

SUN3Law Legal Alert

FDA FSVP explanation:

The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates begin **May 30, 2017**. The final rule requires that importers 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.

For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent.

What is an FSVP? It is a program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection of a Domestic Food Company.

Importers are responsible for actions that include (and are explained further below):

- Determining known or reasonably foreseeable hazards with each food
- Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
- Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
- Conducting supplier verification activities
- Conducting corrective actions

Importers must establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food and the supplier's performance. Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food. There could be several entities in any given food shipment who might serve as the FSVP Importer, therefore, FDA and Customs require the importer of record to supply the designated FSVP Importer at the time of entry. Being designated a FSVP Importer will put your company on the list for FDA inspection under the new rule.

FDA FSVP Enforcement:

March 19, 2019 was the last key date for FDA's rolling enforcement calendar for its Foreign Supplier Verification Program (FSVP) regulations. In 2017 FDA conducted only a few hundred FSVP inspections because the agency struggled to find importers that were subject to the regulation. In 2018 FDA planned to inspect 2275 FSVP Importers, and until now inspected 242 FSVP Importers. This what Glenn Bass Director of FDA Office of Human and Animal Food Operations West, said during the Food Safety Preventive Control Alliance (FSPCA) Annual Meeting in Chicago last July 2018. The FDA approach until March 2019 will be soft, to help the FSVP Importers to better understand their new tasks and obligations and to try to spread awareness about the new FSMA Rules. FDA clarify that there is a lot of confusion inside the domestic market linked to the difference between the Importer of Record and the FSVP Importer and also confusion abroad to understand that FSMA is not a voluntary standard but is the new US mandatory federal law with FDA jurisdiction on its registered food facilities. In April 2016 on the FSPCA community website, FDA answer to a specific question: "How will the existing GFSI certifications of companies be affected by preventive controls?", the answer was: "Firms that have received GFSI recognized certifications will need to comply with FDA's Preventive Controls regulation regardless of their certification. Third party audits and certifications will not be accepted in lieu of an FDA inspection..."

Food Safety is a major focus of our Practice. Contact us for Assistance.