Compliance Dates for the Final Rule](#)
- [FSVP: What Do Importers Need to Know?](#)
- [Questions & Answers](#)
- [What Foreign Supplier Verification Programs Mean for Consumers](#)
- [Am I Subject to FSVP? \(Color PDF: 69KB\)](#)
- [Am I Subject to FSVP? \(Black & White PDF: 78KB\)](#)
- [Print-Friendly Fact Sheet \(PDF: 249KB\)](#)
- [FSVP Final Rule At-A-Glance \(PDF: 220KB \)](#)

Related Guidance

- [Draft Guidance for Industry: Describing a](#)

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Spotlight

- [FDA, European Commission and EMA reinforce collaboration to advance medicine development and evaluation \(PDF - 64KB\)](#)
- [FDA Voice: Globalization](#)
- [Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan \(PEPFAR\)](#)
- [FDA Food Safety Modernization Act \(FSMA\)](#)

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Navigate the International Programs Section

[FDA Globalization](#)

FDA's permanent presence in China, India, Europe, and Latin America.

[International Arrangements](#)

FDA International Arrangements: Cooperative Arrangements (Memoranda of Understanding, etc.) and Confidentiality Commitments

[Partnerships and Collaboration](#)

Education, outreach, webinars, technical assistance with regulatory counterparts

[President's Emergency Plan for AIDS Relief \(PEPFAR\)](#)

About FDA's PEPFAR program, including a listing of medicines approved and tentatively approved in association with the program.

[News and Events](#)

Current information about international program activities at home and abroad

[Imports and Exports](#)

Laws, regulations and policies applicable to imports and exports of FDA-regulated products

[FDA Publications and Other Documents in Foreign Languages](#)

Consumer and professional publications on food safety, nutrition, health promotion, veterinary health, and other topics

FDA Capacity-building Plan

Includes as appropriate:

- Recommendations for bilateral and multilateral arrangements and agreements, including providing for responsibilities of exporting countries to ensure food safety;
- Provisions for secure electronic data sharing;
- Provisions for mutual recognition of inspection reports;
- Training of foreign governments and food producers on U.S. requirements for safe food;
- Recommendations on whether and how to harmonize requirements under the Codex Alimentarius; and
- Provisions for multilateral acceptance of laboratory methods and testing and detection techniques.

FDA's Training Strategy:

“Educate before and while we regulate.”

- **International Outreach, Resources & Technical Assistance**
- **Foreign Supplier Verification Programs (FSVP)**
<https://www.ifsh.iit.edu/fspca/courses/foreign-supplier-verification-programs-fsvp>
- **International Capacity Building**
<https://www.fda.gov/food/guidanceregulation/fsma/ucm301708.htm#plan>
- **FSMA Technical Assistance Network (TAN)**
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

Key Links:

- Compliance Dates for the Final Rule on Foreign Supplier Verification
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>
- Compliance Dates/Calendar
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM568798.pdf>

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FSMA Compliance Dates/Calendar

