

LUNCH & LEARN WEBINAR SERIES

How does the Foreign Supplier Verification Rule Apply to the Produce Industry

July 10, 2019



WEBINAR LOGISTICS

- Everyone is muted.
- Questions will be addressed during the Q&A session at the end of the presentation.
- This presentation is being recorded.
- The recording/slides will be available to WG members only.
- Adjourn (60 minutes).
- There will be 3 important survey questions at the conclusion of this webinar. Your responses will be appreciated.

Presenter



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What we will cover...

- Welcome
- FSVP Key Requirements
- FDA's Draft FSVP Guidance
- Questions

Purpose of the FSVP Rule

- To ensure that imported foods meet the same level of food safety standards that are required of food produced in the U.S.
 - Foreign suppliers produce food using processes and procedures that provide the same level of public health protection as the FSMA Preventive Controls or **Produce Safety** requirements.
 - Food is not adulterated under the FD&C Act or misbranded due to undeclared allergens (*allergens for human food only*).
- FSVP requirements are risk-based (according to types of food, types of hazards, and supplier performance).
- The U.S. importer now has a responsibility of verifying that its foreign suppliers are doing what they need to do to meet those requirements.

Who Is an “Importer” Under FSVP Rule?

- **Definition:** “*Importer* means the U.S. owner or consignee of an article of food that is being offered for import into the United States...” [21 CFR Part 1, Subpart L, 1.500 Definitions]
 - Note that the term “**U.S. owner or consignee**” is also defined separately in the FSVP rule as “**the person in the United States who, at the time of the U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.**”

Who Is an “Importer” Under FSVP Rule? (continued)

- “...If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.” [21 CFR Part 1, Subpart L, 1.500 Definitions]

Importer is referred to as a “person”, it means an individual, a company, or other entity

The Hardest Step is Determining Who Will Be the FSVP Importer

- Often, more than one entity will meet the FDA definition of “importer” for FSVP purposes.
 - The FSVP “importer” must be someone in the U.S. and meet the definition of FSVP importer.
- Entities that meet the definition of FSVP “importer” will need to decide among themselves:
 - Who will agree to be identified as the FSVP importer for a particular food/foreign supplier, and
 - Thus, be responsible for carrying out FSVP obligations.

FSVP Standard Requirements

- Conduct a **hazard analysis** of the food, including hazard identification and hazard risk evaluation (biological, chemical and physical hazards).
- Conduct an **evaluation** of the foreign supplier's food safety performance and risk posed by the food.
- **Approve** the foreign supplier (based on above evaluations).
- Establish written procedures to ensure that food is imported only from approved foreign suppliers.
- Determine and apply appropriate **verification activities** and assess results.
- Implement **corrective action(s)**, if needed.
- **Reevaluate foreign supplier** (at least every three years or when there is a reason to do so).
- **Identify the FSVP importer** at entry (CBP filing).
- Keep required **records and documentation**.

Wallet Card

Compliance Dates for FSVP Importers Importing Produce

FSVP importer whose foreign supplier is not subject to the produce safety rule, i.e. produce that is rarely consumed raw:
May 30, 2017:

FSVP importer whose foreign supplier is required to comply with the produce safety rule. Compliance dates when foreign suppliers are in these categories:

- Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
- Very Small Businesses as defined in as defined in 21 CFR 112.3: **July 27, 2020**
- “All Other” Businesses: **July 26, 2018**

FDA's Draft FSVP Guidance for Industry

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry *Draft Guidance*

This guidance is being distributed for comment purposes only.

Although you can submit comments on any guidance at any time (see 21 CFR 10.115(g)(2)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 120 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2017-D-5225 listed in the notice of availability published in the *Federal Register*.

For questions regarding this draft document, contact the Office of Compliance, Center for Food Safety and Applied Nutrition (CFSAN), at 240-701-5986 (regarding human food), or the Office of Surveillance and Compliance, Center for Veterinary Medicine (CVM), at 240-402-6246 (regarding animal food).

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

January 2018

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-foreign-supplier-verification-programs-importers-food-humans-and-animals>



FDA's Draft FSVP Guidance for Industry

A.5.Q: What if multiple entities meet the definition of “importer” for a particular food?

A: In some cases there might be multiple entities that meet the “importer” definition for the same line of an entry of food offered for import into the U.S.

When there are multiple entities that meet the “importer” definition, these entities will need to determine who will be responsible for meeting the FSVP requirements for the food (and, consequently, who should be identified as the importer of the food at entry).



FDA's Draft FSVP Guidance for Industry

A.14 Q: May a foreign owner or consignee of a food lawfully designate me as their U.S. agent or representative for purposes of FSVP compliance without my knowledge?

A: No. If the foreign owner or consignee of a food designates you as the U.S. agent or representative for FSVP purposes, the designation is not valid unless you confirm in a signed statement that you have consented to serve as the FSVP importer (21 CFR 1.500). We may review the signed statement during a records review to verify the accuracy of the U.S. agent or representative designation. False representations to the U.S. government, including falsely identifying a U.S. agent or representative, may result in criminal prosecution of those involved.

In accordance with section 805(g) of the FD&C Act, we will maintain on our Web site a list of importers subject to the FSVP regulation, using information we obtain through importers' compliance with the importer identification requirements in section 1.509. If you discover, by reviewing this list or otherwise, that you have been inappropriately designated as the FSVP importer, you should contact the Agency.



FDA list of FSVP Importers

- FDA has published an inventory of FSVP importers on FDA's website:

<https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm597095.htm>

- PDF List contains firm names and state



FDA's Draft FSVP Guidance for Industry

A.11 Q: Is the importer, as defined in the FSVP regulation, the same person as the Importer of Record recognized by CBP for import entry?

A: The importer of a food for purposes of FSVP may be, but is not necessarily, the importer of record for CBP purposes. Under the FSVP regulation, the importer is the person who is responsible for verifying that the imported food was produced in accordance with applicable U.S. food safety requirements.

In contrast the CBP importer of record of a food might be an express consignment operator with little to no knowledge of the safety regulations applicable to the products for which they obtain clearance from CBP.



Who could be an FSVP Importer?

- An entity in the U.S. that meets the definition of an FSVP Importer could be:
 - The Importer of Record
 - Manufacturer/Processor
 - Retailer
 - Broker
 - Distributor
 - Consolidator



FDA's Draft FSVP Guidance for Industry

A.16 Q: Who is the foreign supplier of food?

The foreign supplier a food is the establishment that **manufactures / processes the food, raises the animal, or grows the food** that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing / processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature (21 CFR 1.500).

...if you obtain oranges from a packing house that only packs and holds the oranges (and does not perform manufacturing/processing on the oranges of more than a *de minimis* nature), the foreign suppliers would be the farms that grew the oranges.



FDA's Draft FSVP Guidance for Industry

A.17 Q: May an entity that only packs or holds a food be a foreign supplier?

A: No. Although an establishment that only packs or holds food might be a food facility that is required to register with FDA under section 415 of the FD&C Act, it is not a foreign supplier (21 CFR 1.500).

Packing, cooling, and holding performed by a packing house (that only packs and holds produce and cools the produce incidental to packing and holding) would not make the packing house the foreign supplier, because these activities would not be considered manufacturing/processing but only packing and holding.

Waxing, sorting, culling, conveying, and storing of raw agricultural commodities (RACs) would generally be considered packing or holding. Re-packing is a packing activity (i.e., the definition of packing includes re-packing), not a manufacturing/ processing activity.



FDA's Draft FSVP Guidance for Industry

B.2 Q: What does it mean to have an FSVP for “each food?”

A: You must establish an FSVP for each food you import from each of your foreign suppliers. You do not need to establish a separate FSVP for different versions of the *same food* from a single foreign supplier when the differences in the foods do not result in different hazards requiring a control.

Your FSVPs must be specific to *each foreign supplier* of a food. Thus, if you obtain a food from multiple foreign suppliers, you must have a separate FSVP for each supplier. This is appropriate because the FSVP regulation requires you to consider not just hazards inherent in the food you import, but also your foreign suppliers' processes and procedures as well as their compliance and performance history.



FDA's Draft FSVP Guidance for Industry

D.7 Q: What is meant by “type of food” for the purpose of conducting a hazard analysis?

A: You must conduct a hazard analysis for each type of food you import that is subject to the FSVP regulation. “Type of food” refers to foods that are similar and for which the same hazards are known or reasonably foreseeable...

...However, it would not be appropriate to use the same hazard analysis for foods that, though similar, have different hazards requiring control (unless you clearly identify in your hazard analysis what those differences are). For example, if two foods are grown, harvested, and packed under the same conditions, and one food is susceptible to a certain microbiological hazard but the other food is not, it would not be appropriate to use the same hazard analysis for both foods.



FDA's Draft FSVP Guidance for Industry

D.12 Q: What hazard analysis must I conduct for a RAC that is a fruit or vegetable?

A: For your hazard analysis for a RAC that is a fruit or vegetable and is “covered produce” (as defined in 21 CFR 112.3) subject to the produce safety regulation, you are not required to determine whether there are any biological hazards requiring a control. The biological hazards in such fruits or vegetables require a control, and the produce safety regulation establishes requirements to significantly minimize or prevent these hazards.

Under the FSVP regulation, you must determine whether there are any other types of known or reasonably foreseeable hazards (i.e., non-biological hazards) requiring a control in such fruits or vegetables (e.g., chemical hazards such as pesticide residues and physical hazards such as stones and other field debris) (21 CFR 1.504(e)).



FDA's Draft FSVP Guidance for Industry

C.1 Q: Who must develop and perform activities required for my FSVP?

A: A qualified individual as defined in 21 CFR 1.500 must develop your FSVP



Who Is a “Qualified Individual”?

- Food importers are required to do a number of things that can only be done by persons who meet the definition of “*qualified individual*.”
- **Definition:** An FSVP “*qualified individual*” is “a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required” by the FSVP rule, “and can read and understand the language of any records that the person must review in performing this activity... .”
- Qualified individual does not have to be a Preventive Controls Qualified Individual (PCQI)
- Qualified individuals may be, but are not required to be, employees of the importer.
- Qualified auditors are qualified individuals for conducting audits (audits are an example of a verification activity).

Required Tasks Must Be Done by a Qualified Individual

REQUIRED TASKS

- Conduct a **hazard analysis**
- Conduct an **evaluation** of the foreign supplier's food safety performance and risk posed by the food
- **Approve** the foreign supplier (based on above evaluations)
- **Establish written procedures** to ensure that food is imported only from approved foreign suppliers (with limited exceptions)
- Determine and apply appropriate **verification activities** and assess results
- Implement **corrective action(s)**, if needed
- **Reevaluate foreign supplier verification program** (at least every three years or when reason to)
- Keep required **records and documentation**

QUALIFIED INDIVIDUAL

WHO?

WHO?

WHO?

WHO?

WHO?

WHO?

WHO?

WHO?



FDA's Draft FSVP Guidance for Industry

F.8 Q: What foreign supplier verification activities may be appropriate?

- **Audits,**
 - Audits are the default verification activity for a **Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA)** hazard, but another verification activity may be chosen, if adequate,
- **Sampling and testing,**
- **Review of foreign supplier records** that demonstrate production of safe food, and
- **Other** appropriate verification activities for known or reasonably foreseeable hazards requiring a control.



What If You Choose Onsite Audits?

- Your audit must consider all FDA food safety standards that the food is subject to.
- The audit must be performed by a **qualified auditor**.
- The qualified auditor can be a government employee—U.S. or foreign—or a private entity.
- A review of the supplier's written food safety plan, if any, and its implementation **must be included**.

How Do I Document My Onsite Audit?

- You must retain documentation of each onsite audit.
- Documentation must demonstrate that your supplier is using **processes and procedures that control the hazards requiring a control.**
- Include in documentation:
 - Audit procedures,
 - Qualification of the auditor,
 - Dates the audit was conducted,
 - The conclusions of the audit, and
 - Any corrective actions taken in response to noted deficiencies.

Will GFSI certificate from each of my suppliers be good enough to meet the FSVP Audit Requirements?

FDA Draft Guidance F.15 Q:

...Before relying on the results of a third-party onsite audit, you should determine whether the auditing scheme used can help you conclude whether the supplier uses processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety provisions of the **FD&C Act** (and the implementing regulations), as well as provide adequate assurances that the food is not adulterated or misbranded with respect to allergen labeling.



What If You Choose Sampling and Testing?

- You must retain documentation of each sampling and testing of a food, including:
 - Identification of the food tested and the number of samples,
 - The tests conducted (including the analytical methods(s) used) and the dates conducted, and
 - The results of the tests and any corrective actions taken.
- Retain documentation identifying:
 - The laboratory conducting the testing, and
 - That the testing was conducted by a qualified individual.

Is FSVP training required under the regulation?

- The FSVP rule does not require you to attend a training program following a “standardized curriculum” recognized by FDA.
- The FSVP rule does require a “qualified individual” to perform each of the activities under the rule and specifies that a “qualified individual” is a person who has the education, training, or experience (or combination thereof) necessary to perform each of the required activities.



Are there resources to develop an FSVP?

- Food Safety Preventive Controls Alliance (FSPCA) FSVP Training Courses
- FSPCA's Work Aids (forms)
- FDA's Draft FSVP Guidance for Industry



FSPCA FSVP Curriculum

- This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA.
- Taking this course is not required by the regulation.
- Successfully completing this course will:
 - Help you to understand the FSVP requirements, and
 - How those requirements can be met in your particular circumstances.

FSPCA Work Aids are available on FSPCA's website

<https://www.ifsh.iit.edu>

Determining FSVP importer

<https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSVP-WorkaidA.PDF>

Hazard Analysis Form

<https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSVP-WorkaidD.PDF>

Supplier Evaluation Form

<https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSVP-WorkaidE.PDF>

Supplier Verification Activities Worksheet

<https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSVP-WorkaidF.PDF>

Supplier Reevaluation Form

<https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSVP-WorkaidG.PDF>

Who is conducting FSVP Inspections? Have they started?

- FDA initiated inspection program June 2017
- Preannounced inspections
- Evaluating compliance with the FSVP requirements



FDA FSVP Inspections of Importers

FDA may:

- Conduct an onsite inspection of records.
- Request electronic submission of your records:
 - May be delivered by other means, if done promptly.
 - FDA review of these records is the same as an onsite inspection.
- Request that records kept offsite be made available within 24 hours.
- Request that some records be translated into English within a reasonable time.

What to Expect During an Inspection

- Generally FDA does not give advanced notice that it is about to carry out an inspection.
- FDA will present a formal “Request for FSVP Records” (Form FDA 482d)
- You should expect that FDA will:
 - Review all of the different types of documentation that relate to your compliance with the FSVP rule.
 - Look at your records to determine whether you have maintained them in compliance with FSVP requirements.
 - Request copies of some of your records.
- FDA will provide you with "FSVP Observations" (Form FDA 483a) that will describe any deficiencies in compliance.

FDA FSVP Top Inspection Observations

- Failure to have FSVP
- No written hazard analysis
- No written procedures to ensure imported products are from approved suppliers
- Failure to document approval of foreign supplier
- Failure to document Qualified Individual's reviews
- Failure to document determination of verification activities
- Incorrect entry data



FDA's Technical Assistance Network

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question?

[Start Here](#)

The Technical Assistance Network staff has compiled answers to [frequently asked questions on FSMA](#). You may also use [FSMA Guidance Documents](#) to find answers to your questions.

Submit Your Question Electronically

Didn't find your question above? Please [submit your question](#)  to TAN for assistance.





Questions

Q: If I grow avocados in Peru, bring them to the US, sell part of them as fresh whole avocados and part for guacamole?

Are only the fresh whole avocados subject to the FSVP regulation?

How does a commercial processing exemption affect requirements under the FSVP?

FDA Draft Guidance B.10 Q:

It depends...if you are a receiving facility for the food you import and you are in compliance with the supply chain requirements of the preventive controls for human food regulation (21 CFR part 117, subpart G)...

Foods Received and Processed by Importers Who Are Subject to PC Rules

- If you are an importer who is also a processor/manufacturer **subject to and in compliance with the supply chain provisions of the PC rules:**
 - You are deemed to be in compliance with most of the FSVP requirements for the food you import, and
 - You do not have to carry out most of the FSVP requirements.
- **However, as the importer:**
 - You **must** be named on the Customs and Border Protection (CBP) entry filing as the importer in accord with the FSVP rule.

Q: I only distribute fresh produce and do not do any processing or packing, I import about \$20,000 in produce/year (including tomatoes and avocados), most of the produce I distribute are grown in the U.S. Am I subject to this regulation?

FDA Draft Guidance L.2 Q:

Regardless of whether you import human food, animal food, or both, you must consider all your food sales, not just sales of the food you import and not just sales to the United States.

Q&A Session

Questions or Comments?

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