Final Rule on Foreign Supplier Verification Programs (FSVP) Key Requirements

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. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

After input received during the comment period and during numerous engagements that included public meetings, webinars, and listening sessions, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions included providing importers flexibility in determining appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

The final rule has elements of both the original and supplemental proposals, with the addition of greater flexibility in meeting certain requirements to better reflect modern supply and distribution chains. For example, importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as those importers review and assess the corresponding documentation. The FDA is committed to helping ensure that importers can meet the FSVP requirements. To facilitate compliance, FDA will provide guidance, outreach, and training.

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Scope

Who is covered by the rule?

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 of consignee at the time of entry, as confirmed in a signed statement of consent. See Am I Subject to FSVP? (PDF: 69KB) for more information.

There are exemptions discussed below.

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 as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

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

- 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. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers. Similarly, if the importer obtains many different foods, from a single supplier, a separate FSVP would be required for each food.
- Certain importers that are also manufacturers/ processors are deemed in compliance with most FSVP requirements if:
    - they are in compliance with the supply-chain program requirements under the preventive controls rules;
    - they implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules; or
    - they are not required to implement preventive controls under those rules in certain specified circumstances. Examples of such circumstances include when the type of food (e.g., such as coffee beans) could not be consumed without application of a preventive control, or when the customer will be significantly minimizing or preventing identified hazards) and they comply with requirements for disclosures and written assurances.
    - The evaluation of the risk posed by the imported food and the supplier's performance must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance.
    - Importers are not required to evaluate the food and supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the distribution chain, such as the importer's customer, is processing the food for food safety in accordance with applicable requirements. FDA has extended the compliance date for obtaining these written assurances for two years. However, as required by the final rule, importers must disclose in documents accompanying the food that the food is not processed to control the identified hazard.

Hazard Analysis

- **What do we mean by 'hazard'?** An importer is required to identify and evaluate—based on experience, illness data, scientific reports and other information—the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. These include:
    - Biological hazards, including parasites and disease-causing bacteria
    - Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens
    - Physical hazards, such as glass
- They may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient.
- The analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur.
- The evaluation would have to consider factors that include the:
    - Formulation of the food
    - Condition, function and design of the establishment and equipment of a typical entity that produces the food
    - Raw materials and other ingredients
    - Transportation practices

- Harvesting, raising, manufacturing, processing, and packing procedures
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene

- An importer can rely on another entity to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

Evaluation of Food Risk and Supplier Performance

- **What evaluation must be done of the risk posed by an imported food and a supplier's performance?** An importer must evaluate:
  - The hazard analysis
  - The entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier
  - A foreign supplier's procedures, processes, and practices related to the safety of food,
  - Applicable FDA food safety regulations, and information regarding the foreign supplier's compliance
  - The foreign supplier's food safety history, including the responsiveness of the foreign supplier 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.

Supplier Verification

- **What supplier verification activities must be conducted?** Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities.
- Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:
  - Annual on-site audits of the supplier's facility. This is generally required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). However, the importer can choose another means of verification provided that the importer documents that the alternate choice is appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.
  - Sampling and testing
  - A review of the supplier's relevant food safety records
- 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.

Corrective Actions

- **What if something goes wrong?** Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the produce safety and preventive controls regulations, as applicable, or that the supplier produces food that is adulterated or misbranded with respect to allergen

labeling.

- 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.

Exemptions and Modified Standards

- The requirements for dietary supplements vary according to a number of factors, including whether the import is a finished product or an ingredient/component.
  - Importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) required under the separate, pre-existing dietary supplement Current Good Manufacturing Practices (CGMP) regulation will not be required to comply with most of the standard FSVP requirements.
  - The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements.
  - Importers of other dietary supplements, including finished products, would be required to comply with most of the standard FSVP requirements (except the hazard analysis requirement), but their verification activities would focus on compliance with the dietary supplement CGMP regulations.
- Modified FSVP requirements are established for very small importers and importers of food from certain small suppliers. (An example of these modified requirements is that certain importers would not have to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurances from their supplier.)
  - The definition of very small importer is consistent with the definition of very small business in the preventive controls rules: $1 million for human food and $2.5 million for animal food of annual sales (averaged over three year period) combined with the U.S. market value of food that is imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).
  - Importers of certain small foreign suppliers are subject to modified FSVP requirements. Those small suppliers are:
    - Facilities subject to modified requirements under the preventive controls rules because they are qualified facilities
    - Farms that are not covered farms under the produce safety rule because they average $25,000 or less in annual produce sales or because they meet requirements for a qualified exemption
    - Shell egg producers with fewer than 3,000 laying hens
    - Each of these types of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these firms.
- There are modified requirements for certain foods from a foreign supplier in a country whose food safety system has been recognized as comparable or determined to be the equivalent of the United States' system.
- Additionally, certain categories of imported food are not covered by FSVP. These include:
  - Juice, fish, and fishery products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations for those products, and certain ingredients for use in juice and fish and fishery products subject to the HACCP regulations.
  - Food for research or evaluation
  - Food for personal consumption
  - Alcoholic beverages and certain ingredients for use in alcoholic beverages

- Food that is imported for processing and future export
- Low-acid canned foods (LACF), such as canned vegetables, but only with respect to microbiological hazards covered by other regulations, as well as certain ingredients for use in LACF products (but only with respect to microbiological hazards).
- Certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation

Unique Facility Identifier

- The final FSVP rule requires that an importer provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.
- The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP. DUNS numbers, assigned and managed by DUN & Bradstreet, are available free of charge to importers 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.

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**.

Assistance to Industry

The FDA has developed and continues to develop several guidance documents on subjects that include:

- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA
- Training and Technical Assistance: The FDA has established the FSMA Food Safety Technical Assistance Network, to provide a central source of information to support industry understanding and implementation of FSMA.
- FDA has collaborated with the Food Safety Preventive Controls Alliance (FSPCA) to establish training and technical assistance programs.

Additional Information

- FSVP Fact Sheet: https://www.fda.gov/media/94746/download
- Food Safety Preventive Controls Alliance: https://www.fspca.net/
- Am I subject to FSVP? https://www.fda.gov/media/94281/download