

U.S. Food Safety Legislation for Foreign Suppliers



The Food Safety Modernization Act (FSMA) and Foreign Supplier Verification Program (FSVP)

Companies based in the United States (U.S.) are required under FSMA to ensure the food or materials they use are safe and compliant with the [Preventive Controls for Human Food rule \(PCHF\)](#). This means that if they use materials raised, grown, or manufactured outside the United States, there must be an entity responsible for ensuring that a foreign supplier meets the requirements of the PCHF rules.

There are two types of entities that must be compliant with the Foreign Supplier Verification Program (FSVP) rule:

1. Any U.S.-based importer who meets the definition of "importer" in the FSVP rule. This includes any entity who own or are the consignee of food at the time of entry into the U.S. or, if there is no owner or consignee, then the U.S. agent or representative of the foreign owner.
2. Any broker, exporter or foreign supplier of food that will be exported to the U.S. or any person or business owner who currently buys food from foreign sources, and representatives of foreign governments with interest in exporting food to the U.S.

Who is a Foreign Supplier?

You are a foreign supplier if you manufacture or process food that is exported to the United States without another establishment conducting additional manufacturing or processing before it is exported. The establishment that raises animals or grows food that is not further processed before export is also a foreign supplier.

I am a foreign supplier exporting food to the U.S., what is my responsibility under the FSVP Rule?

Foreign suppliers must ensure the safety of food imported into the U.S. and be able to demonstrate that the food is in compliance with the FSMA Preventive Controls or Produce Safety requirements. This means that a HACCP based food safety plan that includes Preventive Controls has been established, verified, and maintained. The foreign supplier must also be able to demonstrate that the food is not adulterated (under the FD&C Act) or misbranded (as to allergen labeling, human food only). The major components of this can be met with IFS Certification.

How do companies in the U.S. verify foreign supplier compliance with the PCHF rule?

The generally accepted standard is that the foreign supplier will have a current certificate in good standing from an accredited audit scheme such as IFS. This standard will provide most of the requirements under the PCHF rule. However, FSMA does not require certification, but does require compliance to the PCHF rule. This may be accomplished through the PCHF training course recognized by the FDA, compliance with the Supply Chain Rule and the addition of Preventive Controls other than CCPs to the HACCP Food Safety Plan.



Which documents and records will you need to provide?

As a foreign manufacturer of food or packaging to be exported to the United States (U.S.) you will be required to comply with the rules governing safe food manufacture for the U.S. This will include the following:

1. **FDA registration**
2. **Food Safety Plan (HACCP) with Preventive Controls**
This includes CCPs, Allergen Controls, Sanitation Controls and adherence to the **21CFR117 Supply Chain rule**.
 - a. **Risk Analysis:** Records to demonstrate that food safety hazards are evaluated by risk and reviewed based on risk at least annually.
 - b. **Allergens:** Records relating to the control of allergens considered by the U.S. to be of primary importance. There are 9 allergens: Eggs, Milk, Wheat, Soy, Sesame, Nuts, Tree Nuts, Shellfish, Crustacean Shellfish.
3. **Preventive Controls Qualified Individual (PCQI)**
This is a person trained in the development and management of a food safety system compliant with the Preventive Controls for Human Food Rule (21CFR117) under the Food Safety Modernization Act (FSMA). Providing a copy of the training record with a traceable ID number is preferable. IFS can arrange training with an FSPCA Lead Instructor. This certificate satisfies the requirements that the HACCP/Food Safety Plan be managed by a Preventive Controls Qualified Individual. Please, contact the **IFS Representative in North America** for more information.
4. **IFS Certification OR other 3rd Party Audits by Qualified Auditors**
The IFS Certificate and Audit Report is a generally recognised certification to demonstrate compliance with the Foreign Supplier Verification Program (FSVP), however it is not required. The auditor conducting the IFS or other 3rd party audit must be a certified auditor. Without the IFS Certificate, the manufacturer will be required to provide additional documents to comply with food safety regulations.
5. **Food Sampling and Testing Records**
These records must include the number of samples tested, type of tests, laboratory conducting tests and reviews conducted by PCQI.
6. **Sampling of Food Safety Monitoring Records**
These records may include CCP and other Preventive Control validation, monitoring and verification records, allergen control records, traceability records and records of traceability and mock recall events.
7. **Label compliance with U.S. Labeling Requirements**
It must include nutrition and ingredient declarations, allergen declarations, safe storage, and handling. See **FDA Labeling requirements** for more information.

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