



The FSVP rule allows the FDA to hold importers accountable for ensuring the products they bring into the country meet the same safety standards as domestically produced foods. Now that companies shoulder most of the burden, it's essential to be proactive. Understanding the definition of "importer" is the initial hurdle companies face in complying with the FSVP rule. We've clarified the importer definition below, along with nine other common FSVP-related mistakes food businesses make. Your company can avoid a warning letter from the FDA or an expensive and brand-damaging recall by understanding these pitfalls.



1. Not understanding the definition of importer.

The importer is the responsible party under FSMA's FSVP rule, so the appropriate first step in the process is to determine who the importer is. The FSVP importer definition can be any of the following: U.S. Consignee, U.S. Customer, or the U.S. Agent. When in doubt, look for the party holding the controlling financial interest, which is often the party interacting with the foreign supplier. It's not unusual for more than one party in the supply chain to act as the importer. Sometimes, the question becomes, "Who should be the FSVP Importer?" In which case, supply chain partners should determine the importer and sign and document an agreement.



2. Failing to draft an FSVP.

According to its Inspection Observation Data report, the FDA requires most U.S. food importers to develop and maintain FSVPs for their foreign suppliers. The most frequently cited violation during 2019 FDA food facility inspections was failing to draft an FSVP, with 340 violations. Delaying the implementation of FSVPs due to competing priorities or the assumption that your suppliers already meet requirements is a risky proposition. The quality and safety of your products rely heavily on how effectively you select and manage suppliers.



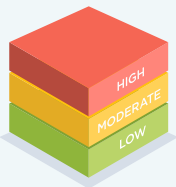
3. Insufficient documentation and recordkeeping.

Under the FSVP rule, the FDA can request records from up to two years ago, and if asked, you must produce all required documentation within 24 hours. Supplier verification procedures, hazard analysis protocols, and supplier performance against standards must be thoroughly documented and tracked. Auditors may ask to see your list of approved foreign suppliers, hazard analysis records, supplier scorecards, supplier approval processes, supplier verification methods, corrective actions initiated, and signed and dated proof of FSVP assessments and modifications.



4. Not reviewing historical FDA records.

When you select a new supplier for your business, you're putting your company's reputation on the line. It's crucial to review each supplier's historical food safety and FDA compliance records. Relevant information includes FDA warning letters issued, the supplier's refusal history, FDA inspection results for supplier facilities, foodborne illnesses traced back to the supplier, and whether the supplier successfully implemented corrective actions for any previously identified problems.



5. Treating all suppliers the same.

Suppliers vary greatly, so treating them the same is a mistake. It's essential to ensure that high-risk suppliers adhere to FSMA's food safety standards. A practical approach is to tier suppliers into high, moderate, and low-risk categories based on the type of materials they provide, historical performance, and compliance status. Once you determine risk categories, you can tailor verification activities to each risk level. For example, high-risk suppliers may require in-person audits annually.



6. Not knowing your foreign supplier named you the importer.

Major U.S. retailers sent a letter stating the definition of FSVP importer meant U.S. Customer or U.S. Consignee, and they didn't want to be named unless there were no other entities. Yet, based on a list published by the FDA, the letters didn't reach the right people. Companies can avoid this disconnect through clear communication with foreign suppliers, who frequently name U.S. buyers as importers, almost by default. Companies can define with suppliers who the importer is at the start of any new partnership and sign and document the agreement for a bulletproof audit trail.



7. Not understanding how Preventive Controls apply.

If your business imports food, you must verify, and document known or reasonably foreseeable hazards you're relying on your foreign suppliers to control. Conduct a risk analysis to assess potential hazards, define strategies for managing those risks, and keep performance on track by issuing corrective actions as needed. Ensuring preventative controls are adequately documented.



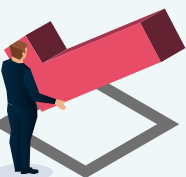
8. Viewing modified rules as exemptions.

There are modified requirements for certain foods from foreign suppliers in countries with food safety systems recognized as comparable or equivalent to the U.S. There are also modified FSVP requirements for very small importers and importers of food from certain small suppliers. An example of modified requirements is that certain importers can skip hazard analyses and verify foreign suppliers with written assurance. However, modified rules still have FSVP requirements, whereas exemptions do not.



9. Using your IRS number, FDA Registration number, or FDA Establishment Indicator.

On U.S. entry of imported food items, customs identifies the FSVP importer. One of the identification elements is the Unique Facility Identifier (UFI). The DUNS number is currently the only UFI approved by the FDA. You can't use your IRS number, FDA Registration number, or FDA Establishment Indicator for identification. The DUNS is a numerical identifier assigned to a specific business location by Dun & Bradstreet.



10. Assuming a GFSI audit is sufficient for supplier verification.

Reviewing a GFSI audit doesn't allow you to approve a foreign supplier. To meet verification requirements, you must conduct a hazard analysis or check the supplier's existing hazard analysis for each imported food. However, a GFSI audit helps ongoing verification once the hazard analysis is complete, and the supplier and food products have been thoroughly evaluated and approved.

TraceGains Supplier Management lets you automate and digitize your supplier and sourcing programs for real-time insight and easy audits.

[Learn More](#)