

FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP): AN OVERVIEW



Introduction

Ensuring food safety is becoming increasingly important with the vast globalization of our food supply. The United States (U.S.) imports food from nearly 200 countries where the safety standards may differ significantly from the U.S. standards (NRC 2010). To assure that imported food products are safe for U.S. consumers, the Foreign Supplier Verification Programs (FSVP) developed a rule titled Importers of Food for Human and Animal. The U.S. Food and Drug Administration (FDA) introduced the new regulation on November 27th, 2015, and the first compliance dates began on May 30th, 2017. Importers must develop and follow the FSVP which provides evidence that the imported food was manufactured following equivalent U.S. food safety standards (FDA 2019).

It is necessary to recognize that importers of food, who are located physically in the U.S. and are financially responsible for bringing the food into the U.S., are required to fulfill the FSVP requirements. Under the FSVP rule, the importer has to ensure that the food manufacturer outside the U.S. (foreign supplier) is manufacturing the food in a safe manner and is following the applicable U.S. FDA regulations, such as the Produce Safety or Preventive Controls for Human Foods rule. Thus, food importers are liable and must guarantee that imported food is safe for consumption by the U.S. population.

Steps in Developing the Foreign Supplier Verification Program

The main goal of developing the FSVP was to ensure that “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” (FDA 2019). Importers covered by the rule must create, maintain, and follow the FSVP. The steps involved in the development of an FSVP plan are presented in Figure 1.

FSVP Key Terms

Following are some key terms found in the FSVP rule:

- **Importer**—“...a person who, at the time of entry to the U.S., owns the food, has purchased it or has agreed in writing to purchase it. If there’s no U.S. owner or consignee at the time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee” (FDA 2018).
- **Foreign Supplier**—“...the establishment that manufactures/processes the food, raises the animal or grows the food that is exported to the U.S. without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature” (FDA 2018).
- **Qualified Individual (QI)**—“...a person who has the education, training, or experience necessary to perform an activity as required by the FSVP and can read and understand the language of any records. A QI may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual” (FDA 2018).
- **Unique Facility Identifier (UFI)**—FSVP rule requiring that each FSVP importer have the unique facility identifier that is acceptable to FDA to be placed in the customs entry filing. The *Data Universal Numbering System (DUNS)* number has been recognized by the FDA as an acceptable UFI for FSVP.

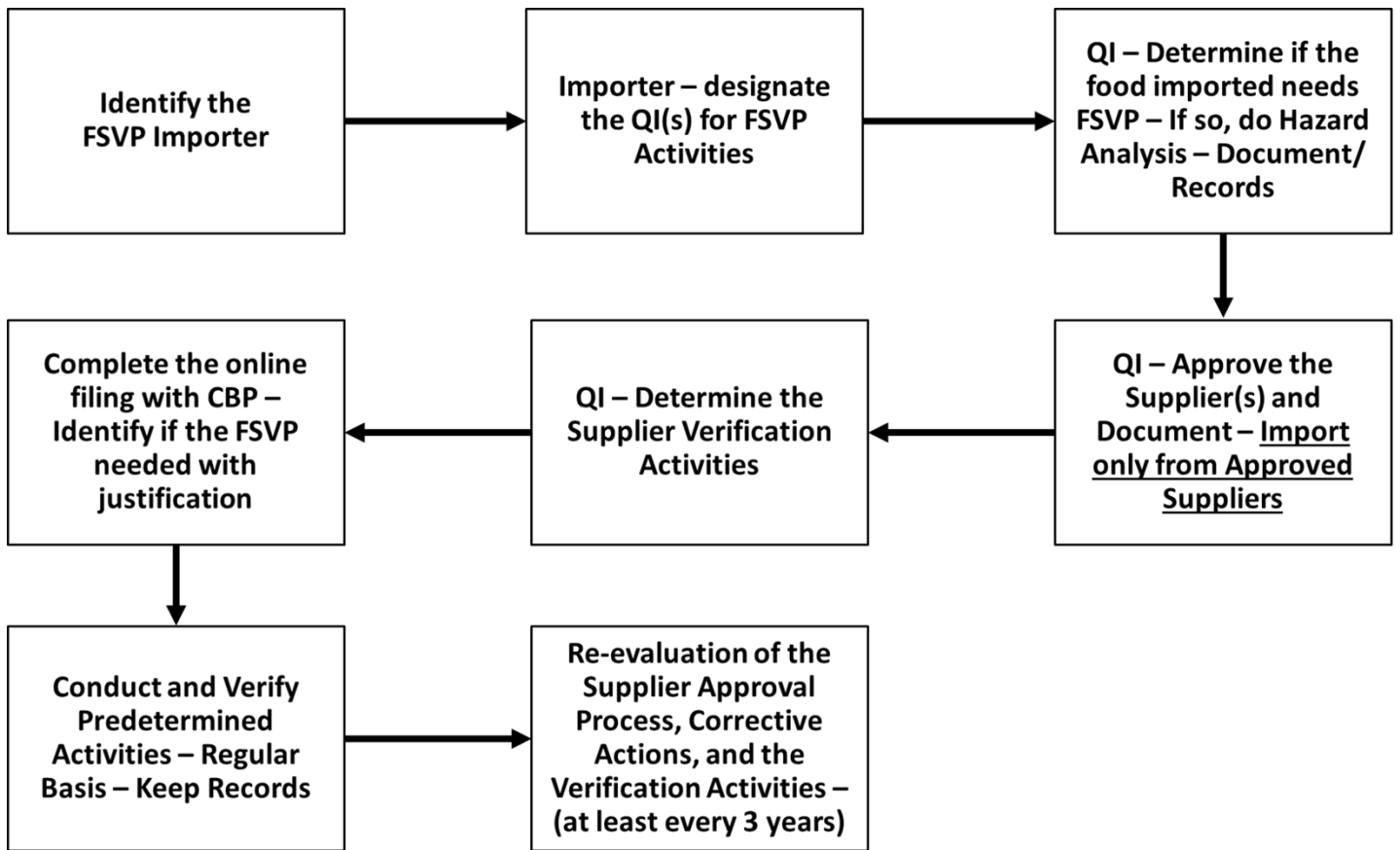


Figure 1. Process flow for developing a Foreign Supplier Verification Program plan.

First, an importer must *designate the qualified individual* (QI) who will be responsible for the majority of the activities related to the FSVP. There can be more than one QI. The QI should then *determine if the food imported needs FSVP*. If the FSVP is required, QI must *perform a hazard analysis* for every food imported and *assess the foreign supplier's performance*. This will allow the QI to *decide if the supplier can be approved and determine appropriate supplier verification activities*.

The QI is also responsible for:

- *Conducting supplier verification activities*, such as an annual on-site audit of the supplier's plant, evaluation of the supplier's food safety records, sampling, and testing
- *Conducting corrective actions* in case of noncompliance, adulteration, or misbranding
- *Maintaining all applicable records*

Who Is Subjected to the FSVP Rule?

With certain exemptions, most food importers are subject to the FSVP. The following foods are not subjected to the FSVP (CFR Title 21 Part 1.501, 2020):

- Certain seafood products

- Certain juice products and ingredients for use in juice products
- Food that was imported for research or examination
- Food imported for personal use and not meant to be introduced to U.S. market
- Certain alcoholic beverages
- Selected poultry, meat, and egg products that are subjected to the requirements of the USDA
- Food that temporarily entered the U.S. with the intention to send to another country
- Food imported to be processed within the U.S. and then exported
- U.S. food that is exported and returned and was not processed in a foreign country

Summary

The FSVP was developed to assure that foreign food suppliers are meeting the same food safety standards that the domestic food processors are required to comply with. The rule is described in Part 1, Subpart L, of Title 21 of the Code of Federal Regulations (CFR). Under the FSVP rule, the responsibility of ensuring the safety of imported food falls directly on importers and their foreign suppliers. The FSVP is a risk-based food safety system in which the importer has to determine all possible food safety hazards related to imported food products and determine if these hazards are properly addressed so the foreign supplier can be approved. Once the foreign supplier has been approved,

the importer is obligated to verify, on a regular basis, if the supplier has complied with established requirements and there is no risk of introducing harmful food products into the U.S. market.

Acknowledgements

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References

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By
Ewa Pietrysiak, Postdoctoral Researcher, School of Food Science,
Washington State University
Girish M. Ganjyal, Associate Professor & Extension Food Processing Specialist,
School of Food Science, Washington State University



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