EAS Consulting Group

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Review of FSVP Guidance for Industry

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June 22, 2023

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Review of FSVP Guidance for Industry

- Agenda
  - Overview / Purpose of FSVP
  - FDA FSVP Inspections
  - Foods Covered and Exempted by the Rule
  - FSVP Requirements
    - Standard Requirements
    - Modified Requirements

About the Presenters

- **Tim Lombardo** is a widely regarded expert in food safety and microbiology with over 25 years of direct experience leading these programs at a variety of manufacturing facilities. Tim's direct experience includes dairy, infant formula, baked goods, nuts and nut products, fruits and vegetables, meat and poultry, spices, color flavors and other ingredients and many others. He is a Lead Instructor through the Food Safety and Preventive Controls Alliance (FSPCA) in Preventive Controls for both Human and Animal Foods, is certified in Thermal / Aseptic Processing and Sterilization through the Better Process Control School and is a Lead Instructor for the HACCP Controls Alliance.
- Mr. Lombardo is a published author and international speaker. He is a member of the Institute for Food Technology (IFT), the International Association of Food Protection (IAFP) and is a member of the US Hemp Authority Technical Committee. He is also a combat Veteran, having served in Operation Desert Shield and Desert Storm.

About the Presenters

- **Omar Oyarzabal, Ph.D.** works directly with EAS' Senior Director for Food Consulting Services to assure client satisfaction and project management. He develops food safety protocols per FSMA and HACCP regulations and facilitate client training programs while collaborating with EAS consultants and clients to provide excellence in service.
- Dr. Oyarzabal holds many food safety certificates through the Association of Food and Drug Officials (AFDO) including Processing Authority, Seafood HACCP Lead Instructor, Sanitation Control Procedures (fish, fish products), Foreign Supplier Verification Program Lead Instructor, Sprout Safety Alliance Lead Instructor. He is also an Acidified Products Lead Instructor through the Better Process Control School. He is widely published in peer reviewed journals including International Journal of Molecular Science and industry publications such as Food Safety News, Food Safety Tech and Food Online. Dr. Oyarzabal's Ph.D. is in Microbiology/Poultry Science Ph.D. from Auburn University.

Overview / Purpose of FSVP

- Foreign Supplier Verification Program
  - 21 CFR 1.500
  - Requires importers to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.
  - Has a set of standard requirements for larger importers, and a modified set of procedures for importers that meet the definition of “very small importer.” There are also modified procedures that can be used when importing from certain small foreign suppliers.

FDA FSVP Inspections

- Unlike traditional facility inspections, FSVP inspections are based on the review of records, rather than observations of food production.

- Most of the FSVP inspections will be at the importer's place of business, we are also going to request that some importers provide FSVP records to FDA electronically.

- In most cases, if any deficiencies are found, the importer will be provided an opportunity to correct them.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

1. DISTRICT OFFICE ADDRESS AND PHONE NO.
FDA Office Address

TO

2. NAME AND TITLE OF INDIVIDUAL

3. FIRM NAME

4. NUMBER AND STREET

5. CITY, STATE AND ZIP CODE

6. DATE OF REQUEST

7. TIME OF REQUEST
_____ ☐ a.m. ☐ p.m.

8. EMAIL ADDRESS

Pursuant to Section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 384a), 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C) we are hereby requesting that you make all records described below promptly available.

9. RECORDS NECESSARY

☐ The records are to be made available for inspection and copying.

☒ The records are to be sent to FDA electronically or through another means that delivers the records promptly.

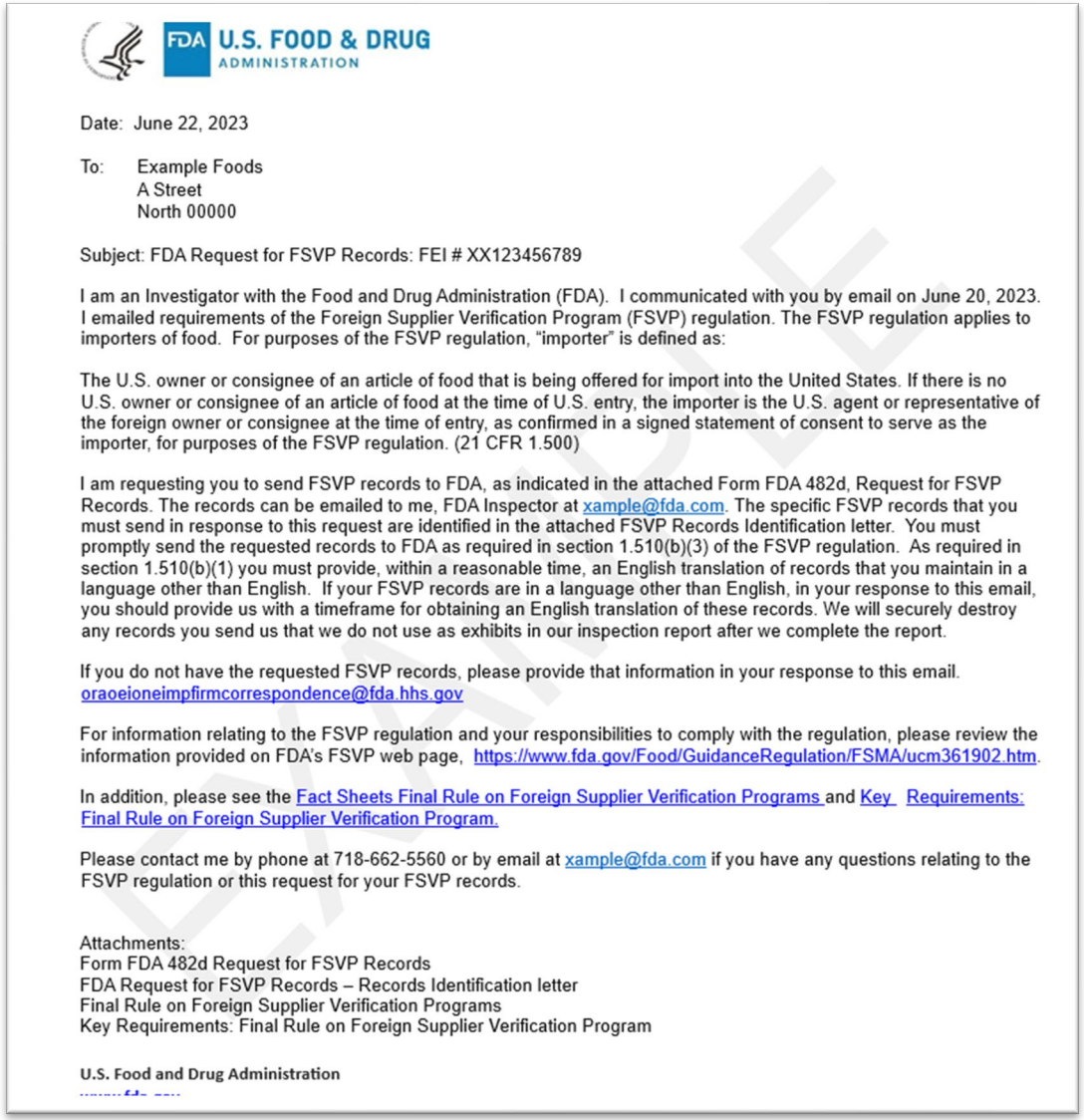
All FSVP Records.

EXAMPLE

10. SIGNATURE *(Food and Drug Administration Employee(s))*
[redacted]

11. TITLE FDA EMPLOYEE
Consumer Safety Officer

FORM FDA 482d (9/17) **REQUEST FOR FSVP RECORDS**



U.S. FOOD & DRUG ADMINISTRATION

Date: June 22, 2023

To: Example Foods
A Street
North 00000

Subject: FDA Request for FSVP Records: FEI # XX123456789

I am an Investigator with the Food and Drug Administration (FDA). I communicated with you by email on June 20, 2023. I emailed requirements of the Foreign Supplier Verification Program (FSVP) regulation. The FSVP regulation applies to importers of food. For purposes of the FSVP regulation, "importer" is defined as:

The U.S. owner or consignee of an article of food that is being offered for import into the United States. 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, for purposes of the FSVP regulation. (21 CFR 1.500)

I am requesting you to send FSVP records to FDA, as indicated in the attached Form FDA 482d, Request for FSVP Records. The records can be emailed to me, FDA Inspector at xample@fda.com. The specific FSVP records that you must send in response to this request are identified in the attached FSVP Records Identification letter. You must promptly send the requested records to FDA as required in section 1.510(b)(3) of the FSVP regulation. As required in section 1.510(b)(1) you must provide, within a reasonable time, an English translation of records that you maintain in a language other than English. If your FSVP records are in a language other than English, in your response to this email, you should provide us with a timeframe for obtaining an English translation of these records. We will securely destroy any records you send us that we do not use as exhibits in our inspection report after we complete the report.

If you do not have the requested FSVP records, please provide that information in your response to this email. oraoeioneimpfirmcorrespondence@fda.hhs.gov

For information relating to the FSVP regulation and your responsibilities to comply with the regulation, please review the information provided on FDA's FSVP web page, https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

In addition, please see the Fact Sheets Final Rule on Foreign Supplier Verification Programs and Key Requirements: Final Rule on Foreign Supplier Verification Program.

Please contact me by phone at 718-662-5560 or by email at xample@fda.com if you have any questions relating to the FSVP regulation or this request for your FSVP records.

Attachments:
Form FDA 482d Request for FSVP Records
FDA Request for FSVP Records – Records Identification letter
Final Rule on Foreign Supplier Verification Programs
Key Requirements: Final Rule on Foreign Supplier Verification Program

U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

Date: June 22, 2023

To: Example Foods
A Street
North 00000

Subject: FDA Request for FSVP Records: FEI # XX123456789

Dear Sir/Madam:

The U.S. Food and Drug Administration (FDA) is requesting you to promptly send us a copy of the following FSVP records:

- All FSVP records relating to the foreign supplier verification activities you conducted prior to initially importing the food and periodically thereafter between January 1, 2021, to January 1, 2023 for ***PINEAPPLE SNAX*** from foreign supplier by the name of PINEAPPLE TRADING COMPANY (Bolivia); ***MARSHMALLOW SNAX*** from foreign supplier by the name of MARSH SNX COMPANY, (Hungary); and ***CARAMEL CORN SNAX*** from foreign supplier by the name of SWEET EXPORT COMPANY, (Canada)

Section 1.510(b) of the Foreign Supplier Verification Programs for Food Importers (FSVP) regulation requires you to make all required FSVP records available promptly to an authorized FDA representative, upon request, for inspection and copying. If requested in writing by FDA, you must send the records to us electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

Please send a copy of the requested FSVP records electronically to FDA Inspector at xample@fda.com. Please reference FEI # XX123456789 in your submission.

Please clearly identify the FSVP records you send to FDA so we can determine the FSVP requirements that apply to the records (e.g., *hazard analysis, evaluation of risk posed by the food and performance of the foreign supplier, Approval of Foreign Supplier, a required written procedure, documentation of a foreign supplier verification activity, documentation of their review and assessment of a foreign supplier verification activity*).

Please contact me by email FDA Inspector at xample@fda.com or phone (555) 555-5555 if you have any questions.

Sincerely,

U.S. Food and Drug Administration

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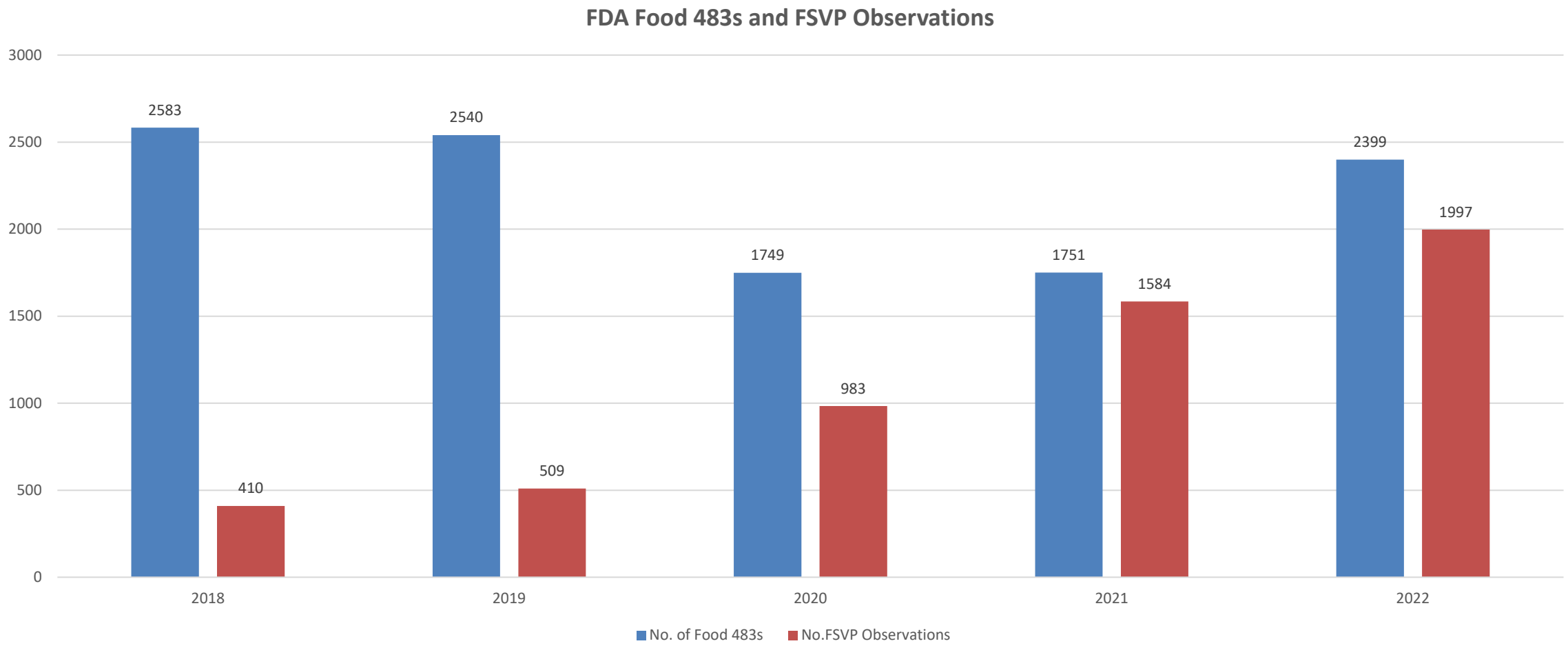
FDA FSVP Inspections



Foods Covered by the Rule

- It is better to review the foods that are NOT covered by the rule to understand the foods that are covered

Foods NOT Covered by the Rule

- Foods subject to the requirements of the U.S. Department of Agriculture (USDA):
  - Meat products subject to USDA requirements under the Federal Meat Inspection Act
  - Poultry products subject to USDA requirements under the Poultry Products Inspection Act
  - Egg products subject to USDA requirements under the Egg Products Inspection Act

Foods NOT Covered by the Rule

- Importers of juice or juice products covered by juice HACCP (21 CFR 120)
  - Requirements for importers under § 120.14

- Importers of fish and fishery products covered by seafood HACCP (21 CFR 123)
  - Requirements for importers under § 123.12

Foods NOT Covered by the Rule

- Food imported for research or evaluation:
  - Not intended for sale or distributed to the public
  - Labeled “Food for research or evaluation use”
  - Small quantities
  - Accompanied by electronic declaration that it will be used for research or evaluation purposes only

Foods NOT Covered by the Rule

- Food imported for personal consumption
  - Provided that the food is not intended for retail sale and is not sold or distributed to the public, or
  - Purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public

Foods NOT Covered by the Rule

- Alcoholic beverages:
  - The foreign supplier is a facility that meets conditions:
    - Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.)

Foods NOT Covered by the Rule

- Alcoholic beverages:
  - The foreign supplier is a facility that meets conditions:
    - Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

Foods NOT Covered by the Rule

- Non-alcoholic beverages:
  - The product is in a prepackaged form that prevents any direct human contact with such food
  - Constitutes not more than 5% of the overall sales of the facility, as determined by the Secretary of the Treasury

Foods NOT Covered by the Rule

- Food that is transshipped through the USA to another country and is not sold or distributed to the public in the USA

- Food that is imported for processing and future export and that is not sold or distributed to the public in the USA

Foods NOT Covered by the Rule

- Inapplicability to U.S. food returned:
  - Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/ processing in a foreign country.

Standard FSVP Requirements

- The FSVP importer must be located in the United States.
- The FSVP importer can identify qualified individuals to perform certain FSVP activities on the importer's behalf, provided that the importer conducts a required review and assessment of the qualified individual's activities.
- The FSVP importer is the entity with the responsibility for developing, maintaining, and following the FSVP regulation.

Standard FSVP Requirements

- The importer of a food for purposes of FSVP may be, but is not necessarily, the importer of record.

- When there is no U.S. owner or consignee of the food at the time of U.S. entry:
  - A U.S. agent or representative must be designated to serve as the FSVP importer of the food.
  - U.S. agent or representative is responsible for meeting the FSVP requirements.

Standard FSVP Requirements

- The foreign supplier of a food exported to the US is the establishment that:
  - Manufactures/processes the food
  - Raises the animal
  - Grows the food

  … And …
  - 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

Standard FSVP Requirements

- For each food you import that is subject to the FSVP regulation
  - You must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the appropriate regulation
    - 21 CFR part 117 (for human food)
    - 21 CFR part 507 (for animal food)
    - 21 CFR part 112 (for produce)

Standard FSVP Requirements

- FSVPs must be specific to each foreign supplier of a food.
  - If you obtain a food from multiple foreign suppliers, you must have a separate FSVP for each supplier.

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Modified FSVP Requirements

Very Small Importers

- With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than $1,000,000 (adjusted for inflation) -- in both sales of human food plus the market value of human food that is imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee), per year during the 3-year period preceding the current calendar year.

For animal food, the financial limit is $2,500,000

Small Foreign Suppliers

A qualified facility under the PC for human food regulation includes:

- Businesses (when including the sales by any subsidiaries, affiliates, and any entity of which the facility is a subsidiary or affiliate) with average annual sales of less than $500,000 with at least half the sales to consumers or to local retailers or restaurants or Indian reservations (within the same state or within 275 miles) or very small businesses as defined in 21 CFR 117.3.

- A very small business (including any subsidiaries and affiliates), averaging less than $1,000,000 (adjusted for inflation) -- in both sales of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (e.g., held for a fee), per year during the 3year period preceding the current calendar year.

For animal food, the financial limits are $500,000 and $2,500,000, respectively.

Modified FSVP Requirements

- Very Small FSVP Importers
  - You must document that you meet the definition of very small importer
  - Document your eligibility for VSI status before initially importing food and thereafter on an annual basis by December 31 of each calendar year
  - You must obtain assurance at least every 2 years that your foreign supplier is producing food consistent with U.S. safety standards
    - The supplier uses processes and procedures that provide at least the same level of public health protection as those required under the PC for human or animal food or produce safety regulations
    - In compliance with section 402 (adulteration) and 403(w) (misbranding with respect to allergen labeling) of the FD&C Act)

Modified FSVP Requirements

- Small Foreign Manufacturers
  - Provide documentation that meet the definition of small foreign manufacturer
  - Provide documentation of the supplier's eligibility for small foreign supplier status before initially importing food and thereafter on an annual basis by December 31 of each calendar year

Modified FSVP Requirements

- Written Assurances
  - A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or
  - A statement that the 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.

Modified FSVP Requirements

- Dietary Supplements and Their Components (21 CFR 111)
  - Establish compliant specifications
  - Ensure that the specifications are met
  - Obtain annual written assurance of compliance
  - Follow the standard recordkeeping requirements

  - If you import a dietary supplement except as specified above, you are subject to FSVP requirements similar to the standard requirements except:
    - Not required to conduct a hazard analysis
    - Supplier verification activities must be designed to provide adequate assurances that your supplier uses processes and procedures that provide the same level of public health protection as those required under the dietary supplement CGMP regulation

Modified FSVP Requirements

- Certain Food from Suppliers in Countries with Comparable Food Safety Systems
  - Canada, Australia, and New Zealand
  - You must document that:
    - The foreign supplier is in, and under the regulatory oversight of, a country with a comparable or equivalent food safety system
    - The food must be within the scope of the official recognition or equivalency determination (food that is not intended for further manufacturing/processing)
    - The supplier must be in good compliance standing with the food safety authority of the comparable or equivalent country

Additional Information

U.S. FOOD & DRUG ADMINISTRATION

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What Do Importers Need to Know About FSVP

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Conversations with Experts on Food Topics

Content current as of: 08/20/2018

Regulated Product(s) Food & Beverages

A Conversation with Sharon Mayl

The first major compliance date for importers covered by the Foreign Supplier Verification Programs (FSVP) rule arrives on May 30, 2017. FSVP is mandated by the FDA Food Safety Modernization Act (FSMA). A central tenet of that law is that the same preventive food safety standards apply to food consumed in the U.S., regardless of where the food is

Additional Information

U.S. FOOD & DRUG ADMINISTRATION

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FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

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Food Safety Modernization Act (FSMA)

- Frequently Asked Questions on FSMA
- FSMA Rules & Guidance for Industry
- What's New in FSMA
- FSMA Training
- FSMA Technical Assistance Network (TAN)

About the Final Rule

The FSVP rule requires importers to perform risk-based foreign supplier verification activities to verify that:

- The food is produced in a manner that provides the same level of public health protection as section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities (RACs) of the FD&C Act (21 U.S.C. 350g and 350h), if applicable;
- The food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and
- The human food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling).

The final rule went into effective January 26, 2016.

- Federal Register Notice

Content current as of: 01/10/2023

Regulated Product(s) Food & Beverages

Law(s) & Regulation(s) Food Safety Modernization Act

Questions

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Contact Information

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Thank you for joining us!