FDA Foreign Supplier Verification Program (FSVP) Inspections – Perspectives and Learnings from the Produce Industry

Background - Striving for a Safer Food System

Before the FDA established FSVP as a component of FSMA, companies only needed to have an importer of record. The FDA could inspect a firm's product at port of entry for pathogens, chemicals, or other documentation to ensure the safety of the product. This was the only way to verify to the safety of the global supply chain of a firm. This process was not as comprehensive as the FSVP that is in place now. On November 16, 2015, FDA published the FSMA final rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals and the first compliance dates began 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. Importers must also verify that the food is not adulterated or that the human food is not misbranded (concerning food allergen labeling). **Only the U.S. based importer or U.S. agency, or representative of the foreign owner are responsible for developing and maintaining a FSVP**. With over 50% of the U.S. fresh produce being imported, FSVP is a critical program to ensure that food entering is wholesome and safe for consumption by Americans.

This resource summarizes insight gained through interviews with IFPA Food Safety Council Members who have undergone one or more FSVP inspections. Additionally, publicly available data from the FDA website (as of July 2023) has been compiled to identify the most common findings in FSVP inspection.

Ultimately, this information is presented as a case study to identify best practices and provide recommendations on how IFPA member companies can effectively pass FSVP inspections.

What the FDA has Found So Far

These are the top citations found during FSVP-related inspections from 2016 – 2023. Inspectional data was collected from the FDA Compliance Dashboards. Note that FDA reports common inspection findings of *all* food companies but produce companies' perspectives will be explored.

1) **Develop FSVP**

"You did not develop an FSVP."

- Developing a FSVP is the first step in ensuring your firm complies with regulations.

2) **Supplier verification - establish written procedures**

"You did not establish adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to a food you import."

- Having a FSVP in place is important, but it must be maintained and followed as well. This citation essentially states a firm does not have a satisfactory procedure for verifying their suppliers.

3) **Verification activity assurance**

"You did not determine and document which verification activity or activities were needed to provide adequate assurances that a food you obtain from a foreign supplier is produced in compliance with processes and procedures that provide the required level of public health protection."

- A firm has not verified that their supplier is producing food in a way that is safe. For example, this could be not having a sufficient hazard analysis for each supplier a firm imports from that identifies and has a plan to control all reasonably foreseeable hazards.

4) **Record – translate to English**

"You did not provide an English translation of an FSVP record that you maintained in a language other than English."

- With companies working with foreign suppliers, it is reasonable that some records are not kept in English. However, the FDA requests that companies provide English translation of all required FSVP documentation for inspections. Companies should try to obtain these translations, if necessary, upon inspection notice.

Recommendations based on IFPA Member Experiences

1) Read the law carefully and understand the basic requirements you need to follow. (food safety audit, checklist, hazard analysis, certificates).
    a. Utilize FSVP guidance documents and FDA resources. Completing additional training programs (e.g. developed by FSPCA) may also be beneficial.

2) Verify all contact information is correct with your firm's customs broker.

3) Have your FSVP documentation organized before business is started with a supplier.
    a. Review your paperwork and keep documentation to know who is responsible for certain FSVP activities.

4) Depending on your firm, it may be beneficial to require your suppliers to undergo third-party GAP certification by a standard that is aligned with FSMA requirements. Alternatively, some standards offer FSMA add-ons.

5) Establish SOPs that comply with FSVP guidelines. SOPs should be accessible to workers and easy for them to understand.

6) Keep it simple. Provide required paperwork to FDA but don't overshare information (can lead to confusion and more digging).

7) Ask for clarification if FDA instructions are vague.

8) Be patient and be prepared to walk the inspector though your supply chain process.

Remember that the FDA is not trying to shut you down. Go into the inspection with a good attitude and be willing to work with the inspector.

IFPA Members' Experiences During FSVP Inspections

1) **Commodities:** Berries

   Supply Chain Area: Grower/Shipper/Distributor

   No. of FSVP Inspections: 1

   Latest Inspection Date: Summer 2022

   Communication with FDA throughout inspection: Good. When initially contacted by FDA, the wrong contact person was listed for the firm. This was ultimately corrected with their customs broker. Once mitigated, the member received an initial alert about inspection via email and inspector followed up with firm in timely manner – 2 weeks after documents submitted for review.

   General Experience: The inspection was done remotely. This member sent the FDA the minimum required documentation for their audit including food safety audit information, FSVP checklist, hazard analyses, and appropriate certificates. Within two weeks, the firm was notified by the FDA that they passed inspection and no corrective action was needed. This member felt prepared for their FSVP inspection and underwent FSVP training through FSPCA, hosted by IFPA (formerly United Fresh Produce Association).

   Approach to Supplier Verification: The member individually reviews the hazard analysis from farms to verify it complies with FSVP.

2) **Commodities:** Avocados and Mangoes

   Supply Chain Area: Grower/Distributor

   Communication with FDA throughout inspection: This member felt they had good communication with the FDA during their inspection process and has started building a connection with their inspector.

   No. of FSVP Inspections: 3

Latest Inspection Date: June 2022

General Experience: This member has had a generally good experience for there FSVP inspections. With two of the inspections, the member experienced consistency from having the same inspector. After the second inspection, this firm had a better understanding of what to expect. In the third inspection, the member had a different inspector and had a different experience. This member expressed some concerns about the subjectivity of inspections and consistency between inspectors, the industry's understanding of FSVP, and the inspectors' knowledge of the produce industry. This member stated that they have had to teach inspectors more about their specific process due to them not being well versed in all types of produce commodities.

In the third inspection, the inspector requested documentation from the farm level that the firm was unable to provide. FSVP requires companies to provide verification all the way down to the farm level (i.e., the foreign supplier), but many farms for this firm do not handle the hazard analyses and food safety plans. Instead, this is managed by packhouses. To mitigate this issue, the member recommended its farms to get a FSMA add-on when they have their current GAP audit. In regard to the designation of importer for FSVP, this firm has become more aware of being put down for a supplier as having dealt with being incorrectly listed before. This member completed FSVP training through FSPCA.

Approach to Supplier Verification: This firm does an initial audit of packhouses to check if their hazard analysis meets FSVP standards. If it does, the firm will accept and use that for documentation. If not, the firm will work with the packhouse to improve their plan. Chemical hazards are the main dictator for this company on where their product will go and then they follow up with a biological hazard check. Chemical hazards concerns for this company are primarily pesticide residues.

3) **Commodities: Berries, Peas, French Beans, Brussel Sprouts**

Supply Chain Area: Grower/Shipper/Packer

No. of FSVP inspections: 2

Latest Inspection Date: February 2023

Communication with FDA throughout inspection: The member had good communication with the inspector, however, the firm did need to have their contact information updated by their customs broker.

General Experience: In the first inspection, the inspector asked many questions and had a structured way of conducting the audit. The second inspection was done by a different inspector and was more informal. This firm now has a plan in place and utilizes excel to organize its supplier information to make it easier to send. The member noted the inspector for their second inspection was also conducting another inspection that was troublesome, which caused the inspector to be delayed in communication and not ask as

many questions. This member also expressed concern with potential inconsistency between different inspectors.

This firm had one issue with being designated as the importer for a supplier that they did not do business with. This member has done standardized FSVP training through FSPCA, which they feel has allowed them to better understand the regulation. However, they also noted they believe the way the regulation is written can lead to confusion as produce companies try to adhere.

Approach to Supplier Verification: This firm creates a hazard analysis for each product country to identify general hazards associated with that country/commodity. The firm also reviews each supplier's hazard analysis for specific hazards each supplier needs to control. For this firm, pesticide residue issues are a common concern.

4) **Commodities: Citrus fruit, Apples**

Supply Chain Area: Wholesaler/Distributor

No. of FSVP inspections: 1

Latest Inspection Date: March 2023

General Experience: This firm experienced some challenges during the inspection. The associates who are responsible for FSVP documentation were undergoing FSVP training during the time of inspection. The FDA inspector pulled 3 of their suppliers at random and requested documentation which the firm was unable to provide at the time. The firm received a two-week extension but was still unable to provide documentation. This firm received an additional extension with the issuance of an FDA 483 Form. Additionally, the FDA inspector sent a letter to the firm's CEO about inspection which detailed the events of inspection, including documents the firm provided and all corrective actions needed to be taken. The firm is still in the process of correcting their FSVP and has been working with their suppliers consistently on these issues. They have encountered problems with translation of documents from their supplier as well as receiving documentation. The inspection was done entirely remote. The firm hasn't had any problems with being designated as importer for a supplier they don't do business with. This member has completed FSVP training developed by FSCPA.

5) **Commodities: Berries and Tomatoes**

Supply Chain Area: Grower/Shipper

No. of FSVP inspections: 1

Inspection date: Spring 2023

Communication with FDA throughout inspection: Generally good throughout the process. This member stated that once they were contacted about an upcoming

inspection, they asked what information could be sent ahead of time. They believe this was helpful in making their audit run smoother.

General Experience: This member had a good experience with their inspection, originally expecting it to be more difficult. They explained how their firm already had a program in place to supervise the implementation of food safety programs for their suppliers. The firm had to adjust their program slightly to align with FSVP regulations, but it wasn't too difficult given the firm already had most of the necessary documentation. This member emphasized a crucial component of their success was creating procedures that team members could understand. This member completed standardized FSVP training through FSPCA, hosted by IFPA (formerly United Fresh Produce Association).

Approach to Supplier Verification: This firm requires their growers to have a food safety person/team to handle the completion appropriate documentation (e.g., hazard analysis). The most troublesome hazard area for their commodities is the treatment/filtration of the water used for growing.

How Does This Stack up?

Compared to the FDA's "What to Expect During a Foreign Supplier Verification Programs Inspection" document, members' experiences have been fairly consistent. Generally, members have had a good experience with inspections considering their interactions and communication with the FDA. This open communication is a crucial component of success during inspections as many times it may be necessary for a firm to further explain their process to an inspector beyond submitting required paperwork. Many members also expressed concern for consistency between inspection due the subjective nature of inspectors. Knowing the requirements of FSVP regulations, having all documentation organized, understanding your firm's process, and having a helpful attitude toward inspectors can help mitigate these issues. As an additional question, members were asked if their firm has considered participating in the Voluntary Qualified Importer Program. VQIP is a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers. The consensus among interviewed members is that the program is not viable for their firm, or their firm already participates in a program that is perceived to grant them similar benefits (e.g., CTPAT).

The Takeaway

With the program being relatively new, it can be understandable that some companies are still in the process of improving their FSVP. There has been a learning curve for companies and inspectors alike on discerning how to best handle FSVP. Ultimately, the goal of FSVP is to make

certain that food imported into the U.S. is safe for consumers. There has to be open collaboration between industry and government to meet this goal.

Additional Resources:

IFPA FSVP Q&A – Answers commonly asked questions about FSVP.

FDA FSVP Main Page – Landing page for all FSVP-related resources.

FDA Key Requirements Document – Offers an at-a-glance overview of all FSVP requirements.

FSMA Technical Assistance Network (TAN) – Additional questions about how the rule may apply to you can also be submitted through TAN. Companies are encouraged to be very specific about their circumstances when they submit questions to help the FDA experts give them the best advice on how the rule applies to them.

This resource was developed by Justin Daniel, 2023 IFPA Food Safety Intern.

For additional questions on imports, FSVP, and related topics, please contact Dr. Emily Moyer, VP Regulatory Compliance and Global Food Safety Standards