

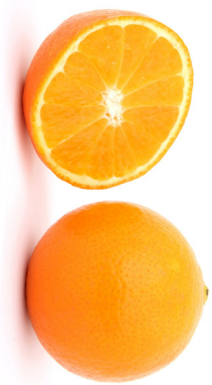
Foreign Supplier Verification Programs

FSVP

A GUIDE FOR IMPORTERS

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Since the government enacted the Food Safety Modernization Act (FSMA) in 2011, the Food & Drug Administration's (FDA) focus has been to educate while it regulates. This guidance especially holds true as it applies the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food and Animals. However, the FDA is quickly moving toward enforcement.



The regulatory body recently issued – July 30th, 2019– the first warning letter under the authority FSMA provides in its final FSVP ruling. The FDA delivered the written notification to Brodt Zenatti Holdings LLC. The Jupiter, FL company had imported tahini implicated in a U.S. salmonella outbreak from Karawan Tahini and Halva of Israel.

The company voluntarily recalled the tahini in May, which prompted the FDA to inspect the importer and its facility. The investigation revealed that Brodt Zenatti lacked an FSVP program for imports. Section 805 of the Federal Food, Drug, and Cosmetic (FD&C) Act and 21 CFR Part 1 Subpart 1 requires that importers establish an FSVP plan for every import.

The FDA gave Brodt Zenatti 15 working days to respond with plans to correct the violations or provide evidence they had fixed the violations. If the company failed to comply, the FDA could put them on the Import Alert #99-41, which is an FDA administrative enforcement tool that puts an import refusal in place. When this happens, a company cannot import the goods until the FDA lifts the ban.

The FDA has conducted FSVP inspections since 2017 to help importers understand the FMSA and FSVP regulatory requirements and correct deficiencies, but this case marks the organization's first foray into enforcement.
This action should grab the attention of importers.

Companies that do not satisfy FSVP requirements may find themselves served with a warning letter, bound by an import alert, or face fines and prosecution. Further, the FDA promises an aggressive increase in audits. Its enforcement actions will include re-inspecting importers with identified deficiencies in previous inspections and acting immediately when FSVP shortfalls pose an imminent public health risk.

The government is cracking down on food imports, and with good reason. The FDA reports in "FDA Strategy for the Safety of Imported Food" that the United States imports about 15% of its overall food supply. The document details that over 200 countries or territories, and roughly 125,000 foreign food facilities and farms, supply approximately 32% of the fresh vegetables, 55% of the fresh fruit, and 94% of the seafood Americans consume annually.

With so much at stake, importers will need to get up to speed on these regulations quickly. As you read through, this guide will break down the most important things you need to know, starting with an overview of why the FDA implemented these changes.



What are FSMA and FSVP?

Foodborne illness is a major public health problem. The Centers for Disease Control and Prevention estimates roughly one in six Americans (or 48 million people) get sick from foodborne diseases, 128,000 are hospitalized, and 3,000 die of foodborne illnesses every year.

The FSMA, signed into law on January 11, 2011, is the regulatory change designed to prevent food-related illnesses by shifting the focus from response to prevention.

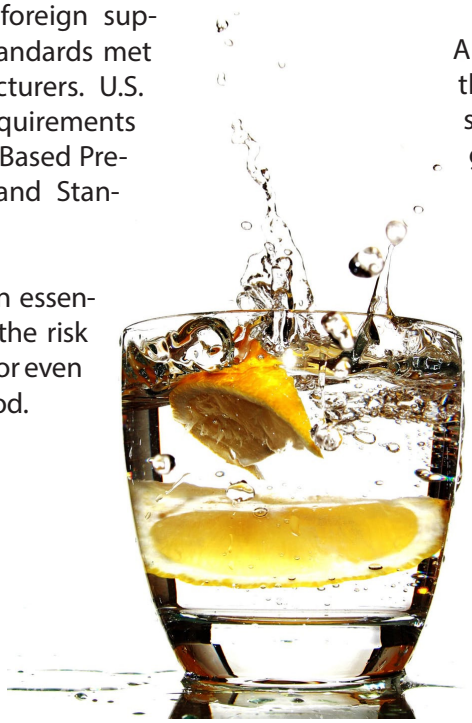
The FSMA overhauls the FD&C Act, which dates back to the 1930s. The regulation enables the FDA to better protect public health by strengthening the food safety system. It employs modern techniques to advance food safety practices and equips the FDA with regulatory tools to enforce this legislation.

The list of rules the FSMA puts forth is a game-changer. They require the industry to adopt procedures, operations, and recordkeeping practices that safeguard the food supply. The FSMA also raised the stakes with stiffer penalties and fines for non-compliance.

Congress established seven major rules for implementing the FSMA. The FSVP rule for Importers of Food for Humans and Animals is among them. This directive, issued November 13, 2015, holds importers and their foreign suppliers responsible for protecting the safety of imported food.

Most imported food shipments became subject to FSVP requirements on March 19, 2018. The rule requires that food importers establish an FSVP plan for foreign suppliers, holding foreign suppliers to the same safety standards met by domestic food manufacturers. U.S. suppliers adhere to the requirements of Hazard Analysis and Risk-Based Preventive Controls (HARPC) and Standards for Produce Safety.

The FSMA and FSVP serve an essential function by minimizing the risk of consumers becoming sick or even dying from contaminated food.



Most imported food shipments became subject to FSVP requirements on March 19, 2018.



Put an FSVP Plan in Place

Both the FSMA and FSVP put traceability tools in place, which allows the FDA to trace an outbreak back to its source.

In the case of Brodt Zenatti, the FDA tracked imported tahini back to the importer of record. In this case, a consumer fell ill and went to the hospital after eating the contaminated food. When the health agency reported that the individual had salmonella, the FDA launched an investigation.

The consumer told authorities the tahini came from a Price Chopper supermarket. The FDA then learned Price Chopper purchased the tahini from Joe's Wholesale, which bought the product from Brodt Zenatti. That company reported the product came from Karawan Tahini and Halva.

The FDA traceability process worked. However, the safety of the import broke down because Brodt Zenatti had never verified that Karawan Tahini and Halva complied with FSMA mandates.

A key part of FSVP is performing risk-based activities that verify foreign suppliers meet U.S. food safety standards and properly label products with allergen information. FSVP applies to all FDA-regulated food that is imported or offered for import into the United States.

FSVP's overarching definition of "food" includes all ingredients in food and beverages, food, and color additives introduced during processing, dietary supplements, packaging, and food contact substances.

There are partial and minor exceptions, though. Food regulated by the USDA or HACCP—such as meat, poultry, and egg products—is not subject to FSVP regulations.

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Determine Country of Origin

The first step toward complying with the FSVP is determining the country of manufacture. It's important to note that FDA rules differ from one country to another.



The FDA recognizes Canada, Australia, and New Zealand as having food safety systems equivalent to the U.S., and as a result, the rules are more relaxed when food comes from these countries. If the goods came from Canada and the company complies with the Canadian Food Inspection Agency (CFIA) standards, the FDA accepts that they also meet U.S. regulations. As a result, the verification process is less stringent. The importer confirms annually that the company complies with all CFIA regulations and requirements.

When importing food products from a country without this recognition, importers must verify their supplier complies with all FSMA regulations and has put an FSVP Plan in place.

What is an FSVP Plan?

An FSVP Plan is a document that shows importers verified their foreign suppliers and meet the same food safety standards as domestic companies.

Under this plan, importers must:

- Determine known or reasonably foreseeable hazards with each food-related product. In other words, look for perils likely to cause illness or injury. These might include biological hazards, such as parasites and disease-causing bacteria; chemical hazards, such as dyes, allergens, radiological waste, pesticides, or drug residue; and physical hazards, such as glass.

- Develop preventive measures to mitigate identified hazards. One FDA-regulated product may need to be kept at a specific temperature to avoid spoiling, while another is safe at any temperature. For example, a company may need to make sure it does not harvest spinach immediately after spreading organic manure. Another may need to install restrooms for its field workers. The point is that mitigation needs will differ for every food product—and every company.

- Document the preventative measures the importer and supplier have taken for identified hazards. The FDA requires companies to keep detailed records of these efforts.

- Evaluate the risk posed by food types, based on the hazard analysis and the foreign supplier's performance. Consider the supplier's procedures, processes, and practices that promote food safety. Review the company's safety history, including its responses to past problems. Evaluate storage and transportation practices.

- Conduct supplier verification activities. A comprehensive risk evaluation helps importers approve suppliers and determine appropriate supplier verification activities. It is important to periodically perform onsite audits of foreign suppliers, sample and test products, and review relevant food safety records.

- Perform corrective actions to maintain supply chain integrity. If a foreign supplier fails to meet FSMA requirements, the importer may need to stop using the supplier until the issue is resolved.

- Develop a separate FSVP Plan for every food-related product and foreign supplier. Importers must also reassess their FSVP Plans every three years.



Hire a Preventative Controls Qualified Individual

Use a qualified individual to develop an FSVP Plan and perform FSVP activities.

CFR Title 21, Section 1.276 defines a "qualified individual" under FSVP as:

"a person who has the education, training, or experience (or a combination of these) necessary to perform an activity required under the FSVP regulation and can read and understand the language of any records that the person must review in performing this activity."

"A qualified individual may be, but is not required to be, an employee of the importer; you might also rely on non-employees such as a consultant or a third-party auditor. A government employee, including a foreign government employee, may be a qualified individual."

Currently, the FDA lacks a structured training program for qualified individuals. However, the Food Safety Preventive Controls Alliance (FSPCA) provides training that, when combined with on-the-job experience, delivers education that meets qualified individual requirements.

Training becomes a moot point if an importer hires a Preventative Controls Qualified Individual (PCQI). These professionals already meet current good manufacturing practices (cGMP) and preventive control rules, which are more stringent than the FSVP's qualified individual mandates.







Use Data for Actionable Insights

FSVP compliance comes down to quality data. Companies need a measurable standard to prove compliance, which means they must keep detailed records. It also ensures they are prepared for an FDA audit of their operations.

Data standards vary and are based upon the food product itself and the policies set up to ensure its safety. There is no gold standard for data because every food product and every manufacturer is different.

Canned versus frozen corn is a great example. A manufacturer of canned corn must keep records of temperatures and processing times. With frozen corn, however, the company may determine that it needs a metal detector to ensure there are no metal objects contaminating the corn as it leaves the blast freezer. Canned corn is shelf-stable when it ships, but frozen corn must be maintained at a specific temperature during transport. A company must document each step the corn goes through, from the field to the manufacturer, to its final destination.

There are eight areas where companies must keep accurate records regarding foreign supplier verification; they include:

1. *Hazard analysis*
2. *Foreign supplier performance evaluation*
3. *Procedures for approving foreign suppliers*
4. *Procedures to assure use of only approved foreign suppliers*
5. *Determination of verification activities and their frequency*
6. *Performance of verification activities*
7. *Corrective and preventive actions*
8. *Re-evaluations of the entire FSVP, either for cause or routinely every three years*

During an audit, records requested by the FDA must be available within 24 hours. The agency's request for records could go back two years.

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Best Practices for Auditing Your Company and Foreign Partners

If a company imports food long enough, they will be audited. It's not a question of if, but when.

The FDA ratchets up its audits every year. In 2018, the FDA performed approximately 1,200 FSVP audits. In 2019, the FDA plans over 2,000 audits of individual companies. Eventually, the FDA hopes to hit 12,000 a year.

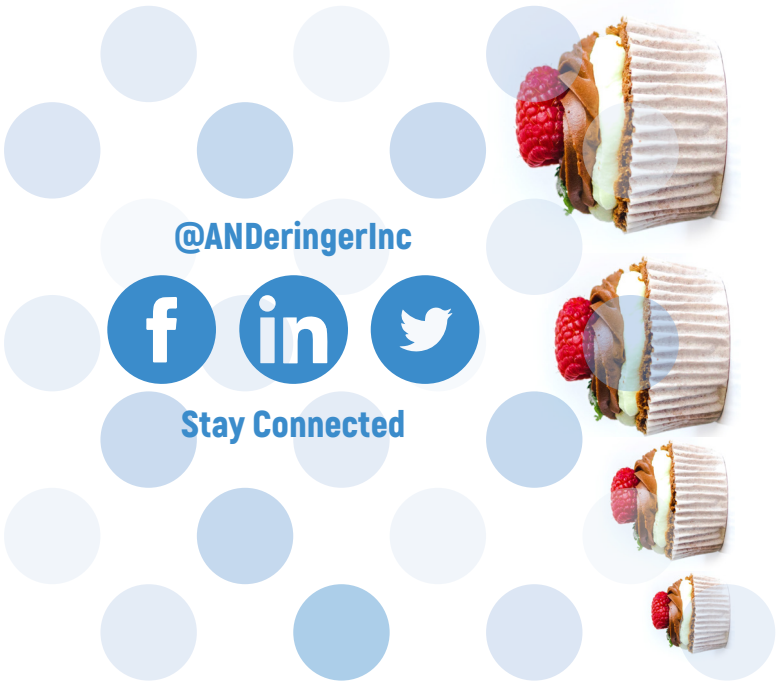
Companies can prepare for an FSVP audit in advance by monitoring and recording all supplier management activities. They can document their in-depth risk analyses for each supplier and show the corrective actions taken. They can also maintain ongoing communication with foreign suppliers and keep records of these conversations.

Digitizing records can also help. Electronic record systems simplify recordkeeping and keep documentation organized and readily accessible.

A Proactive Approach

Before FSVP, the FDA had to uncover evidence that imported food appeared to violate the law before it could reject or refuse its admission. FSVP changes that. Though FDA continues to look for violations, FSVP requires importers to take proactive approaches to food safety. These include verifying that foreign suppliers meet FSMA mandates.

Should the FDA find a company's FSVP efforts lacking, it can stop shipments from entering the country—even if the food is safe and the foreign supplier is complying. The law does not require the FDA to prove the importer is in violation to stop importation. It only needs to demonstrate that the importer appears to be violating FSVP rules. This is a low bar, and importers must stand ready to clear it.



Do Your Due Diligence

As mentioned earlier, the FDA's focus on FSVP has long been to educate while it regulates. However, the agency is quickly moving toward enforcement. It's reasonable to expect many companies will soon face challenges similar to Brodt Zenatti's situation.

Businesses that take a proactive approach and put an FSVP Plan in place will be glad they did when the FDA eventually comes knocking.

FSVP is not just about staying out of trouble with the FDA. It's about ensuring the safety of the people who buy your products. From this perspective, creating an FSVP plan is really about investing in the future health of your company. What could be more important than that?



Build an FSVP Plan

- **Determine where your products come from.**
- **Hire a qualified individual who can verify that your foreign partners are in compliance.**
- **Keep detailed records on hand.**
- **Be ready to provide documentation of records quickly during an audit.**



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