

# **U.S. Import Policy Regarding Food Processors**

## **FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals**

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) to protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. The FDA published the final rule in 2015 for implementing the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP regulation), which is a significant provision of the Food Safety Modernization Act.

The FSVP regulation creates new requirements for importers of food for humans and animals. The FSVP regulation requires importers to 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. Consequently, food processors in foreign countries that supply food products to importers in the U.S. will be required to comply with the U.S. importer's Foreign Supplier Verification Program as required by the FDA.

Imported food products are also subject to FDA inspection when offered for import at U.S. ports of entry. The FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements. Both imported and domestically-produced foods must meet the same legal requirements in the United States.

### **FOREIGN SUPPLIER VERIFICATION PROGRAMS**

The FSVP final rule makes importers accountable for verifying that foreign suppliers are producing food in a manner that meets U.S. safety standards. The rule requires importers of food to the U.S. to use the most appropriate verification activities to significantly minimize or prevent risks and prevent adulterated foods from reaching the U.S., as well as foods that are misbranded with respect to allergen labeling.

The FSVP rule requires importers to implement a specific program to perform risk-based foreign supplier verification activities to verify that:

1. Food is produced in a manner that provides the same level of public health protection as required under FSMA regulations concerning hazard analysis and risk-based preventive controls.
2. Food is not adulterated as required by the FD&C Act; and
3. Human food is not misbranded concerning food allergen labeling as required by the FD&C Act.

The verification activities include:

- Annual onsite audits of a supplier's facility performed by a qualified auditor;
- Sampling and testing of food; and
- Review of the supplier's relevant food safety plan and records.

## **FSVP REQUIREMENTS**

Importers are required to develop, maintain, and follow an FSVP for each food imported into the United States and each foreign supplier of that food. Consequently, importers of food must do the following before importing a food product into the U.S.:

- Establish and follow written procedures to ensure they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food (determined through a hazard analysis of the biological, chemical and physical hazards) and the foreign supplier's food safety practices, procedures and performance history, including their compliance with FDA food safety regulations, results from testing, audit results and record of correcting problems.
- Determine known or reasonably foreseeable hazards with each food, based on experience, illness data, scientific reports and other information;
- Determine and conduct supplier verification activities tailored to unique food risks and supplier characteristics to ensure suppliers are producing food consistent with U.S. requirements;
- Conduct corrective actions promptly if they determine that a foreign supplier has used inappropriate processes and procedures or produces food that is adulterated or misbranded with respect to allergen labeling; and
- Reevaluate the risk posed by the imported food and the foreign supplier's performance every three years or sooner if the importer becomes aware of new information about the hazards in the food or the foreign supplier's performance.

## **HAZARD ANALYSIS**

An importer is required to identify and evaluate—based on experience, illness data, scientific reports and other information—the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. These include:

- Biological hazards, including parasites and disease-causing bacteria;
- Chemical hazards, including natural toxins, food decomposition, unapproved food or color additives, food allergens, pesticide and drug residues; and
- Physical hazards, such as metal and glass.

They may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient.

The analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur.

The evaluation must consider the following factors regarding the foreign supplier's operations:

- Formulation of the food
- Condition, function and design of the facility and the equipment that produces the food
- Raw materials and other ingredients
- Harvesting, manufacturing and processing procedures
- Sanitation and employee hygiene
- Packaging and labeling activities
- Storage and distribution
- Transportation practices
- Intended or reasonably foreseeable use

## **EVALUATION OF FOOD RISK AND FOREIGN SUPPLIER PERFORMANCE**

An importer must specifically evaluate:

- The foreign supplier's hazard analysis and food safety plan for minimizing or preventing the hazards,
- The foreign supplier's prerequisite programs such as Current Good Manufacturing Practices and Standard Operating Procedures for ensuring food safety,
- The foreign supplier's processes and practices related to the safety of food,
- The foreign supplier's compliance with applicable FDA food safety regulations
- The foreign supplier's food safety history, including their responsiveness in correcting past problems

## **SUPPLIER VERIFICATION**

Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure that it only imports food from approved foreign suppliers and must conduct appropriate supplier verification activities. The verification activities include:

- Annual on-site audits of the supplier's facility performed by a qualified auditor. This is required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard).
- Sampling and testing of food
- A review of the supplier's relevant food safety plan and records

## **CORRECTIVE ACTIONS**

Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the produce safety and preventive controls regulations, as applicable, or that the supplier produces food that is adulterated or misbranded with respect to allergen labeling.

The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration, or misbranding has been adequately addressed.