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Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation: Guidance for Industry

Small Entity Compliance Guide

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U.S. Department of Health and Human Services
Food and Drug Administration
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Table of Contents

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation: Guidance for Industry [1]

Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On November 27, 2015, FDA published the final rule *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals* (FSVP regulation) (80 FR 74225).

This regulation became effective on January 26, 2016. It creates new requirements for importers of food for humans and animals.

[1] This guidance has been prepared by the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

This regulation 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. The regulation 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.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guide will focus on the modified procedures for very small importers or importers of food from certain small foreign suppliers. The FSVP regulation is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendation, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

Purpose of This Compliance Guide

This guide was developed to inform U.S. importers about the FSVP regulation and how to comply with it. It contains important information that may affect your firm.

Key Requirements

The FSVP regulation applies to importers of food into the United States and contains binding requirements for those subject to the rule. For purposes of this rule, an importer is the U.S. owner or consignee of a food offered for import into the United States. (A U.S. owner or consignee of an imported food is defined as a person who, at the time of entry, owns the food, has purchased it, or has agreed in writing to purchase it.) If there's no U.S. owner or consignee at the time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee.

In general, the requirements of the FSVP regulation apply to all food imported or offered for import into the United States, unless an exemption applies under 21 CFR 1.501.

The FSVP regulation establishes requirements relating to:

- Use of qualified individuals to conduct FSVP activities,
- Hazard analysis,
- Food and supplier evaluation,
- Foreign supplier verification,
- Corrective actions,
- Recordkeeping, and
- Importer identification for a food offered for entry into the United States.

II. Overview of the Rule

A. Who Is Covered by This Regulation?

The FSVP regulation applies to importers of food into the United States as the term "importer" is defined in 21 CFR 1.500. For the purposes of the FSVP regulation, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent. See "Am I Subject to FSVP?" available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM480038.pdf.

B. What Foods Are Covered by This Regulation?

In general, the FSVP regulation applies to all imported foods regulated by FDA (21 CFR 1.501(a)). Certain categories of imported food are not covered by the FSVP regulation and these are discussed further in Section III.B.

C. What Is Required of Importers Under the FSVP Regulation?

Importers covered by the FSVP regulation must put in place foreign supplier verification programs (FSVPs) to verify that their foreign suppliers are producing food using processes and procedures that provide the same level of public health protection as those required under the preventive controls (for human or animal food) or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling (21 CFR 1.502(a)).

Generally, the FSVP rule requires:

- Conducting a hazard analysis to determine known or reasonably foreseeable hazards with each food that require a control (21 CFR 1.504)
- Evaluating the foreign supplier's performance and the risk posed by a food (based on the hazard analysis) (21 CFR 1.505(a))
- Using that evaluation to approve suppliers and determine appropriate supplier verification activities (21 CFR 1.505(b))
- Conducting foreign supplier verification and related activities (21 CFR 1.506)
- Taking corrective actions (if necessary) (21 CFR 1.508)
- Maintaining records of these FSVP activities (21 CFR 1.510)

D. Who Is Subject to Modified Requirements Under the FSVP Regulation?

There are several types of importers that are subject to modified requirements. For example, very small importers and importers of food from certain small foreign suppliers are subject to modified requirements under the FSVP regulation. Under these modified requirements,

importers do not have to conduct hazard analyses or evaluate the food and foreign supplier (21 CFR 1.512). The full list of modified requirements is discussed further in Sections IV and VI.

E. How Do the Requirements Under the FSVP Regulation Align with Other Supply-Chain Program Requirements Under FSMA?

The FSVP regulation is closely aligned with the supply-chain program requirements established in the regulations on preventive controls for animal and human food (PC regulations). Under the supply-chain program provisions in the PC regulations, facilities that produce food using purchased raw materials or other ingredients must establish supply-chain verification procedures to ensure their suppliers are effectively controlling food safety hazards that the PC regulations define as needing to be controlled by the producer of the ingredient. These "receiving facilities" that are also importers can decide whether they will comply with the relevant PC supply-chain program or FSVP provisions, and they will not have to duplicate their supplier verification activities.

F. Key Terms Used in Part 1, Subpart L

The FSVP regulation uses a number of terms in very specific ways. A full list of these terms appears in this Guidance in Section VII "Definitions." Table 1 lists some of the key terms.

Table 1--Key Terms Used in Part 1, Subpart L

Term	Definition
Facility	A domestic or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.
Foreign supplier	For an article of food, 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.
Importer	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 under part 1, subpart L.
Receiving facility	A facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee	The person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

III. What Foods Are Covered By This Regulation?

A. What Foods Are Subject to the FSVP Requirements?

The requirements of this regulation apply to all "food" imported or offered for import into the United States and to the importers of such food, unless there is an exemption (21 CFR 1.501(a)).

The term "food" includes (21 CFR 1.500):

- Articles used for food or drink for man or other animals,
- Chewing gum,
- And articles used for components of any such article.

B. What Foods Are Exempt from the Requirement to Have an FSVP?

Table 2--Exemptions for part 1, subpart L

Exemption	Conditions
Imports of certain seafood products (21 CFR 1.501(b))	Imports of seafood products produced in foreign facilities in compliance with FDA's seafood HACCP requirements of 21 CFR part 123 are exempt from the FSVP regulation. This exemption also covers imports of seafood raw materials or other ingredients for use by the importer in making seafood products under the seafood HACCP regulation.
Imports of certain juice products (21 CFR 1.501(b))	Imports of juice products produced in foreign facilities in compliance with FDA's juice HACCP requirements of 21 CFR part 120 are exempt from the FSVP regulation. This exemption also covers imports of juice raw materials or other ingredients for use by the importer in making juice products under the juice HACCP regulation.
Food imported for research or evaluation	Food imported for research or evaluation use is exempt from the FSVP regulation provided

Exemption	Conditions
(21 CFR 1.501(c))	it: (1) is not intended for retail sale and is not sold or distributed to the public; (2) is labeled with the statement "Food for research or evaluation use"; (3) is imported in a small quantity consistent with a research, analysis, or quality assurance purpose, is used only for this purpose, and any unused quantity is properly disposed of; and (4) is accompanied, when filing entry with U.S. Customs and Border Protection (CBP), by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.
Food imported for personal consumption (21 CFR 1.501(d))	Food imported for personal consumption is exempt from the FSVP regulation provided it: (1) is not intended for retail sale and is not sold or distributed to the public; and (2) is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose.
Alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department. (21 CFR 1.501(e))	This exemption applies if the manufacturing facility is of a type that if it were a domestic facility it would be required to register with the TTB, and the facility is also a facility that must register with FDA under the Bioterrorism Act. Raw materials and other ingredients that are imported for use in the production or packing of alcoholic beverages are also exempt from FSVP requirements, provided that the relevant manufacturing/processing, packing, or holding of alcoholic beverages is performed by the importer. Non-alcoholic beverage foods in prepackaged form that constitute not more than 5 percent of the overall sales of the facility are also exempt.
Food transshipped through the United States	Food that is transshipped through the United States to another country and is not sold or

Exemption	Conditions
(21 CFR 1.501(f)(1))	distributed to the public in the United States is exempt from the FSVP regulation.
Food imported for processing and export (21 CFR 1.501(f)(2))	Food that is imported for processing and future export and that is not sold or distributed to the public in the United States is exempt from the FSVP regulation.
U.S. food returned (21 CFR 1.501(g))	The FSVP regulation does not apply to 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.
Meat, poultry, and egg products subject to USDA regulation at time of importation (21 CFR 1.501(h))	The FSVP regulation does not apply to meat, poultry, or egg products that at the time of importation are subject to USDA regulation.
Low-acid canned foods, including raw materials and other ingredients in such foods (21 CFR 1.502(b))	This exemption only applies with respect to microbiological hazards that are controlled by part 21 CFR part 113. For all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP. This exemption also covers imports of raw materials or other ingredients for use by the importer in making low-acid canned food products under part 113.

IV. Who Is Eligible to Use Modified FSVP Requirements?

The FSVP regulation includes modified requirements for very small importers (VSIs) and importers of food from certain small foreign suppliers (21 CFR 1.512).

The FSVP regulation also includes modified requirements for importers of dietary supplements and dietary supplement components and importers of certain food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the United States. These are discussed separately in Section VI "What Other Modified FSVP Requirements Might Apply to Food I Import?"

A. Who Is a Very Small Importer?

Table 3--Very Small Importers

Entity	Definition/Condition
Very Small Importer of human food (21 CFR 1.500)	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.
Very Small Importer of animal food (21 CFR 1.500)	With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than $2,500,000 (adjusted for inflation) -- in both sales of animal food plus the market value of animal 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.

B. Who Is a Small Foreign Supplier?

Table 4--Small Foreign Suppliers

Type of Foreign Supplier	Condition
Qualified Facilities as defined in the preventive controls regulations (21 CFR 1.512(a)(2)(i))	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 3-year period preceding the current calendar year.

	A qualified facility under the PC for <u>animal</u> 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 507.3. • A *very small business* (including any subsidiaries and affiliates), averaging less than $2,500,000 (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 3-year period preceding the current calendar year.
Certain Farms (21 CFR 1.512(a)(2)(ii))	Farms that grow produce and are not "covered farms" under the produce safety regulation. Under the produce safety regulation, a farm is not a "covered farm" if either: (1) The farm has sold less than $25,000 (adjusted for inflation) in average annual monetary value of covered produce during the previous 3-year period; OR (2) The farm is eligible for a qualified exemption under the produce safety regulation because: • During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food the farm sold directly to qualified end-users (consumers or local restaurants and retail food establishments) during such period exceeded the average annual monetary value of the food sold by the farm to all other purchasers; and • The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

	If FDA has revoked the farm's qualified exemption status, the farm may not be a small foreign supplier for purposes of the FSVP regulation.
Certain Shell Egg Producers (21 CFR 1.512(a)(2)(iii))	Shell egg producers that are not subject to the FDA regulations in 21 CFR part 118 because they have fewer than 3,000 laying hens.

C. What Documentation of Eligibility Is Required for Importers Subject to Modified Requirements?

For the modified requirements to apply, the importer will need to annually document its "very small importer" status or obtain assurance that its foreign supplier meets the criteria as one of the "small" types of foreign suppliers (21 CFR 1.512(b)(1)).

1. What Documentation of Eligibility Is Required for Very Small Importers?

If you are a very small importer and you choose to comply with the modified FSVP requirements, you must document that you meet the definition of very small importer (the definition is based on your sales volume of human food and/or animal food as summarized in Table 3) (21 CFR 1.512(b)(1)(i)(A)).

You must document your eligibility for VSI status before initially importing food and thereafter on an annual basis by December 31 of each calendar year (21 CFR 1.512(b)(1)(i)(A)).

2. What Documentation of Eligibility Is Required for Importers of Certain Food From Certain Small Foreign Suppliers?

If you are importing food from a small foreign supplier and you choose to comply with the modified FSVP requirements, you must obtain written assurance that your foreign supplier meets the criteria for a type of small foreign supplier as summarized in Table 4 (21 CFR 1.512(b)(1)(ii)).

You must document 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 (21 CFR 1.512(b)(1)(ii)).

V. What FSVP Requirements Apply for Very Small Importers and Importers of Food From Certain Small Foreign Suppliers?

If you meet the eligibility requirements for a very small importer or an importer who is importing food from a certain small foreign supplier, in addition to the requirements in 21 CFR 1.512(b):

- You must have a foreign supplier verification program as required in 21 CFR 1.502 and as discussed further below,

- A qualified individual must develop your FSVP and perform FSVP activities as required in 21 CFR 1.503, and

- You must ensure that you are identified as the importer of the food when filing entry with CBP as required in 21 CFR 1.509.

However, you are not required to comply with the requirements in 21 CFR 1.504 through 1.508 or 1.510 (21 CFR 1.512(b)(2)).

A. What FSVP Activities Must I Conduct?

You must establish a foreign supplier verification program for each food that you import from each of your foreign suppliers (21 CFR 1.502(a)). For very small importers and importers of food from small foreign suppliers, FSVP activities consist of obtaining written assurances from the suppliers.

1. What Are the Written Assurance Requirements for Very Small Importers?

If you are a very small importer, you must obtain assurance at least every 2 years that your foreign supplier is producing food consistent with U.S. safety standards (i.e., that 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, if applicable, and in compliance with section 402 (adulteration) and 403(w) (misbranding with respect to allergen labeling) of the FD&C Act) (21 CFR 1.512(b)(3)(i)).

2. What Written Assurances Are Required from Qualified Facilities?

If your foreign supplier is a qualified facility under the PC regulations, you must obtain assurance at least every 2 years that the foreign supplier produces food in accordance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

- 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.

(21 CFR 1.512(b)(3)(ii))

3. What Written Assurances Are Required from Certain Small Produce Farms?

If your foreign supplier grows produce and is not a covered farm under the specified provisions of the produce safety regulation, you must obtain written assurance at least every 2 years that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) (21 CFR 1.512(b)(3)(iii)).

4. What Written Assurances Are Required from Certain Shell Egg Producers?

If your foreign supplier is a shell egg producer that is not subject to the requirements of 21 CFR part 118 because it has fewer than 3,000 laying hens, you must obtain written assurance before importing the shell eggs and at least every 2 years that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) (21 CFR 1.512(b)(3)(iv)).

5. What Hazard Analysis Must I Conduct?

If you meet the eligibility requirements for a very small importer or an importer who is importing food from a certain small foreign supplier, you are not required to conduct a written hazard analysis, as required by 21 CFR 1.504, to determine known or reasonably foreseeable hazards for each type of food that you import, or to determine whether there are any hazards requiring a control.

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

If you meet the eligibility requirements for a very small importer or an importer who is importing food from certain small foreign suppliers, you are not required to conduct an evaluation of a foreign supplier's performance and the risk posed by a food or to approve your foreign suppliers (21 CFR 1.505).

B. What Corrective Actions Must I Take?

If you learn that your foreign supplier is not producing food consistent with U.S. safety standards, you must take appropriate corrective action. This might mean working with the supplier to address the problem and, in some cases, temporarily discontinuing use of the supplier until the problem is resolved (21 CFR 1.512(b)(4)).

You must document any corrective actions you take. The corrective action requirements under the FSVP regulation do not affect other obligations that you may have with respect to other laws enforced by FDA, such as those relating to product recalls (21 CFR 1.512(b)(4)).

C. What Are the Recordkeeping Requirements for FSVP Activities?

You must keep records of your FSVP activities. The records may be kept as original records, photocopies, scanned copies, or electronic records. You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP (21 CFR 1.512(b)(5)(i)). You can rely on records created for other purposes (e.g., to comply with other regulations) if the records contain the information required under FSVP, and you can supplement existing records with other information to meet FSVP requirements (21 CFR 1.512(b)(5)(v)).

You must make all your FSVP records available promptly to an authorized FDA representative for inspection and copying. Offsite storage is permitted if the records can be provided onsite within 24 hours. In addition, FDA may request that importers send records to FDA electronically or through some other prompt means (21 CFR 1.512(b)(5)(ii)).

Generally, you must retain FSVP records for at least 2 years after you create or obtain the records (21 CFR 1.512(b)(5)(iii)(A)). If you are importing foods from certain small foreign suppliers, you must retain records that relate to your processes and procedures for at least 2 years after their use is discontinued (21 CFR 1.512(b)(5)(ii)). If you are a very small importer, you must retain for at least 3 years the records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer (21 CFR 1.512(b)(5)(iii)(C)).

D. What Are the Additional Requirements When Importing from Certain Small Foreign Suppliers When You Are Not a Very Small Importer?

If you are not a very small importer and you are importing food from certain small foreign suppliers, you must comply with the following additional requirements (21 CFR 1.512(c)):

- Evaluate and reevaluate foreign supplier compliance history (21 CFR 1.512(c)(1))
- Approve foreign suppliers (21 CFR 1.512(c)(2))
- Use only approved foreign suppliers (21 CFR 1.512(c)(3))

1. What Are the Requirements for Evaluation and Reevaluation of Foreign Supplier Compliance History?

You must evaluate your foreign supplier's history of compliance with FDA food safety regulations (or review and assess another's evaluation) and document the evaluation (21 CFR 1.512(c)(1)). For example, you should monitor whether your foreign supplier has been subject to an import alert or warning letter issued by FDA. Import alerts can be found at http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

You must reevaluate the small foreign supplier's compliance history when you become aware of new information that could affect your initial evaluation. If at the end of any 3-year period you have not reevaluated the small foreign supplier's compliance history, you must conduct a reevaluation and take other appropriate actions as necessary. Any reevaluation must be documented (21 CFR 1.512(c)(1)(ii)).

2. What Are the Requirements for Approval of Foreign Suppliers?

You must approve your foreign suppliers based on your evaluation of their compliance history or based on your review and assessment of another entity's evaluation of the small foreign supplier's compliance history. You must document your approval (21 CFR 1.512(c)(2)).

3. What Are the Requirements for Use of Approved Foreign Suppliers?

You must establish and follow written procedures to ensure you import food only from approved suppliers (or, when necessary and appropriate, from unapproved suppliers on a temporary basis). You must document your use of these procedures (21 CFR 1.512(c)(3)(i)).

You may rely on an entity other than the foreign supplier to establish and perform procedures for use of approved and unapproved suppliers and to document use of these procedures, provided that you review and assess that entity's documentation of the procedures and their use, and you document your review and assessment (21 CFR 1.512(c)(3)(ii)).

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

Importers subject to the FSVP regulation must ensure that their FSVP is developed and applied by a "qualified individual" as defined in 21 CFR 1.500 (21 CFR 1.503(a)).

The qualified individual performing FSVP activities for you:

- Must have the education, training, or experience (or combination thereof) necessary to perform the activity; and
- Must be able to read and understand the language of any records reviewed in performing an activity.

(21 CFR 1.503(a))

F. How Must I Identify the FSVP Importer at Entry?

For each line entry of food, you must ensure that your name, email address, and unique facility identifier recognized as acceptable by FDA are provided electronically to CBP at entry (21 CFR 1.509(a)).

The Dun & Bradstreet Data Universal Numbering System (DUNS) number is an acceptable number to use as a unique facility identifier. You can obtain a DUNS number at https://fedgov.dnb.com/webform.

VI. What Other Modified FSVP Requirements Might Apply to Food I Import?

The FSVP regulation also includes modified requirements for:

- Importers of dietary supplements and dietary supplement components (21 CFR 1.511); and
- Importers of certain food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States (21 CFR 1.513).

A. Dietary Supplements and Dietary Supplement Components

If you import dietary supplements or dietary supplement components and you (or your customer) are required to establish specifications under certain provisions of the dietary supplement current good manufacturing practice (CGMP) regulation (21 CFR 111.70(b) or (d)), and you (or your customer) ensure that the specifications are met (in compliance with 21 CFR 111.73 and 111.75),

then for that food you would not have to meet the standard FSVP requirements, except the requirements to use a qualified individual and to ensure that you are identified as the importer at entry. If your customer establishes the specifications and ensures that they are met, you will need to annually obtain written assurance of your customer's compliance and follow the standard recordkeeping requirements (21 CFR 1.511(a) and (b)).

If you import a dietary supplement except as specified above, you are subject to FSVP requirements similar to the standard requirements except that, among other differences, you would not be required to conduct a hazard analysis and your 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 (21 CFR 1.511(c)).

Table 5 -- Modified Requirements for Importers of Dietary Supplements or Dietary Supplement Components

Conditions	**Modified Requirement**
Importers subject to certain dietary supplement CGMP requirements: If you are required to establish specifications under 21 CFR 111.70(b) or (d); and You are in compliance with the requirements in 21 CFR 111.73 and 111.75 (21 CFR 1.511(a))	Then, for that food you must comply with the following requirements: • Use a qualified individual (21 CFR 1.503); and • Identify the importer at entry (21 CFR 1.509) You are not required to comply with the other FSVP requirements.
Importers whose customer is subject to certain dietary supplement CGMP requirements: If your customer is required to establish specifications under 21 CFR 111.70(b) or (d); and Your customer is in compliance with the requirements in 21 CFR 111.73 and 111.75; and You annually obtain written assurance from your customer that they are in compliance with those requirements. (21 CFR 1.511(b))	Then, for that food you must comply with the following requirements: • Use a qualified individual (21 CFR 1.503); • Identify the importer at entry (21 CFR 1.509); and • Follow the standard recordkeeping requirements (21 CFR 1.510). You are not required to comply with the other FSVP requirements.

Other importers of dietary supplements: If the food you import is a dietary supplement; and You or your customer are not required to follow certain dietary supplement CGMP regulations as described in 21 CFR 1.511(a) and (b) (21 CFR 1.511(c))	Then, you must comply with the following requirements: • CFR 1.511(c) – modified FSVP requirements for importers of dietary supplements • 21 CFR 1.503 – use of a qualified individual • 21 CFR 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d) – foreign supplier evaluation • 21 CFR 1.508 – corrective actions • 21 CFR 1.509 – identify importer at entry • 21 CFR 1.510 – FSVP records You are not required to comply with the other FSVP requirements.

B. Certain Food from Foreign Suppliers in Countries with Comparable or Equivalent Food Safety Systems

If you import certain food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, you would not need to comply with most of the FSVP requirements (except the requirements to use a qualified individual (21 CFR 1.503), ensure that you are identified as the importer at entry (21 CFR 1.509), and maintain records (21 CFR 1.510)), provided certain conditions are met. The modified requirements are limited to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption (21 CFR 1.513(a)).

For the modified requirements to apply, 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, and the supplier must be in good compliance standing with the food safety authority of the comparable or equivalent country (21 CFR 1.513(b)).

VII. When Do I Have to Comply With the FSVP Rule?

The date importers must comply with the FSVP regulation is the latest of the following dates:

- 18 months after publication of the final rule;
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations; or
- For an importer that is also subject to the supply-chain program provisions in the preventive controls regulations for human food or animal food, the date the importer, as a receiving facility, is required to comply with the supply-chain program provisions of the relevant regulation.

The compliance dates for importers subject to the FSVP regulation differ according to a number of considerations, including the size of the foreign supplier, the nature of the importer, and whether the foreign supplier must meet the requirements of the rules for preventive controls for human food, preventive controls for animal food, or produce safety.

For a more detailed listing of compliance dates, please see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm.

VIII. Definitions (21 CFR 1.500)

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice.

Audit: The systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement: Has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component: Any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen: A pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this subpart include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeformers.

Facility: A domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Farm mixed-type facility: An establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food: Has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen: A major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier: For an article of food, 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.

Good compliance standing with a foreign food safety authority: the foreign supplier--

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority, or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting: Applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard: Any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding: Storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food

during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer: 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 under this subpart.

Known or reasonably foreseeable hazard: A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot: The food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing: Placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen: A microorganism of public health significance.

Qualified auditor: A person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof)

necessary to perform the auditing function as required by § 1.506(e)(1)(i) or § 1.511(c)(6)(i)(A). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual: A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

Raw agricultural commodity: Has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food): Any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility: A facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee: The person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

You: A person who is subject to some or all of the requirements in this subpart.