FDA IMPORTS Benjamin England & Associates

When do you have to revisit your Foreign Supplier Verification Program?

Once you have completed your Foreign Supplier Verification Programs (FSVP) for each of your food items from your foreign suppliers, you can file away your documents until a time when the Food and Drug Administration (FDA) requests to inspect your written program(s), right?... not so fast!

There are three regulatory requirements for revisiting your programs: 1) the review and documentation of your verification activities, 2) reevaluation at a minimum of every three years, 3) and any event that triggers a corrective action.

The following will walk you through FDA's requirements.

Based on the outcome of your hazard analysis as required by 21 CFR § 1.504 and the evaluation of the identified hazards, you will be required to select appropriate verification activities as identified in 21 CFR § 1.506 and a frequency for which the activities are obtained. These activities include:

- Onsite audits as specified in paragraph (e)(1)(i) of this section;
- Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;
- Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and
- Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

It is your responsibility upon receipt to **assess the activities** and **document in writing** the outcome. The written documentation will be a record maintained within your program as specified per 21 CFR § 1.510 (c)(1) and (2).

Reevaluation of a foreign supplier's performance and the risk posed by a food.

Source: 21 CFR § 1.505 (c)(1) and (2)

As Indicated in 1.505(c)(1), you must promptly reevaluate your Foreign Supplier Verification Program when you become aware of new information about factors that may change the foreign supplier's performance or the risk posed by the hazards of the food.

At a minimum, you must reevaluate your programs at least every three years.

Factors that may trigger a reevaluation include:

1) Changes in the hazard analysis of the food, including the nature of the hazard requiring a control. This may include:

- The formulation of the food;
- The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;
- Raw materials and other ingredients;
- Transportation practices;
- Harvesting, raising, manufacturing, processing, and packing procedures;
- Packaging and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

2) Any changes within the supply chain that significantly minimize or prevent the hazards requiring a control or verifying that such hazards have been substantially minimized or prevented. This may be the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

3) Foreign supplier performance, including:

- The foreign supplier's procedures, processes, and practices related to the safety of the food;
- Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance, including FDA warning letter, import alert, or other FDA compliance action related to food safety.
- Noncompliance with the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States; and
- The foreign supplier's food safety history, including; violative food

testing results, non-conformities based on audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

4) Any other factors as appropriate and necessary, such as storage and transportation practices, which would affect the safety of the imported food.

What corrective actions must I take under my FSVP?

Source: 21 CFR § 1.508

You must take prompt appropriate corrective actions if you determine that a foreign supplier of the food you import:

- Does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under Hazard Analysis and Risk-Based Preventive Controls or Produce Safety, or
- Produces food that is adulterated or misbranding due to failure to provide labeling for the presence of major food allergens (this does not apply to animal food).

Your determination that you need to take corrective actions could be based on:

- The foreign supplier verification activities;
- A reevaluation of the foreign supplier's performance and the risks posed by the food that you conduct;
- Reviewing consumer, customer, or other complaints related to food safety;
- Monitoring FDA compliance action information (e.g., import alerts, warning letters); or
- Any other relevant information you obtain, such as Recalls or product withdrawals.

Examples of appropriate corrective actions will depend on the circumstances but could include:

- Notifying the foreign supplier of the problem and requesting documentation of corrective actions taken by the foreign supplier.
- Assisting the foreign supplier's efforts to correct and prevent recurrence of the problem.
- Revising your FSVP.
- Discontinuing the foreign supplier's use until the cause or causes of noncompliance, adulteration, or misbranding are adequately addressed.

Regardless of the outcome, you must document any reevaluations, investigations, corrective actions, and changes to your FSV

During the roll-out of FSVP FDA initiated guidance to the Field Investigators to "educate the importers" as they conduct the inspections. After a couple of years, the FDA continued to see large numbers of noncompliance. Most Importers were written up for not having any program in place. Due to these excessively high numbers of noncompliance FDA has elevated their enforcement activities. This includes conducting second inspections of non-compliant importers, issuance of warning letters, and placing importers on Import Alerts. What does this mean for you? Under FDA's authority, your non-compliant food can be refused from entering the United States.

Below are important questions to consider if you are an importer of food

- **Question:** How Can I avoid disruptions to my importations?
  - **Answer:** Develop a Foreign Supplier Verification Program through the assistance of an outside Qualified Individual.

- **Question:** What do I do when I have received notification of an inspection?
  - **Answer**: We can conduct a mock inspection and assess your program to ensure compliance. This can also include representation as your Qualified Individual during your inspection.

- **Question**: What do I do when I have received a Form FDA 483a, FSVP Observations, or FDA Warning Letter?
  - **Answer:** Please do not delay. It is not too late to respond and move forward with compliance.

For additional information regarding FSVP, click here:

- Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- FDA Fact Sheet: What to expect during a Foreign Supplier Verification Inspection https://www.fda.gov/media/141269/download