

RETAILERS AND OTHER FOOD IMPORTERS MUST ENSURE FOOD THEY IMPORT MEETS U.S. SAFETY STANDARDS

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Requirements take effect today under the FDA's new Foreign Supplier Verification Program (FSVP), which makes retailers and other businesses that import food into the United States responsible for verifying that the food has been produced in a manner that meets applicable U.S. safety standards.

FSVP is one of the seven foundational rules of the FDA's Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

A central tenet of the FSVP is that the same preventive food safety standards should apply to all food consumed in the U.S., regardless of where the food is produced. The FSVP therefore requires that importers have a program in place to verify that their foreign suppliers are producing food in a manner that satisfies FSMA's requirements for domestic food manufacturers, and also that the food is not adulterated or misbranded with respect to allergen labeling.

Importers must therefore 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 or, when necessary on a temporary basis, from unapproved suppliers whose foods are subjected to adequate verification activities before being imported.

What the FSVP Requires

Importers are required to develop, maintain and follow an FSVP for non-exempt food imported into the United States. The FSVP requires that the importer:

- Determine known or reasonably foreseeable hazards associated with the food, including biological, chemical and physical hazards. An importer can rely on another entity to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.
- Evaluate the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance. This should include evaluation of the foreign supplier's procedures, processes and practices related to food safety, applicable FDA food safety regulations and the foreign

supplier's compliance, the foreign supplier's food safety history, including responsiveness in correcting past problems; other factors as necessary, including storage and transportation practices. The importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

- Establish and follow written procedures that use the evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers, and determine appropriate supplier verification activities.
- Conduct supplier verification activities. An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.
- Conduct corrective actions. The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration or misbranding has been adequately addressed.

Reevaluation of the risk posed by the imported food and the supplier's performance must be conducted at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance.

Exemptions Under the FSVP

A number of foods are exempt from the FSVP, including:

- Fish and fishery products, which are subject to the FDA's Hazard Analysis and Critical Control Point (HACCP) regulations;
- Juice products, which are also subject to HACCP regulation;
- Alcoholic beverages and certain raw materials and ingredients that are imported for use in alcoholic beverages;
- Food that is imported for processing and future export;
- Low-acid canned foods, such as canned vegetables, but only with respect to microbiological hazards; and
- Certain meat, poultry and egg products.

FSVP Importer Must be Identified at Entry Into U.S.

As of today, importers must provide FSVP importer identification information to U.S. Customs and Border Patrol for each line entry of food product that they seek to import into the United States. The

FSVP 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 of consignee at the time of entry, as confirmed in a signed statement of consent.

The importer identification requirement includes the submission of the FSVP importer's name, e-mail address, and Unique Facility Identifier (UFI) recognized as acceptable by FDA. The importer's Data Universal Numbering System (DUNS) number is recognized as an acceptable UFI for FSVP.

However, the FDA recognizes that this is a new requirement and there may be factors that prevent importers from doing so. Therefore, the FDA has stated that for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to temporarily allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field for the FSVP importer. This will allow food offered for import to be processed through the ACE system, even if the importer has not yet provided a DUNS number. FDA intends to contact importers that use the "UNK" value in place of the UFI in order to provide additional information to ensure that they understand this FSVP requirement and can take appropriate steps to obtain a UFI.

Bryan Cave LLP has expertise and can assist your business in complying with FSMA and the FSVP. For questions or more information, contact the authors, Merrit Jones at merrit.jones@bryancave.com or (415) 336-6735.

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