FSPCA WEBINAR

FDA Foreign Supplier Verification Programs (FSVP) Guidance Overview

March14, 2023

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

WELCOME AND INTRODUCTIONS

Juan Silva

FSPCA Trainer of Trainers

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Agenda

Description	Presenter/Moderator	Time
Housekeeping	Juan Silva	1:00 – 1:05 PM CT
FSPCA News	Juan Silva	1:05 – 1:15 PM CT
FDA FSVP Final Guidance Overview	Kevin Kwon	1:15 – 2:15 PM CT
Q&A	All	2:15 – 2:30 PM CT

Webinar Presentation and Recording

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  - A PDF of the webinar presentation
  - A link to a recording of the webinar
    - You will be required to register to view the webinar
    - The webinar recording is **view only**, download is not available

- Please allow up to 3 business days for the presentation and recording to be published

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Q&A

- All attendees are muted
- Ask questions by typing into the chat box
  - Click on the chat icon
  - To pose a question, begin typing in the chat box that is provided on the screen and click "send"
  - Your question will be sent to the moderator of the webinar
    - We will do our best to answer as many questions as time allows but we may not be able to address every question

FSPCA UPDATES

Juan Silva
FSPCA Trainer of Trainers


FSPCA®
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OCTOBER 17-18
2023 ANNUAL CONFERENCE
Building Global Food Safety Capacity through Education, Training and Outreach

SAVE THE DATE! FSPCA 2023 ANNUAL CONFERENCE

- Tuesday, October 17 – Wednesday, October 18, 2023
  - Day 1: 12:00 – 5:00 PM U.S. Central
  - Day 2: 8:00 AM – 3:00 PM U.S. Central
- We are excited to announce this year's Conference will be

  IN-PERSON!
- We are working to secure a venue in the Chicagoland area
- More information coming soon:
  - Agenda
  - Venue
  - Registration Fees

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Upcoming **FREE** FSPCA Webinars

- March 27, 2023: FDA Food Traceability Rule Overview
  - Registration closed
- April 27, 2023: How to Use FSPCA Food Safety Plan Teaching Examples
  - Open to Preventive Controls for Human Food Lead Instructors
  - Registration opening soon
- May 25, 2023: FSPCA FSVP Foreign Supplier Awareness Module
  - Open to the public
  - Registration opening soon

Reminder! A PDF of webinar presentations and link to webinar recordings will be posted on the FSPCA website: https://www.ifsh.iit.edu/fspca/fspca-webinars

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FDA Foreign Supplier Verification Programs (FSVP) Final Guidance Overview

Kevin Kwon, JD
Regulatory Counsel

CFSAN Office of Compliance
Compliance Policy Staff

Kevin Kwon

Kevin Kwon is a Regulatory Counsel within the Compliance Policy Staff in the Center for Food Safety and Applied Nutrition (CFSAN) and is policy lead for the Foreign Supplier Verification Program.

Prior to coming to CFSAN, Kevin worked on compliance policy issues at FDA's Center for Drug Evaluation and Research.

FSVP – Regulations and Guidances

- What do we do?
  - Compliance Policy Staff works on policy issues, particularly those relating to compliance policy affecting the Center. This includes developing regulations, guidances, and other internal policies within the Center relating to CFSAN areas of oversight.

- What is the difference between regulations and guidances?
  - Simply put, regulations are law and must be followed, while guidances represent Agency thinking about how to comply with the law. The guidance can provide helpful information about how to comply with the law but it is not legally binding.

- **Important Dates:**

  – Publication of the FSVP Final Rule* November 27, 2015

  – Publication of the Draft Guidance January 24, 2018

  – Publication of the Final Guidance January 10, 2023

* FDA codified the FSVP regulation at 21 CFR part 1, subpart L

Who Commented on the Draft Guidance?

General stakeholders (scientists, academia, consumers, etc.)

Importers and other food related associations (UFPA, IDFA, NGFA)

FDA Components (OC, ORA, CFSAN etc.)

* We received 21 comments via the Federal Register on the FSVP draft guidance.
* We also received comments and feedback via other source, including the FSMA technical assistance network or TAN and feedback from FDA staff.

Updates in the FSVP Final Guidance

Various sections:

- New questions added (focus of today's presentation)
  - Applicability of FSVP regulation and who can conduct FSVP
  - Territories and others
  - FSVP customer provisions and import admissibility
  - Other new ones that are frequently encountered by FDA
- Revised certain questions to provide clarity
- Removed duplicative information
- Combined certain questions for clarity
- Editorial changes and updates

Question Topics with Changes Based on the Guidance:

- A. To what foods does the FSVP regulation apply? (21 CFR 1.501)
- B. What FSVP must I have? (21 CFR 1.502)
- C. Who Must Develop my FSVP and perform FSVP activities? (21 CFR 1.503)
- D. What hazard analysis must I conduct? (21 CFR 1.504)
- E. What evaluation for foreign supplier approval and verification must I conduct? (21 CFR 1.505)
- F. What foreign supplier verification and related activities must I conduct? (21 CFR 1.506)

Question Topics with changes cont…

- G. 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? (21 CFR 1.507)

- I. How must the FSVP importer be identified at entry? (21 CFR 1.509)

- J. How must I maintain records of my FSVP? (21 CFR 1.510)

- K What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation? (21 CFR 1.511)

- L. What FSVP may I have if I am a very small importer, of I am importing certain food from certain small foreign suppliers? (21 CFR 1.512)

A. To What Foods Does the FSVP Regulation Apply?

A6: Can an entity who is not the FSVP importer assume the responsibilities for developing, maintaining, and following the FSVP.

No. The FSVP importer can identify the qualified individuals to perform certain FSVP activities on the importer's behalf-in some circumstances, provided that the importer conducts a required review and assessment of the individual's activities. But the FSVP importer is the entity with the responsibility for developing, maintaining, and following the FSVP regulation.

A21: Does FSVP apply when food is imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories?

FDA does not interpret the FSVP regulation to apply when food is imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other Territories that are outside the Customs territory of the United States. Therefore, FDA does not expect entities to have conducted FSVP activities or submit FSVP importer identification information when they import food into the U.S. Territories that are outside of the Customs territory of the United States. CBP defines "Customs territory of the United States" to include the 50 states, Puerto Rico, and the District of Columbia. (See 19 CFR 101.1)

Although FDA does not interpret the FSVP regulation as applying when food is imported into the Territories that are outside the Customs territory of the United States, we note that such food is still subject to other FDA food safety requirements because the FD&C Act applies to Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories.

We also note that the FSVP regulation requires the importer to ensure that their importer identification is provided "when filing entry with United States Customs and Border Protection." (See 21 CFR 1.509(a)) This mechanism is generally not available when food is imported into Territories that are not part of the Customs territory of the United States.

- **A22: Does FSVP apply when food is imported into Puerto Rico and the District of Columbia?**

- A: Yes. Puerto Rico and the District of Columbia are not States, but they are part of the Customs territory of the United States. (See 19 CFR 101.1) FSVP requirements apply when food from foreign suppliers is imported into any part of the Customs territory of the United States, including Puerto Rico and the District of Columbia.

- **A23: Does FSVP apply when food is produced by a foreign supplier in a foreign country and then transhipped through Guam, the U.S. Virgin Islands, the Northern Mariana Islands, or other U.S. Territories into the Customs territory of the United States?**

- A: Yes. If a food is produced in a foreign country by a foreign supplier and it is only transshipped through the Territory, then it is subject to FSVP when it is offered for import. FDA will apply FSVP when it is imported into the Customs territory of the United States, even if it was transshipped through a Territory such as Guam. Transshipment of a food in this scenario involves shipment into and out of the Territory without the food undergoing any processing or use in the manufacture of another food. CBP entry is made for articles from the Territories when they arrive in the Customs territory of the United States, and FSVP importer identification required under 21 CFR 1.509(a) can be provided when filing entry with CBP at that time.

- **A24: Does FSVP apply when it is produced in the Territories and then shipped into the Customs territory?**

- No. If the establishment that manufactures/processes the food, raises the animal, or grows the food is located in the Territories of the United States, that entity is not a foreign supplier (see 21 CFR 1.500, defining foreign supplier as 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). Because such food is not produced by a foreign supplier and then exported to the United States, it is not subject to FSVP requirements. (However, if the manufacturing/processing that takes place in the Territories is of only a de minimis nature, there may still be a foreign supplier and the food could be subject to FSVP.)

Summary of FSVP in the Territories

- FSVP applies only when food is produced in foreign countries.
- FSVP does not apply when food is produced in foreign countries and shipped directly to a Territory that is outside the Customs Territory of the United States.
- FSVP does apply when food produced in a foreign country is transshipped via a Territory.
- This approach aligns with the purpose of FSVP as well as the practicality in that there is not easy way to administer FSVP when food enters the U.S. via Territories outside the Customs Territory.

B. What FSVP must I have?

- **B6: If I hire a contractor or consultant to perform an FSVP activity on my behalf (such as conducting the hazard analysis or performing supplier verification activities), would the contractor or consultant be considered "another entity"?**

- No. A qualified individual who is retained as the importer's contractor or consultant to perform FSVP activities is not considered to be "another entity".

C. Who Must Develop My FSVP and Perform FSVP Activities?

- **C8: Can a qualified individual be located outside of the U.S.?**

- Yes, the FSVP regulation does not require a qualified individual to be located in the U.S.

C. Who Must Develop My FSVP and Perform FSVP Activities?

- **C.14 Q: Can an importer continue to use a previously established third-party audit, involving the use of audits conducted by third-party auditors, for a program that was used by the industry prior to issuance of the FSMA food safety regulations?**

- FDA recognizes that many third-party audit programs were used as a business practice prior to the issuance of the FSMA regulations. The audits conducted under these programs were often based on food safety standards that were not necessarily consistent with FDA food safety requirements. Under the FSVP final rule, audits that are designed to fulfill FSVP requirements must consider applicable FDA food safety regulations (21 CFR 1.506(e)(1)(i)). To help the industry determine if particular audits adequately consider applicable FDA food safety standards (as required under 21 CFR 1.506(e)(1)(i)), we have developed templates that you may use to compare the standards used in a third-party audit to certain FDA food safety requirements. The templates can be found on the FDA website "Industry Resources on Third-Party Audit Standards and FSMA Supplier Verification Requirements." The templates are not required to be used. Importers may use other means to determine that audits meet the requirements of the FSVP regulation.

D. What Hazard Analysis Must I conduct?

- D22: Am I required to have a copy of the hazard analysis available during an FDA FSVP inspection?

- A: The FSVP regulation requires the hazard analysis to be written. (21 CFR 1.504(a)). You must keep records of the hazard analysis as an original record, true copy (e.g., scanned copy or other accurate reproduction of the original), or electronic record (21 CFR 1.510(a)). You must provide the records of your hazard analysis promptly to an authorized FDA representative, upon request, for inspection and copying (21 CFR 1.510(b)). We recommend that your records include enough detail to allow us to determine that the requirements of 21 CFR 1.504 have been met (e.g., that you identified all hazards requiring control).

E. What Evaluation for Foreign Supplier Approval and Verification Must I Conduct?

- **E13. How may I obtain information about the FDA compliance history of my foreign supplier?**

- There are a number of ways you can obtain information about the FDA compliance history of your foreign supplier. You can obtain information directly from your foreign supplier. In addition, you may use the FDA Data Dashboard to access and search publicly available information on FDA's website. The Data Dashboard is designed to support the understanding, accountability, and analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics. The datasets and data include the Inspections Database, Recalls, Import Alerts, and other selected data elements from the compliance and enforcement related information on FDA.gov.

F. What Foreign Supplier Verification and Related Activities Must I conduct? (21 CFR 1.506)

F.18 Q: If I import produce that has been consolidated from multiple farms, do I have to annually audit all of the farms?

A: When a hazard in a food will be controlled by the foreign supplier and is a SAHCODHA hazard, the default verification activity is to conduct an annual onsite audit before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)). If you are importing produce that is "covered produce" under the produce safety regulation (as defined in 21 CFR 112.3), the foreign supplier must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, the covered produce. Thus, if you are importing produce that is "covered produce," the default verification activity is to conduct an annual onsite audit of your foreign suppliers. This default applies irrespective of whether you source your food directly from your foreign suppliers, or from a consolidator. However, you can rely on the consolidator to arrange for qualified auditors to conduct the audits, provided that you review and assess the results of the audits and document your review and assessment (see Question F.28; 21 CFR 1.506(e)(2)(i)). You must document your review and assessment, including documentation that the audits were conducted by qualified auditors (21 CFR 1.506(e)(3))...

G. 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? (21 CFR 1.507)

G.8 Q: If I import a food for which an identified hazard will be controlled after importation and I disclose within documents accompanying the food that the food is not processed to control the identified hazard, could the food be subject to refusal of admission if FDA determines that the food is adulterated with the identified hazard?

A: As discussed in the previous questions, the FSVP regulation includes provisions that apply when an importer identifies hazards requiring a control ("identified hazard") but does not conduct supplier evaluation or verification activities for those hazards because the importer is relying on another entity in the distribution chain to provide the necessary control (see 21 CFR 1.507(a)(2)(i), 1.507(a)(3)(i), 1.507(a)(4)(i)). Under these provisions, the importer must provide a disclosure to inform entities in the distribution chain that the food has not been processed to control the identified hazard (see *id.*). The disclosure requirement does not replace or alter FDA's authority under section 801(a) of the FD&C Act, relating to refusal of admission of a food offered for entry that appears to be adulterated or misbranded. Rather, the disclosure requirement provides an alternative to the importer conducting supplier evaluation and verification steps by informing entities in the distribution chain that the food has not been processed to control the identified hazard. Therefore, when FDA determines that a food offered for import is adulterated or misbranded, FDA will not generally consider the importer's compliance with the disclosure requirement as sufficient evidence to overcome the appearance of the violation.

Continued…

- In addition, FDA does not view compliance with the disclosure requirement as a substitute for the information required under section 801(b) of the FD&C Act and 21 CFR 1.95 for reconditioning proposals to bring a product into compliance (e.g., by applying a “kill step” to a contaminated food). Under 21 CFR 1.95(a) - (b), applications for authorization to relabel or perform other action to bring the product into compliance shall contain detailed proposals for bringing the product into compliance and shall specify the time and place where such operations will be carried out and the approximate time for their completion. FDA has the authority to grant or deny an application to recondition. A disclosure provided in accordance with 21 CFR 1.507(a), by contrast, would only state that the accompanying food is not processed to control the identified hazard. Thus, a disclosure provided in accordance with 21 CFR 1.507(a) generally would not provide all of the information that FDA expects for reconditioning proposals. Therefore, when FDA determines that a food offered for import is adulterated or misbranded, FDA will generally not view a disclosure statement, in and of itself, as sufficient evidence to demonstrate adequate reconditioning. For importers that would like to recondition the food, FDA will continue to expect the submission of a reconditioning proposal to assure compliance. Reconditioning proposals are typically submitted using Form FDA 766 to the compliance officer listed on the Notice of FDA Action.

Customer Provisions and Import Admissibility

- Question on if disclosure statement could be used to import a product that is known to be adulterated.
- Issue is addressed for the first time in the final guidance.
- Final guidance makes it clear that compliance with the “customer provisions” has no bearing on whether a product appears adulterated for purposes of admissibility.

K. What FSVP Must I have if I am Importing a Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufacturing Regulation (21 CFR 1.511)

K31. What if I import dietary supplements and I meet the eligibility criteria to be a very small importer?

A. If you import dietary supplements and you meet the eligibility criteria to be a very small importer (see the definition of "very small importer" in 21 CFR 1.500 and the eligibility documentation requirements in 21 CFR 1.512(b)(1)(i)), you may choose to comply with the modified requirements for very small importers in 21 CFR 1.512 (see Section III.L of this document) rather than the requirements for importers of dietary supplements in 21 CFR 1.511.

L. What FSVP May I Have if I am a Very Small Importer or I am Importing Certain Food from Certain Small Foreign Suppliers? (21 CFR 1.512)

- **L.6: Which foods should I include in (and exclude from) the calculation of annual sales plus market value to determine my status as a very small importer?**

- To determine your status as a very small importer of human food, you should include all human food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of what U.S. food safety regulations the food is subject to. For example, you would include food manufactured under the preventive controls for human food regulation as well as food not subject to the preventive controls requirements (e.g., seafood, juice, LACF, and dietary supplements). Likewise, you would include RACs (such as produce (including produce subject to the produce safety regulation), grains, milk, and eggs) and products subject to the jurisdiction of the USDA (e.g., meat products for human consumption).

- To determine your status as a very small importer of animal food, you should include all animal food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates. This would include all animal food subject to the preventive controls for animal food regulation, as well as animal food that is not subject to those requirements. You would not include food intended for consumption by humans or other items that are not animal food.

- **L7: Can an importer that is an affiliate or subsidiary meet the definition of "very small importer" even if the parent company's annual sales exceed the very small importer threshold?**

- The sales of the importer, including all affiliates and subsidiaries, are included in the calculation for determining whether the very small importer threshold is satisfied (21 CFR 1.500). If the parent company owns or controls the importer, then the importer would be a subsidiary of the parent company. The importer would not consider the parent company a subsidiary, because the importer is not the entity that owns or controls the parent company. A subsidiary importer only includes the operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary importer. If the parent company is related to the importer by ownership or other means of control, the importer should consider the parent company an affiliate and include the parent company's annual sales in determining whether the importer meets the "very small importer" definition.

J. How Must I Maintain Records of My FSVP? (21 CFR 1.510)

- **J.9: Does FDA have FSVP templates or examples of FSVP records for importers to use?**

- No. FDA has not created FSVP templates or examples of FSVP records for importers; however, FSPCA does have FSVP Workaids – forms and worksheets that help an FSVP Importer develop a Foreign Supplier Verification Program
  - **FSPCA Workaid A:** Determining the FSVP Importer
  - **FSPCA Workaid D:** FSVP Hazard Analysis Form
  - **FSPCA Workaid E:** FSVP Foreign Supplier Evaluation Form
  - **FSPCA Workaid F:** FSVP Foreign Supplier Performance/Food Product Approval Worksheet
  - **FSPCA Workaid G:** FSVP Foreign Supplier Reevaluation Form

M. What FSVP May I Have if I Am Importing Certain Food from a Country with an Officially Recognized or Equivalent Food Safety System? (21 CFR 1.513)

M4: Do the modified FSVP requirements apply to all foods from a country with an officially recognized or equivalent food safety system?

No. The modified FSVP requirements apply only to food that is not intended for further manufacturing or processing. This includes packaged food and RACs that will not be commercially processed further before consumption. For example, the modified FSVP requirements may apply if you are importing fresh apples that are intended to be sold to consumers in a raw, unprocessed state. However, the modified requirements would not apply if you import frozen apple pieces that are to be used as an ingredient in the commercial production of apple pies. In addition, a systems recognition arrangement or equivalence agreement with a foreign country may cover only certain types of foods. The modified FSVP requirements apply only to foods not intended for further processing that are within the scope of such arrangement or agreement (see Question M.3).

Resources to FSPCA Lead Instructors

- FSVP Final Guidance
- FSMA FSVP Final Rule and Resources
- Frequently Asked Questions on FSMA | FDA
- FSVP Records Requirements for Standard and Modified Requirements
- FSVP Compliance Program
- Conducting Remote Regulatory Assessments

Thank you!

Coming Up Next

Q&A

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Questions?

If you have any questions,
please contact the FSPCA at
fspca@iit.edu
or or visit the FSPCA website at
fspca.net
for resources on preventive controls, lead instructor applications, and details of other FSPCA activities.

THANK YOU!

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