IMPORTER NAME		DATE	
ADDRESS		QI APPROVAL	

FSVP Foreign Supplier Evaluation Form Example*

Foreign Supplier Name		Foreign Supplier Address (location)	
Food Product(s) Imported		Food Product(s) Description(s), including Important Food Safety Characteristics	

Evaluation Considerations and Results

Supplier's Procedures, Practices, and Processes (1.505(a)(1)(iii)(A))	Import Alerts	Recalls	Warning Letters	Other Significant Compliance Action(s) ((1.505)(a)(1)(iii)(B))	Supplier's Corrective Actions	Information related to the Safety of the food**	Rejection Date (if applicable)	Approval Date (if applicable)
	X							

Assessment of Results of Foreign Supplier Evaluation*** [*Note: If the evaluation was performed by another entity (other than the foreign supplier) include Entity's name, address, email, and date of evaluation.*]	

All supporting documentation should be appended to this form.
****Includes previous and recent experience with the supplier (e.g., rejected shipments, lab results, audit results, or other food safety information you may have outside of the government oversight context).***
*****If another entity (other than the foreign supplier) performs the foreign supplier evaluation, you may meet your evaluation requirements by having your QI review and assess the entity's evaluation. Your review/assessment of the evaluation must include documentation that the evaluation was conducted by a QI.***

IMPORTER APPROVAL		APPROVAL DATE	

How to Implement an FSVP Plan in 7 Steps

An FDA ruling put in place in 2017 seeks to ensure that all countries meet minimum food safety requirements to prevent foodborne illness.We can distill the purpose of the Final Rule on Foreign Supplier Verification Programs (FSVP) down to a single principle: foreign food companies must meet the standards of the Food Safety Modernization Act (FSMA). The new law shifts the burden of keeping imported food safe for consumption onto importers. The regulation requires U.S. food importers to develop, maintain, and follow an FSVP Plan for every food-type and every foreign supplier of that food.

What is an FSVP Plan?

An FSVP Plan is a program importers put in place to verify their foreign suppliers produce food in a manner that protects public health. The plans prove foreign suppliers export unadulterated food, identify allergens, and meet U.S. preventive controls or provide safety regulations.

Food covered in an FSVP Plan includes all ingredients in food and beverages, food and color additives introduced during processing, dietary supplements, packaging, and food contact substances.

There are partial and minor exceptions to the FSVP rule. Food regulated by the United States Department of Agriculture (USDA) or Hazard Analysis and Critical Control Point (HACCP)—such as meat, poultry, and egg products—is not subject to FSVP regulations. For foods that fall under FSVP rules, companies must have a written program—preferably vetted by a third party—that explains their supplier verification process. A written FSVP Plan helps the FDA understand an importer's approach to verification.

Gather Your Data, Start Documenting Your Processes, and Strive for Reasonable Care with this Workbook.

Who Should Develop an FSVP?

The law requires a qualified individual (QI) to develop an importer's FSVP Plan and perform FSVP activities. The importer's QI must have the knowledge, skills, and abilities needed to test foreign supplier compliance. This know-how can come from education, on-the-job experience, or both.

A QI can be someone on staff, or importers can rely on a consultant or third-party auditor. A government employee, including one from a foreign government, can also qualify. A Preventive Controls Qualified Individual (PCQI) fits the bill, too. These professionals already meet current

good manufacturing practices (cGMP) and preventive control rules, which are more stringent than FSVP QI requirements.

The QI fills an important role, no matter the route an importer takes. They perform seven key steps to develop an FSVP Plan for every foreign supplier and all food imported from those suppliers.

Step 1: Review Compliance Status

The QI first reaches out to a foreign supplier to review their current compliance status. The QI also considers the supplier's compliance history by examining Customs warning letters, import alerts, and requirements for certification issued by the FDA under section 801(q) of the Food, Drug, and Cosmetic Act (FD&C Act).

Step 2: Perform Hazard Analysis

Importers must check the potential hazards associated with each imported food, including the likelihood and severity of the hazard if it were to occur. Most times, a foreign supplier has already performed a hazard analysis. In these situations, the QI looks over and documents his or her review of the existing hazard analysis.

If a supplier lacks a hazard analysis, importers assume responsibility for examining the company's operations and looking for hazards requiring control. If the review does not identify any risks, it eliminates the need for product verification. However, an importer should keep the hazard analysis on file as proof.

Step 3: Verify Suppliers

Importers can verify suppliers through a variety of methods. Verification measures can include on-site audits, periodic sampling and testing, and review of foreign supplier food safety records and documentation.

On-site Audit: Importers can conduct their own on-site audits or hire a third-party auditor to examine a foreign supplier's operations and review the results. Importers do not need on-site audits unless there is a reasonable probability that a hazard may cause serious adverse health consequences or death, according to the Code of Federal Regulations (CFR) Title 21.

Sampling and Testing of Food: If an importer relies on product testing and sampling for verification, they must keep specific information about the sampling and testing process. They need to maintain records about:

- The number of and types of samples tested
- The lot numbers of the samples tested

- The tests conducted
- Corrective actions taken for detected hazards
- Information about the testing laboratory
- Documentation showing a QI performed the tests

Review of Food Safety Records: Importers can review a foreign supplier's food safety records for verification. If so, they must keep information about the records they reviewed, the dates of their reviews, and the nature of the records they examined. They must also maintain records of their findings and the corrective actions taken in response to identified deficiencies.

Step 4: Take Corrective Action

Importers can require corrective actions of their suppliers when warranted. Verification activities may find a company is not keeping a product at a specific temperature to avoid spoiling, or that a company is harvesting lettuce after spreading organic manure. The review may find a company needs to install restrooms for field workers. Each of these examples requires a specific corrective action showing that remedies will differ for every company and every product.

Step 5: Provide Importer Identification Upon Entry

All importers need a Data Universal Numbering System (DUNS) number for their company. Importers should provide their name and DUNS number when filing for entry with Customs and Border Protection.

Step 6: Keep Thorough Records

Keeping copious records is also critical. Under the FSVP rule, the FDA requires that importers maintain records related to compliance status, foreign supplier verification activities, hazard analyses, investigations, corrective actions, and FSVP reassessments.

Importers must keep original copies of their records, photocopies, or digital records for at least two years unless otherwise specified. In addition, the documents must be available to the FDA upon request.

Related Content: How to Plan an SOP for Freight Forwarding

Step 7: Periodically Reassess the FSVP Plan

Once verification is complete, an importer can source products from an approved supplier. However, a successful FSVP plan requires ongoing review and maintenance. The law stipulates that importers reassess their FSVP Plans every three years. If at any time an importer learns of

new hazards with imported products, such as a new source of raw materials or a different product formulation, a review must occur sooner.

If the review finds an imported food no longer meets FSVP requirements, importers must take corrective action. Their steps could include not working with a supplier until they address identified hazards or electing to update their FSVP Plan to ensure they vet suppliers more thoroughly.

The purpose of the FSVP to ensure importers do their due diligence before importing food into the United States. Taking a proactive approach to compliance prevents problems down the road. Should the FDA find a company's FSVP efforts lacking, it can stop shipments from entering the country-even if the food is safe and the foreign supplier is complying. By sharpening their FSVP Plans, importers can protect themselves while also safeguarding the US food supply.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements

This list of records required by the FSVP regulation, including a record referred to as a document, documentation, and written procedures, is organized into:

FSVP Records - Standard Requirements 21 CFR
1.502, 1.504, 1.505, 1.506, 1.508, 1.509, 1.510

FSVP Records -Modified Requirements
21 CFR 1.507, 1.511, 1.512, 1.513

Additional information on the FSVP regulation is available on FDA's FSVP web page.

FSVP Records - Standard Requirements
21 CFR 1.502, 1.504, 1.505, 1.506, 1.508, 1.509, 1.510

Section 1.502 - What foreign supplier verification program (FSVP) must I have?

Unless exempt, all importers of human and animal food must develop, maintain, and follow an FSVP for each food and foreign supplier (1.502(a)). (See enforcement policies: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs; Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals; Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities; and Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds)

Records: *Importer of LACF* (1.502(b)(1)):

- ❑ FSVP (not required to address microbiological hazards controlled by 21 CFR part 113 in LACF). See records requirements below for specific applicable sections of the FSVP regulation.
- ❑ Foreign supplier's compliance with 21 CFR part 113

Records: *Importer is LACF manufacturer/processor* (1.502(b)(1)):

- ❑ FSVP (not required to address microbiological hazards in raw materials and ingredients used to manufacture/process LACF if controlled by 21 CFR part 113). See records requirements below for specific applicable sections of the FSVP regulation.

Records: *Importer is subject to section 418 of FD&C Act (preventive controls)* (1.502(c)):

- ❑ An importer who is also a manufacturer and is subject to both FSVP and the supply chain program provisions of either the human food or animal food preventive controls regulation (21 CFR 117 subpart G or 21 CFR part 507 subpart E, respectively) may choose to be in compliance with the applicable preventive controls regulation or with FSVP. If the importer chooses to comply with the supply chain provisions of the applicable preventive controls regulation, they are not required to have an FSVP, except must comply with section 1.509.

Section 1.504 – What hazard analysis must I conduct?

Records: Hazard Analysis

- ❑ Hazard analysis
  - ❑ Hazard identification
    - ❑ Analysis of known or reasonably foreseeable hazards in each food:
      - Biological, chemical, and physical hazards
      - Foreseeable hazards that may be present in a food because (i) hazard occurs naturally; (ii) hazard may be unintentionally introduced; or (iii) hazard may be intentionally introduced for purposes of economic gain.
  - ❑ Hazard evaluation
    - ❑ Evaluation of identified hazards to assess probability that hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur
    - ❑ Evaluation of environmental pathogens when a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure
    - Consideration of effect of relevant factors on the safety of the finished food for the intended consumer, including: (i) formulation; (ii) condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food; (iii) raw materials and other ingredients; (iv) transportation practices; (v) harvesting, raising, manufacturing, processing, and packing procedures; (vi) packaging and labeling activities; (vii) storage and distribution; (viii) intended or reasonably foreseeable use; and (ix) sanitation, including employee hygiene factors.
  - ❑ Hazard analysis performed by qualified individual

OR

Records: Hazard Analysis

- ❑ Review and assessment of another entity's hazard analysis
  - ❑ Include documentation that qualified individual conducted the hazard analysis

Records: Reevaluation

- ❑ Reevaluation of the foreign supplier's performance and risks posed by the food. (Reevaluation if importer obtains new information or concerns relating to foreign supplier or at the end of any 3-year period)
  - ❑ Actions taken or changes to FSVP based on reevaluation (e.g., discontinue use of foreign supplier, change verification activities)

OR

Records: Reevaluation

- ❑ Review and assessment of the other entity's documentation or reevaluation
  - ❑ Include documentation that qualified individual conducted the hazard analysis

Section 1.505 – What evaluation for foreign supplier approval and verification must I conduct?

Records: Evaluation of foreign supplier's performance and risk posed by food

- ❑ Document the evaluation of foreign supplier's performance and risk posed by the food
- ❑ Approval of foreign supplier, based on evaluation of foreign supplier's performance and risk posed by food
  - Consideration of appropriate and necessary factors, including: (i) hazard analysis, including nature of the hazard requiring a control; (ii) entity or entities that will significantly minimize or prevent hazards requiring a control or verifying that hazards have been significantly minimized or prevented; and (iii) foreign supplier performance
- ❑ Reevaluation of supplier approval based on new information relating to factors used as basis for approval, or at least every three years. If concerns relating to importing food from a foreign supplier change, including:
  - Determination of whether it is appropriate to continue to import the food from the foreign supplier
  - Determination of whether supplier verification activities need to be changed
  - Any actions taken based on results of reevaluation

OR

Records: Evaluation of foreign supplier's performance and risk posed by food

- ❑ Review and assessment of another entity's evaluation or reevaluation of risk posed by the food and performance of the foreign supplier, including:
  - Evaluation or reevaluation performed by qualified individual

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Section 1.506 - What foreign supplier verification and related activities must I conduct?

Records: *Importer develops procedures for importing food only from approved foreign suppliers or importer conducts review and assessment of procedures established by another entity for importing food only from approved foreign suppliers*

- ❑ Procedures for importing food only from approved foreign suppliers

OR

- ❑ Review and assessment of procedures established by another entity for importing food only from approved foreign suppliers

- ❑ Use of procedures for importing food from approved suppliers

Records: *Importer develops procedures for importing food from unapproved foreign suppliers or importer conducts review and assessment of procedures established by another entity for importing food from unapproved foreign suppliers*

- ❑ Procedures for importing food from unapproved foreign suppliers, when necessary and appropriate

OR

- ❑ Review and assessment of procedures established by another entity for importing food from unapproved foreign suppliers when necessary and appropriate

- ❑ Use of procedures for importing food from unapproved suppliers
- ❑ Procedures for ensuring appropriate verification activities conducted
- ❑ Determination of supplier verification activities that will be conducted, including:
  - Frequency of conducting activity
  - Entity or entities significantly minimizing or preventing hazard or verifying hazards significantly minimized or prevented
  - If SAHCODHA hazard, determination that less frequent auditing or alternate verification activity is appropriate rather than an initial and annual onsite audit

OR

- ❑ Review and assessment of another entity's determination of appropriate supplier verification activities, including:
  - Other entity's determination is appropriate, including frequency
  - Determination made by qualified individual

Records: *Performance of one or more foreign supplier verification activities*

- ❑ Onsite audit
  - Include audit procedures, audit dates, conclusions, corrective actions, performed by qualified auditor
    - If the food is subject to one or more FDA food safety regulations, must consider applicable FDA food safety regulations or, when applicable, may consider relevant laws and regulations of country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States
    - Must include review of supplier's written food safety plan, if any, and its implementation, for the hazard being controlled
  - Conducted before importing the food and periodically thereafter
  - Must be performed by entity other than foreign supplier
  - Results of inspection can be substituted for onsite audit (inspection within 1 year of date audit would have been conducted)
- ❑ Sampling and testing of the food
  - Include number of samples tested, type of tests conducted, dates of tests, date of test report, results, any corrective actions, testing laboratory, performed by qualified individual
  - Conducted before importing the food and periodically thereafter
- ❑ Review foreign supplier's food safety records
  - Include dates, general nature of records reviewed, conclusions, any corrective actions taken, conducted by qualified individual
  - Cannot be performed by foreign supplier
  - Conducted before importing the food and periodically thereafter
- ❑ "Other" verification activity - Conduct and document or obtain documentation of other supplier verification activity

- Documentation of each activity, including description of activity, date activity conducted, findings or results, any corrective actions taken, and conducted by qualified individual
- Conducted before importing the food and periodically thereafter

OR

- ❑ Review and assessment of results of supplier verification activity performed by another entity
  - Documentation that appropriate supplier verification conducted for each foreign supplier before importing the food and periodically thereafter
  - Actions taken if results of verification activity do not provide adequate assurance that hazards requiring a control in the food were significantly minimized or prevented
  - Foreign supplier itself or its employees may not perform supplier verification activities, except with respect to sampling and testing of food
  - Not required to retain documentation of verification activity conducted by another entity, but must obtain the documentation and make it available to FDA upon request

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Section 1.508 – What corrective actions must I take under my FSVP?

- ❑ Corrective actions taken (if applicable)
- ❑ Investigations (if applicable)
- ❑ FSVP modifications (if applicable)

Section 1.509 – How must the importer be identified at entry?

- ❑ Importer identification information provided electronically when filing entry with CBP
- ❑ Before food is imported or offered for import, if no U.S. owner or consignee, importer designated a U.S. agent or representative as the importer

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Section 1.510 – How must I maintain records of my FSVP?

- ❑ Records kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records
  - May use existing records that contain all required FSVP information or may supplement existing records as necessary to include all required information.
  - Required FSVP information need not be maintained as one set of records (i.e., new FSVP information may be maintained separately or combined with existing records)
- ❑ Records signed and dated upon initial completion and any modification
- ❑ Records legible and stored to prevent deterioration or loss
- ❑ Records available promptly to authorized FDA representative, upon request, for inspection and copying
- ❑ English translation provided within a reasonable time, upon FDA request
- ❑ Records stored offsite retrieved and provided onsite within 24 hours of FDA request.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements

- ❑ Records sent to Agency electronically, or through another means that delivers the records promptly, upon written FDA request
- ❑ Records retained until at least 2 years after created or obtained, or records related to processes and procedures retained for at least 2 years after their use was discontinued.

FSVP Records -Modified Requirements
21 CFR 1.507, 1.511, 1.512, 1.513

Section 1.507 – What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

On January 5, 2018, FDA issued guidance stating the Agency's policy regarding enforcement discretion regarding certain entities and activities covered by the FSMA regulations, including the written assurances in section 1.507 of the FSVP regulation. The records requirements relating to these written assurances are marked with asterisks (**), below at the beginning and end of each requirement. During the enforcement discretion period, the Agency does not intend to enforce the provisions in section 1.507 relating to these written assurances, indicated below with asterisks (**). The enforcement discretion policy will be in place until FDA takes further action to address concerns relating to application of the written assurance requirements. For additional information on the Agency's enforcement discretion policy, please see "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs."

Records: *Food cannot be consumed without application of a control*

- ❑ Hazard analysis
  - ❑ Determination that food cannot be consumed without application of a control

Records: *Customer subject to Preventive Controls regulation*

- ❑ Hazard analysis
- ❑ Document accompanying food discloses that food is "not processed to control [identified hazard]"
- ❑ **Customer's annual written assurance, including:
  - Customer established and following procedures that will significantly minimize or prevent the identified hazard
  - Effective date, printed names and signatures of authorized officials, applicable assurance**

Records: *Customer not subject to Preventive Controls regulation*

- ❑ Hazard analysis
- ❑ Document accompanying food discloses that food is "not processed to control [identified hazard]"
- ❑ **Customer's annual written assurance, including:
  - Customer is manufacturing, processing, or preparing food according to applicable food safety regulations
  - Effective date, printed names and signatures of authorized officials, applicable assurance**

Records: *Entity in supply chain subsequent to customer controls hazard*

- ❑ Hazard analysis
- ❑ Document accompanying food discloses that food is "not processed to control [identified hazard]"
- ❑ **Customer's annual written assurance, including:
  - Customer will disclose in document accompanying food that food is "not processed to control [identified hazard]"
  - Customer will only sell food to entity that agrees, in writing, to follow procedures that will significantly minimize or prevent identified hazard, or obtain similar written assurance from the entity's customer
  - Effective date, printed names and signatures of authorized officials, applicable assurance**

Records: *Importer established and implemented a system to ensure customer or subsequent entity in supply chain controls hazard*

- ❑ Hazard analysis
- ❑ System established by importer
- ❑ Implementation of established system

Section 1.511 - What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

Records: *Importer who is subject to certain dietary supplement CGMPs* (i.e., 21 CFR 111.70(b) or (d) and 111.73 and 111.75)

- ❑ Use of qualified individual and qualified auditor, when applicable (21 CFR 1.503)

Records: *Importer whose customer who is subject to certain dietary supplement CGMPs* (i.e., 21 CFR 111.70(b) or (d) and 111.73 and 111.75)

- ❑ Annual assurance that customer is in compliance with requirements in 21 CFR 111.73 and 111.75 applicable to determining that the specifications they established are met
  - Effective date, printed names, signatures of authorized officials, and a paragraph describing the specifics related to the type of assurance
- ❑ Use of qualified individual and qualified auditor, when applicable (21 CFR 1.503)

Records: *Importer for which neither they nor their customer is subject to certain dietary supplements CGMPs* (i.e., 21 CFR 111.70(b) or (d) and 111.73 and 111.75)

- ❑ Evaluation of risk posed by the food and performance of the foreign supplier (section 1.505(a)(2))

- ❑ Procedures for importing food from approved foreign suppliers

OR

- ❑ Review and assessment of procedures established by another entity for importing food from approved foreign suppliers

- ❑ Procedures for importing food from unapproved foreign suppliers when necessary and appropriate, including adequate verification activities prior to importation

OR

- ❑ Review and assessment of procedures established by another entity for importing food from unapproved foreign suppliers when necessary and appropriate, including adequate verification activities prior to importation

- ❑ Use of procedures for importing food from approved foreign suppliers and, when necessary and appropriate, from unapproved foreign suppliers
- ❑ Approval of foreign supplier (section 1.505(b))
- ❑ Reevaluation of supplier approval based on new information relating to factors used as basis for approval, or at the end of any 3-year period during which a reevaluation was not conducted (section 1.505(c)), including:
  - Appropriateness of continuing to use foreign supplier
  - Any subsequent actions taken based on reevaluation
- ❑ Corrective actions, investigations, and FSVP modifications based on determination that foreign supplier is not producing food in compliance with applicable (dietary supplement) regulations (section 1.508) (if applicable)
- ❑ Procedures for ensuring appropriate supplier verification activities conducted

- ❑ Determination of verification activities that will be conducted, including
  - Frequency of conducting activity

OR

- ❑ Review and assessment of another entity's determination of appropriate verification activities (section 1.505(d)), including:
  - Other entities determination is appropriate, including frequency
  - Determination made by qualified individual

- ❑ Use of qualified individual and qualified auditor, when applicable (21 CFR 1.503)

Records: *Foreign supplier verification activities* (document or obtain documentation of appropriate foreign supplier activity conducted by another entity)

- ❑ <u>Onsite audit</u>
  - Audit procedures, audit dates, conclusions, corrective actions, conducted by qualified auditor
  - Considers applicable requirements of dietary supplements regulations (21 CFR part 111)
  - Includes review and implementation of foreign supplier's written food safety plan, if any

  OR

  - Considers relevant laws and regulations of a systems recognition country

  OR

- Results of an inspection (substituted for onsite audit)
  - Conducted within 1 year of date by which onsite audit would have been required
  - Determined foreign supplier's compliance with applicable requirements in 21 CFR part 111
  - Conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies
    OR
  - Conducted by food safety authority of a systems recognition country
    → Food is within the scope of the official recognition or equivalence determination
    → Foreign supplier is in, and under regulatory oversight of the systems recognition country

❑ Sampling and testing of dietary supplement
- Number of samples tested, type of tests conducted, dates of tests, date of test report, results, corrective actions, testing laboratory, performed by qualified individual
- Conducted before importing the dietary supplement and periodically thereafter

❑ Review foreign supplier's food safety records
- Dates, general nature of records reviewed, conclusions, corrective actions, conducted by qualified individual
- Conducted before importing the dietary supplement and periodically thereafter

❑ Other verification activities
- Description of activity, date activity conducted, findings or results, any corrective actions taken, conducted by qualified individual
- Conducted before importing the dietary supplement and periodically thereafter

❑ Review of results of supplier verification activity performed by the importer

OR

❑ Review of results of supplier verification activity performed by another entity to ensure the supplier is producing the dietary supplement consistent with part 111. (Not required to retain documentation of supplier verification activity conducted by another entity but must obtain the documentation and make it available to FDA upon request.)

❑ Documentation of any corrective actions taken, investigations, and FSVP modifications based on determination that foreign supplier is not producing food in compliance with applicable dietary supplement regulations

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Section 1.512 - What FSVP may I have if I am a very small importer or if I am importing certain food from certain small foreign suppliers?

Records: *Very small importer*

- ❑ Meets definition of very small importer, before initially importing food and thereafter on an annual basis by December 31 of each calendar year
- ❑ Written assurance that foreign supplier is producing food in compliance with processes and procedures that provide applicable public health protection, before importing food and at least every 2 years thereafter
- ❑ Corrective actions taken in response to determination that foreign supplier does not produce food in a manner as stated in written assurance (if applicable)
- ❑ Use of qualified individual and qualified auditor, when applicable (21 CFR 1.503)

Records: *Importer of food from small foreign supplier that is a qualified facility*

- ❑ Written assurance before importing the food and at least every 2 years thereafter, that foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system the FDA has officially recognized as comparable or determined to be equivalent to that of the United States)
  - > Brief description of preventive controls supplier is implementing to control the applicable hazard;
    OR
  - > Statement that supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

Records: *Importer of food from small foreign supplier that is a farm that grows produce that is not "covered produce"*

- ❑ Written assurance before importing the food and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to the relevant laws and regulations of a country whose food safety system the FDA has officially recognized as comparable or determined to be equivalent to that of the United States)

Records: *Importer of food from small foreign supplier that is a shell egg producer with fewer than 3,000 laying hens*

- ❑ Written assurance before importing the shell eggs and at least every 2 years thereafter, that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system the FDA has officially recognized as comparable or determined to be equivalent to that of the United States)

Other Records: *Importer of food from small foreign supplier*

- ❑ Written assurance that foreign supplier meets the criteria for a small foreign supplier before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements

- ❑ Corrective actions taken if importer determines that foreign supplier does not produce the imported food consistent with a written assurance

- ❑ Initial evaluation of foreign supplier's compliance history
  - Evaluation of applicable food safety regulations and information relevant to the compliance history of that foreign supplier
    - Other factors relevant to the foreign supplier's performance

OR

- ❑ Review and assessment of another entity's initial evaluation of foreign supplier's compliance history, including:
  - Evaluation performed by qualified individual

- ❑ Reevaluation of foreign supplier's compliance history if new information or concerns are obtained or at the end of any 3-year period, including:
  - Appropriateness of continuing to use foreign supplier
  - Corrective actions taken (if applicable)

OR

- ❑ Review and assessment of another entity's reevaluation of foreign supplier's compliance history, including:
  - Reevaluation performed by qualified individual

- ❑ Approval of foreign supplier

- ❑ Procedures for importing food only from approved foreign suppliers

OR

- ❑ Review and assessment of procedures established by another entity for importing food only from approved foreign suppliers

- ❑ Use of procedures for importing food from approved suppliers

- ❑ Procedures for importing food from unapproved foreign suppliers when necessary and appropriate
  - Must subject food to adequate verification activities prior to importing the food

OR

- ❑ Review and assessment of procedures established by another entity for importing food from unapproved foreign suppliers when necessary and appropriate

- ❑ Use of procedures for importing food from unapproved suppliers when necessary and appropriate
- ❑ Use of qualified individual and qualified auditor, when applicable (21 CFR 1.503)

Records Requirements

- ❑ Records kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records
- ❑ Records signed and dated upon initial completion and any modification
- ❑ Records legible and stored to prevent deterioration or loss
- ❑ Records available promptly to authorized FDA representative, upon request, for inspection and copying
- ❑ English translation provided within a reasonable time, upon FDA request
- ❑ Records stored offsite retrieved and provided onsite within 24 hours of FDA request
- ❑ Records sent to Agency electronically, or through another means that delivers the records promptly, upon written FDA request
- ❑ Records retained until at least 2 years after created or obtained, or records related to processes and procedures retained for at least 2 years after their use was discontinued.
- ❑ Records relied on during the 3-year period preceding the applicable calendar year to support importer status as a very small importer retained for at least 3 years

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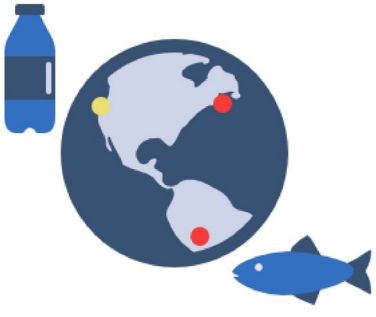
Section 1.513 - What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

- ❑ Documentation required before importing a food and annually thereafter:
  - > Foreign supplier is under the regulatory oversight of the officially recognized or equivalent food safety system
  - > Food is within the scope of official recognition or equivalency determination
  - > Foreign supplier is in good compliance standing with comparable or equivalent food safety authority
- ❑ Any corrective actions taken (if applicable)

Guide to Developing a Foreign Supplier Verification Program (FSVP)

FEBRUARY 18, 2019 FOOD IMPORT REGULATION (/BLOG/TAG/FOOD+IMPORT+REGULATION), FOREIGN SUPPLIER (/BLOG/TAG/FOREIGN+SUPPLIER), FOREIGN SUPPLIER VERIFICATION PLAN (/BLOG/TAG/FOREIGN+SUPPLIER+VERIFICATION+PLAN), FOOD IMPORT (/BLOG/TAG/FOOD+IMPORT), SUPPLIER VERIFICATION (/BLOG/TAG/SUPPLIER+VERIFICATION), FSMA (/BLOG/TAG/FSMA), FSVP (/BLOG/TAG/FSVP), SUPPLY CHAIN (/BLOG/TAG/SUPPLY+CHAIN), FOOD IMPORTER (/BLOG/TAG/FOOD+IMPORTER), DISTRIBUTION (/BLOG/TAG/DISTRIBUTION), TITLE GUIDE TO DEVELOPING A FOREIGN SUPPLIER VERIFICATION PROGRAM (/BLOG/TAG/TITLE+GUIDE+TO+DEVELOPING+A+FOREIGN+SUPPLIER+VERIFICATION+PROGRAM)

To learn more about Foreign Supplier Verification Programs overall, see our (/blog?tag=title%20foreign%20supplier%20verification%20program)*introduction article* (http://fdareader.com/blog/foreign-supplier-verification-program)



How Do I Develop a Foreign Supplier Verification Program?

If you import products for consumption into the US, you likely are required to develop a foreign supplier verification program (FSVP).

Below is a step by step guide to developing and implementing an FSVP.

Contents

This article applies to you if...

Δ You are a food importer

Δ The products you import are regulated by the FDA

Δ You do not qualify for a small-food-importer exemption (<$10mm/yr imported)

Δ You need to build a foreign supplier verification plan

MORE ABOUT SUPPLY CHAIN

How to Pass Quality Assurance and Get Your Product Into Major Retailers (/blog/how-to-win-over-qa-teams-and-get-your-product-into-major-retailers)

Getting Started: Small Food Importers (/blog/getting-started-small-food-importers)

Guide to Developing a Foreign Supplier Verification Program

1. Determine your Qualified Individual

First, The FSVP must be prepared by a "qualified individual" who has the education, training or experience necessary to perform the activity. If this person is a 3rd party or consultant, that's fine. However, note that supplier verification is an ongoing process and it must always be completed by a qualified individual. For most companies, the easiest solution is to have someone on staff undergo a 2 day training course on developing a Foreign Supplier Verification Program.

Source 21 CFR 1.503 (https://www.ecfr.gov/cgi-bin/text-idx?SID=5b4d31f6de6da0e530ca504a07d2c2ab&mc=true&node=se21.1.1_1503&rgn=div8)

2. Decide How Your Program Works

Before you begin approving suppliers, you must establish the procedures you will use to approve suppliers. The goal is to provide assurance that hazards in the food you import are being prevented.

You can rely on a 3rd party to conduct your supplier verification if you review and assess the documentation yourself and document your review and assessment of the materials.

Examples of appropriate verification activities:

- Onsite audit by a qualified individual
- Sampling & testing
- Review of foreign suppliers food safety records
- Other appropriate supplier verification activities

3. Conduct Your Verification Activities

This step is the bulk of the process: collecting information from your suppliers, reviewing it, and documenting your review process.

You may rely on a 3rd party to conduct supplier verification activities (i.e. a 3rd party audit) if you assess their documentation with appropriate frequency. You must document your review and assessment of the activities and document that the activities were performed by a qualified individual.

(/blog/foreign-supplier-verification-program-sw8fc)
Verification Program (FSVP) (/blog/foreign-supplier-verification-program-sw8fc)


(/blog/foreign-supplier-verification-program)
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Does the FDA

The following are common verification methods for approving suppliers:

HAZARD ANALYSIS

You are required to review a hazard analysis for each type of food you import. Hopefully, each of your foreign suppliers has completed one and can provide this to you. If not, then you must conduct a hazard analysis to determine whether there are any hazards requiring a control. This hazard analysis must be written and contain an evaluation of environmental hazards.

Some key points about the hazard analysis:

- You must either conduct a hazard analysis for each type of food you import OR use a supplier hazard analysis.
- If you are importing Raw Agricultural Commodities (RACs) then no biological hazards need be considered in the Hazard analysis.
- If you are reviewing a hazard analysis supplied by the supplier or a 3rd party, then you must document your review of the hazard analysis and confirm that it was conducted by a qualified individual.
- If no hazards are identified which require a preventive control, then no verification is required for those products. Still you must have a hazard analysis on file to show that this has been determined. This provision does not apply to produce.

Subpart L - FSVP for Food Importers (https://www.ecfr.gov/cgi-bin/text-idx?SID=efb31815e88767aceef5827e442857f1&mc=true&node=sp21.1.1.l&rgn=div6)

ONSITE AUDIT

Certain importers may wish to independently conduct onsite audits of the foreign supplier. Or, they may simply review the audit results conducted by a reputable 3rd party auditor.

An audit is required as part of the supplier verification process when there is "reasonable probability that exposure to the hazard will result in serious adverse health consequences or death" you must conduct or obtain documentation of an onsite audit at least annually. (1.506 (d) (ii) (2) (https://www.ecfr.gov/cgi-bin/text-idx?SID=efb31815e88767aceef5827e442857f1&mc=true&node=sp21.1.1.l&rgn=div6#se21.1.1_1506)

In this case, an audit may be replaced by written inspection results by the FDA, USDA, or a food safety authority of a country whose food safety system is equivalent to that of the US.

SAMPLING & TESTING OF FOOD

If you choose to use product testing and sampling as part of your verification, you must retain documentation of the following:

- The number and type of samples tested
- identification of the food tested (lot numbers)
- tests conducted and the methods of the testing
- Any corrective action taken into detection of hazards
- Information identifying the lab
- Documentation that the tests were performed by a qualified individual.

REVIEW OF FOREIGN SUPPLIER'S FOOD SAFETY RECORDS

The most common method of supplier verification is the review of a foreign supplier's food safety records.

If you choose to use your foreign supplier's food safety records as part of your verification, you must retain the following information:

- The records reviewed
- Dates of review

Regulate My Food Business? (/blog/2018/11/30/does-the-fda-regulate-my-food-business)

Intro to Foreign Supplier Verification Program (/blog/foreign-supplier-verification-program)

Processes and Controls (/blog/2018/12/17/processes-and-controls)

Requirements for FDA Food Producers (/blog/2018/12/17/requirements-for-fda-producers)

What You Need to Know Before Joining an Incubator Kitchen (/blog/2019/02/06/what-you-need-to-know-about-food-regulation-and-incubator-kitchens)

CONSULTING SERVICES

Foreign Supplier Verification Program Review (/consulting-services/nm3w4ra)

Have your FSVP verified by a Mile Rock consultant

- Dates of review
- General nature of the records reviewed
- Conclusions of review
- Any corrective actions taken in response to significant deficiencies identified.
- Documentation that the review was conducted by a qualified individual.

You may not allow on the foreign supplier to conduct supplier verification activities for their own business.

FINAL CONSIDERATIONS:

Hazards Not Controlled by the Foreign Supplier

Does a 3rd party control one of the hazards on behalf of your supplier (i.e. your overseas milk supplier has their pasteurization completed offsite by another company.) If so, you must collect this verification data from the 3rd party or have your supplier send it to you.

Supplier Performance & History

It is perfectly acceptable to take into consideration your supplier's history, procedures, practices, storage, transportation, etc as part of your verification activities.

Document Your Verification Activities

Remember, it's not enough to simply collect these documents from your foreign suppliers -- you have to assess them *and* document that assessment.

For example, let's say I'm an importer of *Ned's Italian Tomato Sauce* and they send me their most recent audit result. Beyond having that audit result on file, I need to record that I reviewed that audit, that it showed me they controlling the hazards in their process, and that my review occurred on such-and-such date.

The Whole Picture

For fear of stating the obvious, you must approve your foreign suppliers on the basis of your evaluation. In other words, you must consider all the information you gather in your approval process and cannot discount any piece of information simply because it is contrary to the result that you're looking for.

This doesn't mean that one failed audit in your supplier's history means you cannot approve them. However, you must acknowledge this information if it is revealed in your verification activities or outside of them.

Source 21 CFR -- 1.504 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=5b4d31f6de6da0e530ca504a07d2c2ab&mc=true&n=sp21.1.1.l&r=SUBPART&ty=HTML#se21.1.1_1504)

4. Approve your Suppliers and Maintain the Program

Once you have completed your verification activities, you may add the relevant supplier's to

Once you have completed your verification activities, you may add the relevant supplier's to your approved supplier list and begin sourcing product from them. At that point, the program should require only occasional ongoing maintenance

Keeping Records of Your Foreign Supplier Verification Program (FSVP)

Your records should comply with the following provisions:

- They must be originals, photocopies or digital records
- You must keep them for 2 years unless otherwise specified
- They must be available for review by the FDA
- You do not need to have a specific copy of each record for the FDA (e.g. you can have one copy of a record to satisfy both a state requirement and a federal requirement)

Source 21 CFR §1.510 (https://www.ecfr.gov/cgi-bin/text-idx?SID=a662be58219bb197189121c9cb296344&mc=true&node=se21.1.1_1510&rgn=div8)

There are several exemptions to Foreign Supplier Verification Requirements. This section applies to:

Taking Corrective Actions

You must take corrective actions if you determine that the food you are receiving is not meeting the requirements of the FDA regulations. Simply put, if the food you receive could cause harm to a consumer or is unsafe, then you must take some type of corrective action. This determination could be based on customer complaints or verification activities that you conduct (i.e. records review or viewing an inspection result.)

The appropriate corrective action to take could include discontinuing your use of that supplier until the hazards have been addressed.

If this determination occurs outside of the scope of your supplier verification activities, then it may reveal that your verification activities are not comprehensive. Simply put -- you didn't catch the mistake in your normal supplier verification practices therefore something is inherently wrong with your process. In this case you are obligated to update your plan so that you are able to adequately verify your suppliers.

Source 21 CFR §1.508 (https://www.ecfr.gov/cgi-bin/text-idx?SID=a662be58219bb197189121c9cb296344&mc=true&node=se21.1.1_1508&rgn=div8)

Re-evaluating Suppliers

You must re-evaluate your foreign suppliers (and document it),

- Every 3 years, at minimum
- When you learn anything new or when anything has changed that would warrant a re-evaluation.

You may use a 3rd party foreign supplier review as your re-evaluation, insofar as you document your assessment of that evaluation. The evaluation must be performed by a qualified individual.

Source 21 CFR -- 1.504 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=5b4d31f6de6da0e530ca504a07d2c2ab&mc=true&n=sp21.1.1.l&r=SUBPART&ty=HTML#se21.1.1_1504)

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U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

"What to Expect During a Foreign Supplier Verification Programs Inspection"

Inspections are an important tool the U.S. Food and Drug Administration (FDA) uses in ensuring human and animal foods are safe for U.S. consumers. The Foreign Supplier Verification Programs (FSVP) rule, which is one of the seven rules that make up the Food Safety Modernization Act (FSMA), requires that importers perform certain risk-based activities to verify that the human and animal food they import into the United States has been produced in a manner that meets applicable U.S. safety standards. This fact sheet provides an overview of steps FDA investigators will take when conducting routine inspections to determine compliance with the FSVP Rule.

An inspection of an FSVP importer to review FSVP records can occur if:

- The importer is subject to routine surveillance and follow-up;
- The importer has an inspectional history that includes a violative inspection and a compliance follow-up inspection is needed to observe voluntary corrections; or
- Products imported by the FSVP importer are associated with a recall, foodborne outbreak investigation, or complaint.

Pre-Inspection Contact

For initial inspections, an FDA investigator will email and/or call the person or entity identified at the time of entry as the FSVP importer.

The investigator will confirm the entity as the FSVP importer for the specific product(s)/foreign supplier(s) assigned to be reviewed, including clarification of the importer's location and contact information. The investigator will also determine if the FSVP records are in English and available onsite, if they can be retrieved within 24 hours of written request; and if documents are not maintained in English, how soon an English translation can be provided.

Please note that if FDA's pre-inspection contact attempts are unsuccessful, the FDA will still plan to conduct the inspection at the address transmitted at entry.

How to Prepare for the Inspection

Once contacted regarding an FSVP inspection, the importer should retrieve any records that may be stored offsite so that the documents are ready for the investigator at the start of the inspection. If records are not in English, the FSVP importer should have the records translated into English, prior to the inspection date.

The FSVP Regulation Records Requirements provide a list of FSVP records the investigator may request to review during the inspection. The list may be used to help the FSVP importer prepare for and facilitate the inspection.

During the Inspection

FSVP inspections are generally conducted at the FSVP importer's location during normal business hours. When the

investigator arrives, they will ask to speak to the most responsible individual onsite. The investigator will introduce themselves (name, title, agency), provide the reason for the inspection, and show identification. The investigator will also request FSVP records in writing (Form FDA 482d). If the firm is a warehouse, or other type of facility that stores or holds food, the investigator will also issue a Notice of Inspection (FDA Form 482) if a warehouse inspection is scheduled to take place as well. Inspections of warehouses are covered under a different section of the Food Drug and Cosmetic Act.

The owner or the individual responsible for creating and maintaining the FSVP (e.g., a qualified individual) should be present for the inspection. If at the time of the inspection, the owner or the person responsible for creating or maintaining the FSVP is not available in person, he or she should be accessible by telephone. If another qualified entity performed FSVP activities on behalf of the importer, the importer may obtain records from their qualified individual during the inspection.

During the inspection, the investigator will review FSVP records for the product(s)/supplier(s) identified during the pre-inspection contact. They will ask questions and take notes to determine the adequacy of the FSVP records and may ask for copies of the records. They may also ask for labeling, if available, and take pictures.

The amount of time an inspection takes depends on the basis on which the inspection is being conducted, and what is observed during the inspection. The investigator will report their observations to the most responsible individual present during the inspection. The FDA encourages open dialogue among all parties throughout the inspection.

Please note: FSVP inspections may also take place remotely. Under section 1.510(b)(3), if requested in writing by FDA, the importer must send records to the Agency electronically, or through another means that delivers records promptly. This section provides the regulatory basis for conducting remote inspections. For a remote inspection, the FSVP records are reviewed by the investigator at a site other than the importer's premises.

Close of the Inspection

The inspection concludes with an exit interview with the most responsible individual onsite. If the investigator made significant observations during the inspection, they will provide those observations in writing (Form FDA 483a, FSVP Observations), and discuss corrective actions. Less significant observations found during the inspection will also be discussed during the exit interview. For more information about written inspectional observations, please see the **FDA Form 483 Frequently Asked Questions webpage.**

If the importer responds during the inspection by making corrections to issues pointed out by the investigator, the investigator will take note and collect evidence, if possible. If the deficiency is something that cannot be corrected during the inspection, the investigator should ask the importer about the corrective actions they plan to take. The FDA highly encourages the importer to provide a written response to the FDA within 15 business days following the inspection. The response should include newly created and updated records and evidence of corrections. During the exit interview, the investigator will also answer any additional questions regarding the inspection and next steps.

More information about FSVP can be found on www.FDA.gov/FSMA.

U.S. FOOD & DRUG ADMINISTRATION

FSVP.com

Foreign Supplier Verification Program

Foreign Supplier Verification Program (FSVP) 101 PART I

Filed in FDA, Foreign Suppliers by FdsImports .Com on July 19, 2022 • 0 Comments

FSVP Changes: DUNS Number Entry

Filed in FDA, Foreign Suppliers, Importers by FDAImports on July 7, 2022 • 0 Comments

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What is an importer verifying? All importers must verify the safety of the food they offer for importation. They must More //

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U.S. FOOD & DRUG ADMINISTRATION

WARNING: FSVP Importers, Time is Running Out

Filed in FDA, Foreign Suppliers, Importers by FDAImports on July 7, 2022 • 0 Comments

Beginning July 24, 2022, consistent with 21 CFR 1.509(a), food importers will be required to ensure that their valid, 9-digit DUNS number is provided in the Entity Number field. As an Importer, what does this mean for you and your operation? Simply put, without having a valid DUNS number entered at the time of entry, **YOUR ENTRIES WILL BE REJECTED!**

For each entry line of food subject to the Foreign Supplier Verification Program (FSVP), offered for importation into the United States, you must ensure that your name, electronic mail address, and Unique Firm Identifier (UFI) are all recognized as acceptable by the Food and Drug Administration (FDA) and are provided electronically when filing entry with Customs and Border Protection (CBP). With the rollout of the regulation, FDA issued guidance recognizing the DUNS number as the acceptable UFI for the FSVP regulation. The DUNS number, a nine-digit unique number, is assigned and managed by Dun and Bradstreet (D&B) and is location-specific.

Since the implementation of FSVP 5 years ago, FDA has utilized its Enforcement Discretion regarding the use of the UFI for fear of interfering with stopping trade. Working with CBP, an entity identification code “UNK” was developed and accepted as an “Entity Number Field” which could be used in place of a DUNS number.

Additionally, the DUNS number, which is location-specific, must correspond to your U.S. location. If you have multiple U.S. locations and, thus, multiple DUNS numbers, you may choose to provide the DUNS number that applies to the location at which you maintain your FSVP records. FDA investigators may conduct FSVP records reviews at the location associated with the DUNS number you provide to CBP at entry. For example, if you maintain your FSVP records at your corporate headquarters, you may choose to provide the DUNS number of your headquarters when you identify yourself

at entry as the FSVP importer. However, because the FSVP regulation allows importers to store records offsite if they can be retrieved and provided within 24 hours of request (see 21 CFR 1.510(b)(2)), you may instead provide the DUNS number for another of your locations. Once chosen, the same DUNS number should be used for all the importer's FSVP entries, to the extent the DUNS number is applicable to an entry line.

The DUNS number is available free of charge to all importers and can be obtained by contacting D&B by phone at 866-705-5711, via email at govt@dnb.com, or by visiting D&B's Websites at http://www.dnb.com/duns-number.html or https://fdadunslookup.com. Although a DUN'S number may be obtained within a few business days, in some circumstances it could take longer.

Consequences of non-compliance are easily avoidable. The regulatory specialists and attorneys at FDAImports and Benjamin L. England & Associates, LLC have the substantive expertise needed to develop compliant FSVP procedures for your operation. Please feel free to contact us or call us at 410.220.2800.

Additional Information may be found:

Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation

This blog/post is provided for informational and educational purposes only and does not constitute legal advice, and is not intended to form an attorney-client relationship. Please contact your regular Benjamin L. England & Associates, LLC attorney contact for additional information.

Consequences of FSVP Non-Compliance…

Filed in FDA, FSMA, Importers by FDAImports on May 18, 2022 • 0 Comments

Did you know that your imported entry of food can be refused admission into the United States if it appears that you failed to comply with the requirements of the Foreign Supplier Verification Program (FSVP)?

Over the course of the last five years, FDA's mantra has been "educating while regulating" while using its discretionary enforcement authority. However, we have recently observed that the educational tone has taken a marked shift towards one of an enforcement-guided nature. During an FDA FSVP inspection, the investigator obtains evidence documented with the

issuance of an FDA Form 483a entitled “FSVP Observations.”

Just as with other types of FDA inspections, there is an enforcement progression with all FDA FSVP inspections starting with the inspection classifications as noted in FDA’s Field Management Directive (FMD) # 86:[1] No Action indicated (NAI)-If the supervisory investigator concludes that no objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action, an Inspection Conclusion of No Action Indicated (NAI) should be entered; Voluntary Action Indicated (VAI)-If significant objectionable conditions and practices were observed, but the District is not prepared to take or recommend any regulatory action, the supervisory investigator should then assign the District Decision of Voluntary Action Indicated (VAI); and Official Action Indicated (OAI)-If the significant, objectionable conditions or practices warrant a Warning Letter or other regulatory actions listed below in the Regulatory Actions (Advisory, Administrative, or Judicial) section, the Supervisory Investigator will enter the District Decision, Official Action Indicated (OAI).

With the Food Safety Modernization Act (FSMA) signed into law, Congress’s intent was made quite clear. Specifically, FSMA requires each importer of food to perform certain risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is produced in compliance with the requirements regarding hazard analysis and risk-based preventive controls of human and animal foods and standards for produce safety; and that the food is not adulterated or allergen misbranded. Complying with the request of Congress, the FDA added that refusal of admission can be a consequence if an importer fails to comply with FSVP requirements. In addition, FSMA further amended the Federal Food, Drug & Cosmetic Act to include Section 301(zz), which, in pertinent part, states that, *“*…importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under the law.

To assist in the uniform enforcement of these requirements, FDA drafted and implemented Import Alert 99-41, “Detention Without Physical Examination of Human and Animal Food Imported from a Foreign Supplier by an Importer who is not in compliance with the requirements of the Foreign Supplier Verification Program (FSVP) Regulations.” Specific food or foods from a specific foreign supplier may be included on a red list to identify the food or foods subject to the Import Alert when imported or offered for import by the identified importer. Often added to these alerts are those importers who are “blatantly disregarding” the regulatory requirements, something which FDA investigators are well-trained to

identify.

These consequences are easily avoided by implementing a written Foreign Supplier Verification Program. **Are you in compliance?** The regulatory specialists and attorneys at FDAImports and Benjamin L. England & Associates, LLC have the substantive expertise needed to develop compliant FSVP procedures for your operation. Please feel free to contact us or call us at 410.220.2800.

[1] FMD 86: Establishment Inspection Report Conclusions and Decisions https://www.fda.gov/media/87643/download

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FSVP – Five Years After Roll Out, Importers Receive A Failing Grade

Filed in FDA, FSMA, Importers by FdsImports .Com on May 18, 2022 • 0 Comments

It has been nearly five years since FDA began inspections under the Food Safety Modernization Act's (FSMA) Foreign Supplier Verification Program (FSVP) regulations. Based on inspectional data from FDA's Data/Compliance Dashboard for the last three years (2019-2022 YTD) FDA has conducted 1,645 FSVP inspections, of which only **17 inspections** were found to comply with FSVP regulations – *equaling a compliance rate of 1%*… Giving the importing community a **failing grade** for their compliance with FSVP!

As a result of the enactment of FSMA in 2011, Congress mandated that FDA create regulations for a food safety system focusing on prevention rather than reacting to problems after they occur. Among other things, FSMA outlines rules for Hazard Analysis Critical Control Points (HACCP), which are risk-based preventive controls for food facilities that manufacture/process, pack, and hold human and animal foods. These rules apply to domestic food producers and those in other countries who export to the United States.

Over the last several years, the FSVP regulation has negatively impacted most food importers. FSVP requires importers to be responsible for approving their own suppliers by verifying that they meet certain food safety standards. Other than a few exceptions, the FSVP importer (*i.e.,* the owner of the food at the time of importation) is required to develop, maintain, and follow a compliant FSVP for each food imported. FSVP compliance aims to ensure that food is produced in a manner that provides a specific level of

public health protection, including preventive controls, safety regulations, and that helps to ensure that the food is not adulterated or misbranded concerning allergen labeling.

Leading up to FSVP's implementation in May 2017, FDA was diligent in educating the industry on FSMA and the rules of importing affecting the importer community. The phrase "Educating while Regulating" was FDA's strategy during the first couple of years of FSVP roll-out, with the Agency using enforcement discretion alongside its industry education efforts. Now, however, FDA has ramped up its enforcement of these regulations, placing many importers on Import Alert. And such administrative actions can be catastrophic to businesses; once on an import alert, FDA will continue to detain the affected products until the manufacturer, shipper, grower, or importer proves to the satisfaction of FDA that the violation has been corrected.

Importer's FSVPs need to be in place and available for review upon request from FDA. During the last few years, we have seen changes in the Agency's enforcement strategy with the issuance of Warning Letters. In October 2019, the first firm was placed on Import Alert 99-41, "Detention without Physical Examination of Human and Animal Food Imported from an FSVP Importer Who is Not in Compliance with the Requirements of the Foreign Supplier Verification Program Regulation." Since that time many more have been issues and now there are currently 27 importers on this particular import alert alone.

Brian Ravitch, a Senior Regulatory Advisor with FDAImports, was instrumental in developing and implementing FSVP for the FDA. Mr. Ravitch has achieved a Level II certification in Seafood HACCP and is a Qualified Individual in Preventive Controls. Currently, he primarily concentrates on Import Compliance, Foreign Supplier Verification Program (FSVP), Seafood HACCP, and Hazard Analysis Risk-based Preventive Controls.

Brian and the staff at FDAImports have the knowledge and experience to help you meet FSVP requirements with the ultimate goal of compliance; if you have legal questions relating to FSVP, please contact us or call at 410.220.2800.

This blog/post is provided for informational and educational purposes only and does not constitute legal advice and is not intended to form an attorney-client relationship. Please contact your regular Benjamin L. England &

Associates, LLC attorney contact for additional information.

Now is the Time to Reevaluate Your Foreign Supplier Verification Program

Filed in FDA, Foreign Suppliers, FSMA, Importers by FDAImports on February 24, 2021

As an importer, once you have completed Foreign Supplier Verification Programs (FSVP) for each of your food items from your foreign suppliers, you can file away your documents until a time when the Food and Drug Administration (FDA) requests to conduct an inspection of your written program(s), right? …. Not so fast!

There are three regulatory requirements for when you should revisit your programs: review and documentation of your verification activities, reevaluation at a minimum of every three years, and when an event triggers a corrective action.

The following will walk you through FDA's requirements.

Based on the outcome of your hazard analysis and the evaluation of the identified hazards, you will be required to select appropriate verification activities and a frequency for which the activities are obtained. These activities include:

> Onsite audits as specified in paragraph (e)(1)(i) of 21 CFR § 1.506 – "What foreign supplier verification and related activities must I conduct?";
>
> Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;
>
> Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and
>
> Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

It is your responsibility upon receipt to **assess the activities** and **document in writing** the outcome. The written documentation will be a record maintained within your program.

Reevaluation of a foreign supplier's performance and the risk posed

by a food.

As indicated in 1.505(c)(1), you must promptly reevaluate your Foreign Supplier Verification Program when you become aware of new information about factors that may change the foreign supplier's performance or the risk posed by the hazards of the food.

At a minimum, you must reevaluate your programs at least every three years.

Factors that may trigger a reevaluation include:

1)Changes in the hazard analysis of the food, including the nature of the hazard requiring a control. As stated in 1.504(c)(3), this may include:

The formulation of the food;

- The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of 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; and
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

2)Any changes within the supply chain that significantly minimize or prevent the hazards requiring a control or verifying that such hazards have been substantially minimized or prevented. This may be the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

3) Foreign supplier performance, including:

The foreign supplier's procedures, processes, and practices related to the safety of the food;

- Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance, including FDA warning letter, import alert, or other FDA compliance action related to food safety;
- Noncompliance with the relevant laws and regulations of a country whose food safety system FDA has officially recognized

as comparable or determined to be equivalent to that of the United States; and

- The foreign supplier's food safety history, including violative food testing results, non-conformities based on audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

4) Any other factors as appropriate and necessary, such as storage and transportation practices, which would affect the safety of the imported food.

What corrective actions must I take under my FSVP?

You must take prompt appropriate corrective actions if you determine that a foreign supplier of the food you import:

Does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under Hazard Analysis and Risk-Based Preventive Controls or Produce Safety, or

Produces food that is adulterated or misbranding due to failure to provide labeling for the presence of major food allergens (this does not apply to animal food).

Your determination that you need to take corrective actions could be based on:

The foreign supplier verification activities;

A reevaluation of the foreign supplier's performance and the risks posed by the food that you conduct;

Reviewing consumer, customer, or other complaints related to food safety;

Monitoring FDA compliance action information (e.g., import alerts, warning letters); or

Any other relevant information you obtain, such as recalls or product withdrawals.

Examples of appropriate corrective actions will depend on the circumstances but could include:

Notifying the foreign supplier of the problem and requesting documentation of corrective actions taken by the foreign supplier.

Assisting the foreign supplier's efforts to correct and prevent recurrence of the problem.

Revising your FSVP.

Discontinuing use of the foreign supplier until the cause or causes of

noncompliance, adulteration, or misbranding are adequately addressed.

Regardless of the outcome, you must document any reevaluations, investigations, corrective actions, and changes to your FSVP.

During the roll-out of FSVP, FDA initiated guidance to the Field Investigators to “educate the importers” as they conduct the inspections. After a couple of years, the FDA continued to see large numbers of noncompliance. Most importers were written up for not having any program in place.

Due to excessively high numbers of noncompliance, FDA elevated their enforcement activities. This includes conducting second inspections of non-compliant importers, issuance of warning letters, and placing importers on Import Alerts. What does this mean for you? **Under FDA’s authority, your non-compliant food can be refused from entering the United States.**

Below are important questions to consider if you are an importer of food.

Question: How can I avoid disruptions to my importations?

> **Answer:** Develop a Foreign Supplier Verification Program through the assistance of an outside Qualified Individual.

Question: What do I do when I have received notification of an inspection?

> **Answer:** We can conduct a mock inspection and assess your program to ensure compliance. This can also include representation as your Qualified Individual during your inspection.

Question: What do I do when I have received a Form FDA 483a, FSVP Observations, or FDA Warning Letter?

> **Answer:** Please do not delay. It is not too late to respond and move forward with compliance.

If you need help understanding your FSVP obligations or with any of your importing needs, please contact us and get professional advice from our consultants and affiliated attorneys.

** This blog was written by Brian Ravitch, an affiliated consultant with FDAImports.com. He has had a 39-year career in the Federal Government, during which he served as a Subject Matter Expert instrumental in the

development and implementation of FSVP.

FDA Issues First Warning Letter for Failure to Comply with FSVP

Filed in FDA, FSMA, Importers by FDAImports on August 13, 2019

FDA issued their first Warning Letter to an importer for not complying with the Foreign Supplier Verification Program (FSVP) that was introduced 8 years ago with the Food Safety Modernization Act (FSMA).

For this first Warning Letter, FDA selected a food importer that was associated with an outbreak of foodborne illness. In May of this year (2019), a *Salmonella* outbreak was identified as originating from tahini products imported by Brodt Zenatti Holding. Following current practices, FDA, Center for Disease Control (CDC), and state health officials worked together to identify the outbreak's source and remove the product from the market. This led to Brodt Zenatti (the importer) issuing a recall and voluntarily ceasing to import the product.

Beyond the recall, FDA conducted an FSVP inspection of the importer only to identify that they needed to "develop an FSVP for sesame paste tahini manufactured by Karawan Tahini and Halva in the West Bank." When FDA completed the inspection, they issued a Form 483 observing this violation of the Food, Drug, and Cosmetic Act. The importer never responded and thus FDA issued a public Warning Letter.

Noticeably, the importer failed to respond to FDA's Warning Letter and

voluntarily resolve the issue. FDA has threatened to place the importer on a new import alert, which lists companies that fail to comply with FSVP. Once an importer is placed on this list, FDA will not allow it to import the covered food product until the importer has resolved the violation (which we discussed more here).

With this first Warning Letter, FDA is seeking to connect failing to comply with FSVP and the risk of violative products entering the food supply, which could cause illnesses and injury. Attorney John Johnson explains, "this Warning Letter is also a cautionary tale for importers, if their products are associated with a recall, especially one involving illnesses or injuries, FDA will conduct an inspection of the FSVP program to ensure its existence and implementation."

This represents the beginning shift away from "educate while you regulate" to traditional regulation and enforcement.

If you need help understanding your FSVP obligations or with any of your importing needs, please contact us and get professional advice from our consultants and affiliated attorneys.

Coming Soon: FSVP Enforcement?

Filed in FDA, FSMA by FDAImports on August 6, 2019

Last week the Food and Drug Administration (FDA) took a critical step towards enforcement of FSVP by creating Import Alert 99-41, "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation." To date, FDA has not taken any enforcement action against an importer for not complying with the regulations, which first went into effect May of 2017. However, that may change soon.

Under the law, food imported by an importer who does not comply with FSVP may be refused admission into the United States. An import alert is

an administrative enforcement tool that FDA uses to issue an import refusal. It is an internal directive that the local FDA office should detain (stop) an imported product because it appears to violate an FDA requirement and, after a hearing, issue an import refusal unless the importer overcomes the appearance of a violation. In this case, it means that an importer may not be able to successfully import food until the alert is lifted.

It remains unforeseen when FDA will place the first importer on Import Alert 99-41, thereby taking the first enforcement action. However, now with the import alert created, it is only a matter of time.

If you need help understanding your FSVP obligations or with any of your importing needs, please contact us and get professional advice from our consultants and affiliated attorneys.

So it Begins: FSVP Inspections

Filed in FDA, FSMA by FDAImports on September 7, 2017

FDA has begun inspecting U.S. food importers for their compliance with the

Foreign Supplier Verification Program (FSVP). The FSVP regulation has a staggered compliance date between May 30, 2017 through July 27, 2020 (depending on the food type and the foreign supplier's size). Those subject to that first compliance date may soon be inspected by FDA, if not already.

It is our understanding that these first inspections are part of an "educate while regulate" paradigm discussed by Sharon Mayl and others, during which FDA has their regulatory "hammer put away. Thus FDA is pre-announcing the inspections and spending additional time explaining the rules and the Agency's expectations. While the hammer is away, importers must take these inspections seriously as first impressions are long lasting in that they set the tone with FDA.

We have been working closely with our clients to understand the regulation, establish a robust FSVP protocol, and counsel them on how to make a good lasting first impression. FDAImports.com is pleased to report that the FSVP plans we have helped clients put into place are receiving very favorable comments from FDA's inspectors with only minor suggestions for improvements. When asked about this outcome John F. Johnson III, our lead FSVP authority replied, "one of many important keys to getting control of the inevitable FDA inspection is to not copy and paste the foreign food supplier's hazard analysis and substantive preventative controls into the FSVP protocol. You must make the hazard analysis your own, and understand the preventive controls. This is to seek to prevent the inspection from turning into a proxy inspection of the foreign supplier and their technical application of HARPC (Preventive Control Rule), and not about your FSVP operations."

For help setting up your FSVP and staying compliant with the FDA contact us today!

FSVP: Understanding FDA's Foreign Supplier Verification Plan

Filed in Foreign Suppliers, Importers by FDAImports on May 2, 2017