TRACEGAINS

Foreign Supplier Verification Program

A Comprehensive Guide to FSMA's Crucial Rule

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What Is FSMA's Foreign Supplier Verification Program?

On Nov. 27, 2015, the FDA published its final rule for implementing the Foreign Supplier Verification Program (FSVP), a significant provision of the Food Safety Modernization Act (FSMA). FSVP requires that anyone importing food into the United States perform certain risk-based activities to ensure it meets U.S. safety standards. On Mar. 19, 2018, most imported food shipments became subject to FSVP requirements. To answer questions surrounding FSVP, we asked Marc Sanchez – a regulatory attorney specializing in FDA and USDA law.

Does FSMA's FSVP Apply to Me?

How the rule applies is one of the first questions asked about the FSVP. Many different parties can have their hands on a shipment as it enters the United States, so how is an importer defined within FSVP? Since the importer is ultimately the responsible party under the FSVP rule, we must begin by defining the importer. Is it the buyer, owner, consignee, or even broker?

The U.S. owner or consignee is the person in the United States who, at the time of entry, owned the food, purchased the food, or agreed in writing to buy the food, this might seem straightforward, but it can get convoluted.

For example, suppose there's no U.S. owner or consignee at entry. In that case, the importer is the U.S. agent or representative of the foreign owner or consignee, as confirmed in the signed statement of consent. Companies need to have an agent if they import into the United States.

What About Brokers?

Brokers may, on behalf of their clients, bring food into the United States. In this scenario, who is the importer? Often, brokers assume they're not responsible for the imported food since they don't see or touch it; conversely, their clients also assume they're not responsible because the broker is bringing the food into the country.

Every circumstance is different, but it helps to break down the situation with three questions to get the right answer.

1

Who controls the money?

When the food arrives in the United States, who gets paid, how are they being paid, and in what form are they getting paid? Suppose the broker is purchasing a product, and the money is deposited into the broker's account and paid to the foreign supplier. In that case, that might suggest the importer is the broker when the food enters the country. This scenario can be a bit confusing as well, leading us to the next question.

2

Who controls the agent?

What if a client tells a broker to secure a good from a supplier, and the broker arranges the sale? Is the broker acting as an agent on behalf of their client, or are they working as an employee? Sometimes, the agency's principles might suggest the broker is acting no differently than an employee of the client. In this case, you might argue that the customer is the importer and should bear the responsibility of ensuring the foreign supplier is compliant.

3

Who controls the goods?

When the goods arrive in the United States, whose trucks pick them up? Did the client arrange for transportation? After the goods arrive, does the broker/distributor store the product in a warehouse to be held and shipped later? In the latter example, the broker/distributor would be the FSVP Importer. But if the product is for a single customer and is going to one distribution center, owned by the client, maybe the customer is the importer.

When in doubt, look for the individual with a financial interest, or whoever controls or interacts with the foreign supplier. You're not looking at the intermediaries, but at the consignee, owner, or U.S. agent.

The takeaway here is to document extensively to ensure that if the FDA questions who the importer of record is, you can provide adequate proof.

Exemptions, Exclusions, and Modifications

As with any law or regulation, there are a few exclusions to the FSVP rule. Some exclusions exist because sufficient regulations are already in place for the product, these include:

- Juice: Subject to Hazard Analysis Critical Control Point (HACCP).
- Seafood: Subject to HACCP.
- Research use only: For research and evaluation purposes only.
- Foods used only for personal consumption.
- Transshipped foods.
- Foods imported for processing and export.
- Meat and poultry: Subject to USDA regulations at import.
- Alcoholic beverages: ATF retains jurisdiction.
- Low-acid canned foods: Micro-hazards only.

Modified Requirements

Certain modified requirements are narrow and require analysis. You'll need to make sure these apply continually, not just once. These modified requirements apply to:

- Dietary supplements (finished vs. ingredients/components): Finished dietary supplements are required to comply with most of the standard FSVP requirements (except the hazard analysis requirement), and verification activities must comply with the dietary supplement Current Good Manufacturing Practices (CGMPs), whereas ingredients/components are subject to Part 111.
- "Very small" suppliers or importers: These apply to very small importers and importers of food from certain small suppliers (e.g., certain importers don't have to conduct hazard analyses and can verify their foreign suppliers by obtaining written assurance from their supplier). The definition of "very small" supplier or importer is consistent with the definition of a very small business in the preventive control rules: $1 million for human food and $2.5 million for animal food of annual sales (averaged over three years) combined with the U.S. market value of food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).
- FDA-approved countries: Certain foods from foreign suppliers in countries with food safety systems recognized as comparable or determined to be equivalent to the U.S. system are subject to these modifications.

Exemptions

As with each FSMA rule, certain exemptions exist as well, including:

- Food that doesn't require a control (e.g., vinegar).
- Food that can't be consumed in the absence of a control (e.g., coffee beans).
- Food that's shipped with an adequate disclosure statement.
- Food in which controls will be applied within the United States by the importer or customer.
- Foreign suppliers under oversight of a comparable food safety system.
- Very small suppliers with less than $1 million in human food sales annually.
- Very small suppliers with less than $2 million in animal food sales annually.
- Food shipped from qualified facilities or suppliers not covered by FSMA.

Of course, additional details exist within each of these exclusion and exemption categories. Additionally, if there's any chance your company might be exempt, it's essential to verify this and to have adequate documentation to prove it.

For clarification on whether the FSVP requirements apply to your company, the FDA has published a color-coded chart with decision logic to help.

Note: If you're the importer and must adhere to the preventive controls for human food or animal food rules, you might be exempt from FSVP if you already have hazard controls.

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Verification Program Contents

The FDA finalized seven major rules to implement FSMA, recognizing that food safety is a shared responsibility throughout the global supply chain for both human and animal food. The FSMA rules provide specific actions to prevent contamination.

When considering the FSMA framework for any rule, there's a two-tiered system in place. FSMA uses these rules to set safety standards, and it relies on industry verification to ensure compliance.

With FSVP, manufacturers no longer rely on the FDA to be the primary body enforcing safety standards. FSVP shifts the burden of ensuring the safety of imported food directly onto importers and their foreign suppliers. This shift in accountability means importers, or the responsible party within the supply chain, must verify that both upstream and downstream suppliers meet safety standards. This change has increased the demand for compliant suppliers within the global supply chain.

How Can Foreign Suppliers Assist Importers?

- By conducting the hazard analysis.
- By putting together the FSVP.
- By handing the FSVP off to the importer.
- By performing each of these elements as if the foreign supplier were the importer itself.

There are some requirements you need to follow to pass regulatory scrutiny, but foreign suppliers can do a lot of work on behalf of importers.

Why?

The easier foreign suppliers make it to import food, the more likely importers will continue sourcing products from their facilities. On the contrary, the more difficult foreign suppliers make it, the less likely importers will source from those facilities in the future. Instead, importers will choose supply chain partners that help them satisfy FDA requirements.

Foreign suppliers compete not only on the quality and price of their products but also on regulatory compliance.

Who Prepares the FSVP?

Like the preventive controls rules regarding who prepares the food safety plan, whoever prepares the FSVP must be a "qualified individual'; this shouldn't be confused with the Preventive Controls Qualified Individual (PCQI).

Who Is a Qualified Individual?

The FDA defines a qualified individual as someone who has the education, training, or experience necessary to perform activities as per 21 CFR 1.503. Qualified individuals develop the FSVP and related activities such as hazard analysis, supplier approvals, verification procedures, corrective actions, and more. Qualified individuals must be able to read and understand the records, and this means they must be fluent in English, and they might also need to know the local language at the point of product manufacture or farming.

If the foreign supplier is conducting a hazard analysis on behalf of the importer, they should ensure a qualified individual will be performing the work.

The FSVP's Contents

At the core of how the verification process works is a program requiring the following:

Hazard Analysis

The hazard analysis is at the heart of the FSVP rule requiring the evaluation of any known or reasonably foreseeable hazards relating to the imported food, including biological, chemical – including radiological – physical, and food safety hazards.

Hazards include:

- **Biological hazards:** Such as listeria in frozen celery or carrots.
- **Chemical hazards:** Such as the introduction of melamine into baby formula.
- **Physical hazards:** Such as stones or twigs shipped with the products.
- **Food safety hazards:** Such as unintentionally introduced ingredients through an accident, or intentionally added ingredients for economic gain.

Importers can also assess their foreign supplier's hazard analysis to determine the hazards for the imported foods and whether a qualified individual conducted the proper review.

The analysis should focus on experience, illness data, scientific reports, and other information. A hazard is defined as anything that could contaminate a product and cause harm or otherwise violate established safety program criteria if left uncontrolled.

Because the foreign supplier is the expert regarding their facilities, it's helpful to involve them. They can provide the most reliable information regarding facility and equipment design, raw materials, product formulation, packaging and labeling, storage, and distribution.

Evaluation of Food Risk and Supplier Performance

After conducting the hazard analysis, the next step is to evaluate the food and foreign supplier. Why?

1. **To approve suppliers.** When approving suppliers, consider:
   a. The risk posed by the food (determined by the hazard analysis).
   b. The supplier's compliance history.
   c. Whether the supplier can control for the hazard.
   d. Whether the supplier has sufficient controls in place to control for the hazard.
   e. How the supplier intends to control for the hazard.
2. **To determine the required supplier verification activities.** The verification activities are those necessary to ensure the foreign supplier is controlling for hazards identified in the analysis.

Verification Activities

Based on the evaluation of risk, the importer must establish and follow written procedures to ensure they only import from approved foreign suppliers. The importer also must conduct appropriate supplier verification activities.

For example, let's say a foreign supplier has indicated it has a kill step in place for a particular hazard. The importer would need to understand what procedures, processes, and practices were in place to achieve that. What documents could the foreign supplier provide for verification?

Appropriate verification activities vary. According to the FDA, they can include onsite auditing, sampling, testing of food products, or reviewing supplier food safety records.

Note: Foods deemed Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA) require annual onsite audits.

Corrective Actions

What if something within the FSVP goes wrong? The appropriate corrective actions must be put in place and documented. Corrective actions will tell individuals what to do if there's a deviation in verification activities. These corrective actions can include discontinuing the use of the supplier until it makes corrections or disqualifying them.

Periodic Assessment

Importers must reevaluate the FSVP and their foreign suppliers every three years or when new food safety concerns arise. Importers are also required to promptly determine whether it's appropriate to continue importing food from that supplier and if the verification activities need revision. Importers have an obligation to reassess the programs and the approval of suppliers continuously.

Recordkeeping

All elements of the hazard analysis and FSVP must be documented, maintained, and made available to the FDA within 24 hours upon request.

Recordkeeping is one of the critical aspects of the FSVP rule. The FDA has a few items outlined in the rule, and it appears they prefer electronic recordkeeping:

The FDA wants records to be easily and quickly retrievable. They don't want to wait for a company's supplier to mail the records.

The FDA wants records in a form that won't deteriorate. If a company needs to go back and pull sampling data from within the year, they need to ensure data integrity.

Note: The FSVP rule allows importers to hire a third party to perform the hazard analysis and risk evaluations, set up their food safety plan, and even monitor them. Still, the importer is ultimately responsible for ensuring it conducts the proper evaluations and reviewing the documentation.

To Summarize...

- **Review and strategize:** The hazard analysis must be robust. It's also crucial to consider compliance history.
- **Establish frequency:** Track hazard control effectiveness on an ongoing basis. Performance records are as crucial as establishment records.
- **Verify, adapt, and verify again:** How is the supplier performing? How is the client performing? Have adverse events changed the analysis?

FSVP in Action

Hazard Type

One of the critical points of an FSVP is the hazard type.

Hazard Type

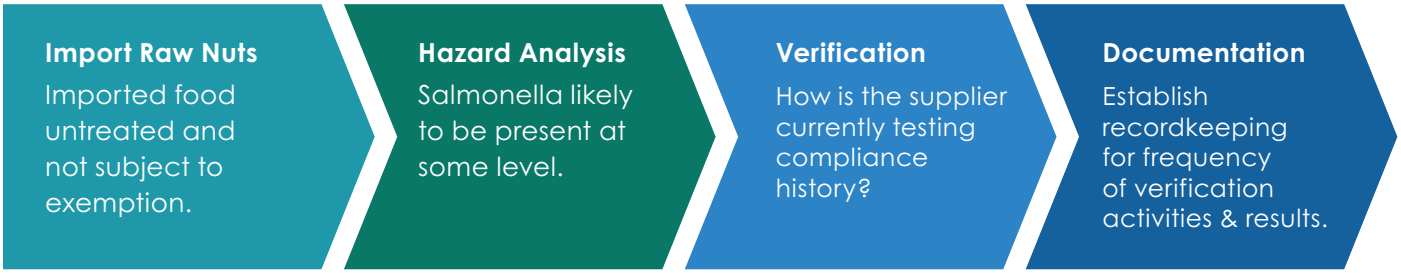
Identifying the hazard type will drive what the verification activities should be. Then, the company can decide who controls the hazard and determine the steps needed for verification:

- **SAHCODHA:** If the hazard is determined to be SAHCODHA and is reasonably likely to occur, then the highest level of verification activities are required, and an onsite audit is essential.
- **Not SAHCODHA:** If the hazard is not determined to be SAHCODHA, other verification methods are available, such as examining a supplier's compliance history to ensure they're capable of controlling the hazard. For example, if the supplier has a Form 483, companies may deduce they aren't good at pH testing. If the supplier's history is unsatisfactory, companies must consider this when deciding on the proper verification activities. In some cases, companies might want to escalate to an onsite audit.

FSVP in Action: Importer Controls Risk

Say you run a company that imports raw nuts. You import raw nuts for bulk sale, either in retail outlets or for additional processing such as mixing, where you might create variety packs. This arrangement defines you as an importer; therefore, you control the hazard. You can then conduct a hazard analysis to determine the potential health consequences of this import.

You could identify salmonella as a possible micro-contaminant and certain pesticides as chemical hazards. For this example, we'll use salmonella.



Salmonella is likely a severe health hazard, which might require an onsite audit as a verification step. You'll need to look at the supplier's compliance history. Do they have a kill step, or do you need to implement a new kill step? Will this meet your requirements?

The final step in this process is documentation. You'll need to establish recordkeeping practices and identify the frequency of verification activities and results.

This work is all done by the importer in coordination with the foreign supplier to verify the hazard (in this case, salmonella) is under control and documented.

FSVP in Action: Customer Controls Risk

As another example, take the same scenario but change the control. Now, the importer passes the raw nuts along to a customer who uses them in other products. The customer is now in control of the hazard, which means the customer now bears the risk of salmonella with raw nuts and will have to implement practices to control. It also means the verification activities have changed.

- **Same Supplier:** We can assume the same supplier of the raw nuts.
- **Same Importer:** We can assume the same importer of the ingredient.
- **Change in Control:** BUT if there is a change of control where a customer will use the ingredient for further processing, then...
- **New Verification:** The importer is now not responsible for the hazard analysis and verification, BUT must still maintain annual documentation of the customer's compliance.

Instead of doing an onsite audit or introducing a new kill step, the importer must ensure they're conducting annual documentation of the customer's compliance. It's like passing the baton and saying, "You're in the United States and subject to the preventive control rules. We expect you to comply with those rules and we're going to document your compliance."

Documentation is critical at this point; however, some situations remain unclear, such as disagreeing with how your customer controls the hazard.

Examples of Serious Hazards

Should you do an onsite audit?

- **Imported Semi-Soft Cheese:** Imported in the final form.
- **Hazard?** *L. Monocytogenes.*
- **Control:** Foreign supplier.
- **Verification:** Onsite audit if SAHCODHA, periodic *L. Monocytogenes* testing, written assurance.
- **Records:** Testing records is a vital part of verification and compliance.

An Example of a Foreign Supplier's Compliance History When the Supplier Has Had Issues Controlling the Hazard:

Low-Acid Canned Food (LACF) Import	**Compliance Review**	**Hazard?**	**Control Options**	**Recordkeeping**
Partial exemptions requiring verification.	Compliance review finds inadequate pH controls and deviations from scheduled processes.	C. botulinum toxin, likely SAHCODHA, exempt or now part of verification program?	Onsite audit if SAHCODHA, periodic pH testing, written assurance.	Document corrections to compliance issues identified as part of the verification program.

Foodborne illnesses are responsible for 420,000 deaths annually around the world, 125,000 of them in children under 5.

Food Safety as a Competitive Advantage

It was once common throughout the food, beverage, and supplements industries for safety to not be considered a competitive advantage. But after FSMA, food safety has become a differentiating factor.

When looking at the FSVP specifically, if an importer can source from four potential foreign suppliers, they'll choose the supplier that exhibits the most effective food safety program. If that foreign supplier markets its food safety program, it will carry more weight than quality and price alone.

In the United States, according to the FDA, "about 15% of the food supply is imported from more than 200 countries or territories, including 32% of the fresh vegetables, 55% of the fresh fruit, and at least 94% of the seafood Americans eat each year."

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TraceGains Can Help

TraceGains' cloud-based solutions ensure all FSMA compliance gaps are closed.

Supplier Management delivers turnkey risk reporting. If you're adhering to FSVP recordkeeping requirements and need to evaluate supplier performance and risk efficiently, TraceGains tracks and digitizes all information and document exchange with suppliers, and automatically sends alerts to collect missing, incomplete, or ready to expire documentation. Extract the data to configure custom supplier performance dashboards and reports and share them with any stakeholders instantly.

Audit Management automates and streamlines the audit process. Teams can schedule, conduct and track audits on a single platform with any connected device. Customize audit checklists or use pre-loaded checklists. Notifications, workflows, and task assignments track progress, and real-time reporting flags, key findings, and corrective actions. Configure the system to manage any regulatory or voluntary standards, including FSMA, FSVP, GFSI, HACCP, and CGMPs.

Supplier Compliance allows manufacturers to extend inventory visibility to the loading dock, stopping out-of-spec shipments. From the time manufacturers place an order to the time ingredients enter production, TraceGains evaluates product performance from every supplier, lot by lot.

Quality Management automates internal compliance FSMA requirements. TraceGains automatically manages all critical control points and prerequisite programs (PRP and OPRP), while providing a centralized location for food safety plans, workflows, and standard operating procedures, giving users real-time, actionable data.

About TraceGains

Founded in 2008, TraceGains connects people and information so teams can work smarter. As a global technology company, we provide networked solutions to consumer brands that want to reduce supply chain risk, speed up business processes, and take control of their data. On average, companies find that 80% of their suppliers are already on TraceGains Network, allowing them to connect and collaborate instantly.

About Marc Sanchez

Marc Sanchez is an FDA and USDA regulatory attorney in private practice representing FDA-regulated companies in the food, dietary supplement, beverage, cosmetic, medical device, and drug industries. He also teaches part-time at Northeastern University on regulatory topics including U.S. and international food law and regulation.

Want to learn more?

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