

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

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

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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

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

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

- 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

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

- 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)
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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.

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

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**

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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
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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

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

- 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)

- Onsite audit
 - 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**

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

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

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- 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)

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

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)