Final Rule on Foreign Supplier Verification Programs *At-A-Glance*

The FDA Food Safety Modernization Act of 2011 mandates the creation of a food safety system in which the focus is on preventing contamination rather than primarily reacting to problems after they occur. The FSMA rules include those that require preventive controls for food facilities that manufacture/process, pack, and hold human and animal foods, and establish science-based standards for produce grown on farms. These rules apply to domestic food producers and those in other countries who export to the United States.

The import community will be most impacted by the Foreign Supplier Verification Programs (FSVP) rule, which requires FSVP importers to verify that the food they import meets U.S. safety standards. FSVP importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. The goal is to ensure that each food is produced in a manner that provides the same level of public health protection as the preventive controls and produce safety regulations, if applicable, and the food is not adulterated or misbranded with respect to allergen labeling.

Who Is Covered by the FSVP Rule?

The FSVP importer is the U.S. owner or consignee of the food offered for import (i.e., owns the food, has purchased it, or has agreed in writing to purchase it at the time of U.S. entry). If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent/representative of the foreign owner/consignee, as confirmed in a signed statement of consent. The key is that there be a FSVP importer in the United States who takes responsibility for meeting the FSVP requirements.

What Will I Have to Do Under the FSVP rule?

Unless exempt, or subject to modified requirements, an FSVP importer may need to perform the following activities:

- Use a qualified individual to develop an FSVP and to perform FSVP activities.
- Perform a hazard analysis that includes identifying known or reasonably foreseeable hazards associated for each type of food and determining whether they require a control. Potential hazards include:
    - biological hazards, including parasites and disease-causing bacteria;
    - chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and
    - physical hazards, such as glass.
- Evaluate risks posed by the food and the performance of the foreign supplier, considering:
    - the hazard analysis for the food;
    - the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier;
    - the foreign supplier's food safety practices and procedures;
    - applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject

of an FDA warning letter or import alert; and
    - the foreign supplier's food safety performance history, including results from testing, audit results, and the supplier's record of correcting problems.
- Conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented. These activities may include:
    - annual onsite audits (must be performed by a qualified auditor);
    - sampling and testing of a food;
    - a review of the supplier's relevant food safety records; and/or
    - other appropriate activities.
- Take corrective actions (if necessary) and investigate the adequacy of the FSVP (when appropriate).
- Reevaluate the food and foreign supplier every three years or sooner if the FSVP importer becomes aware of new information about the hazards in the food or the foreign supplier's performance.
- Identify the FSVP importer when filing for entry with U.S. Customs and Border Protection using the FSVP importer's name, electronic mailing address, and unique facility identifier (UFI) recognized as acceptable to FDA.
    - The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP. A DUNS number can be obtained by visiting https://www.dnb.com/duns.html.
    - FDA issued updated guidance in April 2022 that removes the temporary policy of permitting the use of the entity role code "UNK" in lieu of a DUNS number. The guidance states that beginning on July 24, 2022, FSVP importers must comply with the requirement in 21 CFR 1.509(a) of providing a unique facility identifier recognized as acceptable by FDA (i.e., DUNS number) when filing entry with CBP.

FSVP importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as the FSVP importer reviews and assesses corresponding documentation.

When Would Modified Requirements Apply Under the FSVP Rule?

- Importation of foods that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation under specified circumstances.
- Importation of dietary supplements and dietary supplement components that will be subject to certain provisions of the dietary supplement Current Good Manufacturing Practice regulation under specified circumstances, or other dietary supplements.
- Importation by a very small importer or importer of foods from certain small foreign suppliers.
- Importation of certain food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent to that of the United States.

What Foods and Beverages Are Exempt from FSVP?

- Juice and seafood from foreign suppliers that are in compliance with the respective HACCP regulations (21 CFR part 120 or 123) and certain ingredients that are used by the importer in the manufacturing or processing of juice and seafood products in accordance with the respective HACCP regulations.
- Small quantities of food imported for research and evaluation purposes that are not intended for retail sale and are not sold or distributed to the public.
- Small quantities of food imported for personal consumption that are not intended for retail sale and are not sold or distributed to the public.
- Food produced in compliance with FDA's low acid canned food requirements in 21 CFR part 113 (exempt with respect to microbiological hazards controlled by 21 CFR part 113 only), as well as certain ingredients for use in LACF products but only with respect to microbiological hazards).
- Certain alcoholic beverages
- Food that is transshipped through the United States or that is imported for future export and not sold or distributed in the United States.
- Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing.
- Certain meat, poultry, and egg products.

What Are the FSVP Compliance Dates?

All compliance dates have passed.

Read more on **Compliance Dates for the FSVP Final Rule** and **Compliance Date Extensions and Clarifications for FSMA Final Rules**.

Additional Information

- FSVP Fact Sheet: https://www.fda.gov/media/94746/download
- The FDA has worked with the Food Safety Preventive Controls Alliance (FSPCA) on training and technical assistance programs to facilitate compliance with the FSVP rule: https://www.fspca.net/
- Am I subject to FSVP? https://www.fda.gov/media/94281/download
- Still have questions? Contact the FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan
- The FDA is in the process of developing FSVP guidance to help further explain the rule.