

FSMA FACT SHEET

How do I Comply with Supplier Verification Requirements?

Overview

The Preventive Controls regulation requires facilities to engage in supplier verification whenever they rely on a supplier to control a hazard. For example, if you are seasoning almonds with a spice blend and rely on your supplier to provide you with spices that are safe to eat, you would need to implement a supply chain program. The purpose of a supplier verification program is to ensure that your suppliers are providing you with safe ingredients, since you won't be doing anything additional as part of your own process to ensure the hazards in the ingredients are controlled. Likewise, it is important for the almond industry to recognize that your customers may be required to conduct supplier verification of you. This FSMA fact sheet provides an overview of the requirements under the Preventive Controls supplier verification regulations.

When Is Supplier Verification Required?

Incoming ingredients require supplier verification if a "hazard requiring a preventive control" (HRPC) is controlled before your receipt of the ingredient and you will not be implementing any controls for this hazard (nor will your customers). Thus, the determination of whether supplier verification is needed under FSMA ties back to the hazard analysis for the food(s) in which you use the ingredient. For example, if a facility seasons almonds with a cheese powder seasoning blend, they would be relying on their supplier to control potential biological hazards in this seasoning and would need to engage in supplier verification to ensure that the seasoning is safe. Similarly, if a Custom Processor is providing treated almonds to a confectionary manufacturer who will enrobe the almonds in chocolate, that confectionary manufacturer will be required to perform supplier verification of the Custom Processor. The Custom Processor may be asked by the confectionary manufacturer to provide certain information so that the customer can fulfill its own supplier verification obligations.

Who Is a Supplier?

Supplier is defined as the establishment that manufactured/processed the food, raised the animal, or grew the produce. Thus, the "supplier" you are required to verify may not be the company that supplies food to you directly (e.g., a broker or distributor).

What Are the Specific Requirements?

The supplier verification regulation is very detailed. It is not enough to just obtain a third-party audit for each supplier. The following is a summary of the specific requirements under the rule:

- Conduct a hazard analysis to determine whether the food has any HRPCs that are controlled earlier in the supply chain.
- Evaluate the supplier's performance and the risk posed by the food to determine appropriate verification activities. The regulation includes a list of the specific factors to consider for this assessment:
 - The hazard analysis for the food;
 - The entity that will be applying hazard controls, such as the supplier or the supplier's supplier;
 - The supplier's food safety practices and procedures;
 - Applicable U.S. food safety regulations and information regarding the supplier's compliance with those regulations (e.g., FDA Warning Letters); and
 - The supplier's food safety performance history, including results from testing, audit results, and the supplier's record of correcting problems.
- Conduct appropriate verification activities prior to using the ingredient and periodically thereafter, including one or more of the following:
 - Annual on-site audit (2nd or 3rd party) (Note: Annual on-site audits are expected for suppliers controlling hazards that present the risk of serious adverse health consequences or death, unless you can support another approach.)
 - Sampling and testing (e.g., Certificate of Analysis)
 - Review of supplier records (e.g., review of Food Safety Plan)
 - Other appropriate measures
- Document approval of the supplier.
- Ensure receiving procedures are in place at the facility to ensure ingredients are received only from approved suppliers.
- Conduct corrective actions as needed (e.g., based on consumer complaints).
- Re-evaluate the assessment of supplier performance and the risk posed by the food at least every three years or when you become aware of new information.
- Document everything and retain records for at least two years after the use of records is discontinued.
- Ensure a "qualified individual" performs all required activities.
- Confirm who will be declared as the "FSVP importer" for imported foods (see below).
 - This may involve consulting with business partners (e.g., Customs brokers).

Imports

The FDA has parallel supplier verification regulations for imports under the Foreign Supplier Verification Programs (FSVP) rule. For the almond industry, that regulation is only going to affect companies that source ingredients or finished products from outside the U.S., such as value-added operations that may be sourcing seasoning blends. Although a facility is deemed in compliance with the FSVP regulation for any ingredients for which supplier verification is conducted under the Preventive Controls rule, it is important to be aware that you may have to declare additional information at the border to enable entry of these ingredients if you are the party making the import filings with U.S. Customs and Border Protection.

Training Opportunity

The Food Safety Preventive Controls Alliance has developed a training program specific to the FSVP regulation.¹ Although most almond facilities that are required to conduct supplier verification would need to do so under the Preventive Controls regulation, this training program can be a helpful resource to understand the supplier verification requirements under this rule, as well as how to decide who the FSVP importer is under the FSVP rule.

Compliance Dates

The compliance dates for supplier verification depend both on the size of your business and the size of your supplier. The general rule is that once your Preventive Controls compliance date has passed, you have to verify suppliers for whom at least six months has passed after their own FSMA compliance date (or verify any suppliers that are not subject to FSMA regulations). The following is a summary of key compliance dates:

- March 17, 2017: For a company with 500+ full-time equivalent employees (FTE) to conduct supplier verification of any suppliers who also have 500+ FTE employees and are covered by the Preventive Controls rule.
- Sept. 18, 2017: For a company with less than 500 FTE to conduct supplier verification of any suppliers who have 500+ FTE employees and are covered by the Preventive Controls rule.
- March 19, 2018: For a company with any number of employees to conduct supplier verification of any suppliers who have less than 500 FTE employees and are covered by the Preventive Controls rule.
- July 26, 2018: For a company with any number of employees to conduct supplier verification of any suppliers with more than \$500,000 in average annual produce sales who are covered by the Produce Safety rule.
- July 29, 2019: For a company with any number of employees to conduct supplier verification of any suppliers with more than \$250,000 but no more than \$500,000 in average annual produce sales who are covered by the Produce Safety rule.

¹<https://www.ifsh.iit.edu/fspca/courses/foreign-supplier-verification-programs-fsvp>