

Final Rule on Foreign Supplier Verification Programs

2018 American Hop Convention and
Hop Research Council Winter Meeting

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FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

Agenda

- ▶ What is the Foreign Supplier Verification Program (FSVP) Rule?
- ▶ Who must comply?
- ▶ What are supplier verification activities?
- ▶ What are the compliance dates?
- ▶ Where can I get more information?

Key Principles of FSVP Rule

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

Purpose of FSVPs

- ▶ 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 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

Am I subject to FSVP?

► Website:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>

FSVP
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AM I SUBJECT TO FSVP?

Are you an importer as defined under Part 1 subpart L?

[see 21 CFR 1.500]

That is, are you the U.S. owner or consignee of an article of food that is being offered for import into the United States? Or, if there is no U.S. owner or consignee of an article of food at the time of U.S. entry, are you the U.S. agent or representative of the foreign owner or consignee at the time of entry?

NO



FSVP does NOT apply to you.

YES

Do you only import these foods?

[see 21 CFR 1.501]

- Fish and Fishery Products (in compliance with part 123), or certain ingredients for use in fish and fishery products in compliance with part 123
- Juice (in compliance with part 120), or certain ingredients for use in juice products in compliance with part 123
- Food for research or evaluation
- Certain alcoholic beverages, or certain ingredients for use in alcoholic beverages
- Certain meat, poultry, and egg products regulated by USDA
- Food imported for personal

YES



FSVP does NOT apply to these foods.



Exemptions from FSVP

- ▶ Firms subject to juice or seafood Hazard Analysis and Critical Control Plan (HACCP) regulations
- ▶ Food for research or evaluation
- ▶ Food for personal consumption
- ▶ Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)

FSVP Exemptions (cont.)

- ▶ Food transshipped through U.S.
- ▶ Food imported for processing and export
- ▶ “U.S. food returned”
- ▶ Meat, poultry, and egg products subject to USDA regulation at time of importation

Importers in Compliance with Preventive Controls

- ▶ Importers are deemed in compliance with most of FSVP when they:
 - Comply with PC supply-chain provisions
 - Implement preventive controls under PC regulation for hazards in food they import
 - Are not required to implement a preventive control under certain PC provisions

Use of Qualified Individuals

- ▶ Must use a *qualified individual* to perform all required FSVP tasks
 - 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

Perform a Hazard Analysis

- ▶ Evaluate known or reasonably foreseeable hazards to determine if they require a control
 - Biological, chemical (including radiological), and physical hazards
 - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain
- ▶ May assess another's hazard analysis

Evaluation of Food and Foreign Supplier

- ▶ To approve suppliers and determine appropriate supplier verification activities
- ▶ Consider:
 - Risk posed by the food (hazard analysis)
 - Entities controlling hazards or verifying control
 - Supplier characteristics (procedures, processes, and practices; FDA compliance; food safety history)

Supplier Verification Activities

- ▶ Procedures to ensure food is obtained from approved suppliers
- ▶ May use unapproved suppliers on temporary basis when subject food to verification
- ▶ Written procedures for verification activities

Verification Activities (cont.)

- ▶ Determine appropriate verification activities (and frequency) based on food and supplier evaluation
 - Activities may include: onsite auditing; sampling and testing; review of supplier records; other appropriate measures
- ▶ Annual onsite auditing is default approach when a food has a SAHCODHA hazard

Reliance on Verification Activities Conducted by Others

- ▶ May rely on another entity's determination or performance of appropriate verification activities (e.g., farm audits conducted by produce distributor)
- ▶ Must review and assess results of verification activities (importer's own or others on which it relies)

Verification Activities (cont.)

Onsite audits:

- ▶ Must be conducted by “qualified auditor”; may be government employee
- ▶ Consider applicable FDA food safety regulations
- ▶ Substitute results of inspection by FDA or other entities

Other Circumstances

- ▶ Food cannot be consumed without application of control (e.g., coffee beans)
- ▶ Hazard controlled by importer's customer or subsequent entity in U.S. distribution
 - Disclosure statement
 - Written assurance
- ▶ Importer establishes other system to ensure control of hazard at subsequent distribution step

Other FSVP Requirements

- ▶ Corrective actions
- ▶ Importer identification at entry
- ▶ Recordkeeping

Modified FSVP Requirements

- ▶ Hazards are being controlled after entry into the U.S.
- ▶ Dietary supplements
- ▶ Very small importers and importers of food from certain small foreign suppliers
- ▶ Certain food from suppliers in countries with comparable or equivalent food safety systems

Compliance Dates

Website:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>

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Guidance and Outreach

- ▶ Developing FSVP draft guidance for industry
- ▶ Food Safety Preventive Controls Alliance has developed course materials for FSVP

Website: <https://www.ifsh.iit.edu/fspca/courses/foreign-supplier-verification-programs-fsvp#FSPCA-FSVPCourse>

- ▶ FDA Technical Assistance Network
- ▶ Webinars and meetings

For More Information

► Website:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm560689.htm>



The screenshot shows the FDA website page for "FSVP: What Do Importers Need to Know?". The page features a navigation menu with categories like Home, Food, Drugs, Medical Devices, etc. The main content area includes a sidebar with links to "The Law, Rules & Guidance", "Fact Sheets & Presentations", "Frequently Asked Questions on FSMA", "FDA Actions and Meetings", "FSMA Rules & Guidance for Industry", "FSMA Training", and "FSMA Technical Assistance Network (TAN)". The main heading is "FSVP: What Do Importers Need to Know?" with social sharing options for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. Below the heading is a large image of a woman in a purple blazer sitting at a desk, with a smaller inset image of her smiling.

For More Information

- ▶ Website: www.fda.gov/fsma (subscription feature available)
- ▶ To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)



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Questions?

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