5 Common FSVP Myths

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The U.S. Food and Drug Administration (FDA) requires most U.S. importers to develop Foreign Supplier Verification Programs (FSVPs) for each food product that they import from foreign suppliers. Common myths can lead to misunderstandings regarding when or how facilities need to develop FSVPs. Failing to develop FSVPs can

lead to FDA enforcement such as product detentions, import refusals, warning letters, and placement on import alert. These events can harm your brand and become very costly. To help industry avoid these consequences, we are bringing you the truth behind common misconceptions about FSVP requirements.

Get help with FSVP Requirements

Registrar Corp's Qualified Individuals can develop and implement your FSVPs

GET STARTED

Myth 1: Anyone can write and implement an FSVP

FDA requires that FSVPs be developed by a "Qualified Individual" which the Agency defines as "a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart; this person may be, but is not required to be, an employee of the importer."

The Qualified Individual is responsible for writing and implementing the FSVP, reviewing the imported products' compliance history, identifying hazards associated with the food, determining and conducting the appropriate verification activities, importer identification at entry, and more. Registrar Corp can serve as a Qualified Individual to develop, review, and implement your FSVPs for compliance.

Myth 2: I can choose not to act as the FSVP Importer

FDA regulation states that the U.S. owner or consignee of a shipment is the FSVP Importer. FDA defines the U.S. owner or consignee as "the person in the United States who, at the time of entry of an article of food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food".

Some importers may believe that they can hire an agent to assume the liability of being the FSVP Importer for them. Importers may hire a third-party to act as their qualified individual for developing and implementing an FSVP on their behalf, but the importer is entirely responsible for ensuring they have one for each product from each supplier and must be the one listed as the FSVP Importer on the customs entry.

For shipments that have no owner at the time of US entry, the exporter must designate a U.S. agent or representative to act as the FSVP Importer and fulfill FSVP responsibilities. The exporter must obtain a signed statement of consent from the designated party.

Myth 3: FDA is not enforcing FSVP requirements

FDA is actively enforcing FSVP requirements through inspections and issuing Form 483s, warning letters, and placing importers on import alert as necessary when non-compliance is observed.

The citations included facilities that failed to develop, translate, and sign FSVPs as well as those that failed to properly verify their suppliers. Even during the COVID 19 pandemic, FDA has continued to conduct remote FSVP inspections.

In 2020, FDA has issued 43 Warning Letters for FSVP violations (up from 5 in 2019) for FSVP violations. Warning Letters are public documentation indicating how a company has failed to meet compliance and what they can do to fix it. Warning Letters can be damaging to a brand. Additionally, FDA may also detain products that fail to meet FSVP requirements, potentially resulting in costly delays.

FDA also established Import Alert # 99-41 for the detention of food products brought in by importers who are not in compliance with FSVP regulations. Currently, there are 10 companies on the Import Alert. If an importer is listed on the Alert, shipments of their products listed in the Alert will be detained each time they arrive in the US, consistently delaying the release of the importer's shipments until compliance and the safety of the food is demonstrated.

Myth 4: Once I develop an FSVP, I am compliant

Importers are required to update their FSVP when there are changes in their suppliers' operation that affect the safety of the products they import or the verification activities procedures. For example, if a foreign supplier were to change the ingredients or steps in the processing of a product, the importer would be required to update the FSVP considering new potential hazards associated to that new ingredient or process. Additionally, the verification activities may need to be updated if that ingredient or process poses a new hazard. Another example may be if your foreign supplier moves the production of your product to another location. Even if the process and controls don't change, the old facility address location would not need to be monitored for FDA compliance anymore, but the new address would.

Importers are also required to continuously verify their suppliers' compliance, as changes in compliance can be cues that you should re-evaluate and/or revoke approval of your suppliers. Specifically, FDA requires that importers monitor "whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety." Registrar Corp's FDA Compliance Monitor makes it easy to track all your suppliers in one place and gives you a reliable source to maintain a record of their compliance history. In addition to other compliance data, the Monitor informs you whether your suppliers are subject to any FDA warning letters, import alerts, refusals, or recalls, and notifies you of any status changes.

Additionally, importers are required to re-evaluate their FSVPs every three years. Importers must re-evaluate the foreign supplier's performance and risks posed by the food, as well as their food safety procedures, processes, and practices. The Qualified Individual must conduct these activities.

Myth 5: I only need one FSVP per supplier

FSVPs are intended to verify that each product imported meets FDA

food safety standards. Facilities are required to develop an FSVP for each supplier they import from, as well as each individual product category. For example, if an importer imports both beans and cheese from Supplier A and Supplier B, the importer will need four FSVPS: Supplier A Cheese, Supplier A Beans, Supplier B Cheese, and Supplier B Beans.

Variants of products may require additional FSVPs if they have different hazards and controls that result in different verification procedures. Also, it may occur that a supplier may comply with FDA for one of their products, but not another. So, it is important to evaluate each product and applicable regulations separately.

Not a Myth: Registrar Corp Can Help

Throughout 2020, FDA has continued to enforce FSVP requirements and issuing enforcement actions. Registrar Corp can provide the tools to reduce the risk of food safety problems and to help you maintain compliance. Our Qualified Individuals have the resources and expertise necessary to help you develop and maintain your FSVPs. Additionally, we provide a 100% online course to help you familiarize yourself with FSVP requirements.

CLICK HERE TO GET STARTED.

For assistance, call us today at +1-757-224-0177, email us at info@registrarcorp.com, or chat with a Regulatory Advisor 24/7 at www.registrarcorp.com/livechat.

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