Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Docket No. FDA-2011-N-0143

Reference 2: FDA, Proposed 21 Code of Federal Regulations, Part 1, Subpart L – Foreign Supplier Verification Programs for Food Importers (indicating revisions proposed in supplemental notice of proposed rulemaking), 2014

In the *Federal Register* of July 29, 2013 (78 FR 3646), the Food and Drug Administration (FDA or we) issued a proposed rule (the 2013 proposed preventive controls rule) that would adopt provisions on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The proposed regulations would require importers to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act, is not adulterated, and is not misbranded with respect to food allergen labeling.

On September 19, 2014, we announced an expected date for publication in the *Federal Register* (i.e., September 29, 2014) for a supplemental notice of proposed rulemaking (the 2014 preventive controls supplemental notice) to amend certain specific provisions of the 2013 proposed preventive controls rule. For the convenience of readers and ease of reference, the document below largely identifies the proposed additions and deletions in the 2014 preventive controls supplemental notice relative to the 2013 proposed preventive controls rule. In general, we tried to identify the proposed additions and deletions in a way that we believe would be most useful to readers.

Subpart L--Foreign Supplier Verification Programs for Food Importers

Sec.

Subpart L--Foreign Supplier Verification Programs for Food Importers

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

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

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, and, as appropriate, sampling and laboratory analysis) to assess a foreign supplier's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

Dietary supplement component means 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 (21 U.S.C. 321(ff)) and other ingredients.

Environmental pathogen means 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. Environmental pathogen does not include the spores of pathogenic sporeformers.

Facility means 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.

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

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests 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 means that 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 manufacturers and processors 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.

Hazard means any biological, chemical (including radiological), or physical~~, or radiological~~ agent that is reasonably likely to cause illness or injury in the absence of its control.

~~Hazard reasonably likely to occur means a hazard for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls.~~

Importer means the person in the United States who has purchased an article of food that is being offered for import into the United States. If the article of food has not been sold to a

person in the United States at the time of U.S. entry, the importer is the person in the United States to whom the article has been consigned at the time of entry. If the article of food has not been sold or consigned to a person in the United States 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.

Known or reasonably foreseeable hazard means a potential 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 means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means 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 are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained by a combination of training and experience appropriate to perform onsite auditing of foreign suppliers. A foreign government employee could be a qualified auditor.

Qualified individual means a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart. This person may be, but is not required to be, an employee of the importer. Regarding the performance of verification activities related to preventive controls implemented by the foreign supplier in accordance with section 418 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g), a qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety system. A qualified individual includes, but is not limited to, a third-party auditor that has been accredited in accordance with section 808 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384d). A foreign government employee could be a qualified individual.

Raw agricultural commodity means "raw agricultural commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)).

Significant hazard means 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, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

Very small importer means an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or

affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million~~500,000~~, adjusted for inflation.

Very small foreign supplier means a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million~~500,000~~, adjusted for inflation.

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

§ 1.501 To what foods do the regulations in this subpart apply?

(a) General. Except as specified otherwise in this section, the regulations in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) Exemption for certain juice and seafood products. The regulations in this subpart do not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the regulations on juice in part 120 of this chapter or the regulations on fish and fishery products in part 123 of this chapter. If you import juice or fish and fishery products that are subject to the regulations in part 120 or part 123 of this chapter, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

(c) Exemption for food imported for research or evaluation. The regulations in this subpart do not apply to food that is imported for research or evaluation use, provided that such food is not intended for retail sale and is not sold or distributed to the public, that it is labeled with the statement “Food for research or evaluation use,” and that, when filing entry with U.S. Customs and Border Protection, the customs broker or filer for the food provides 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 is imported for research or evaluation purposes only if it is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose and the entire quantity is used for this purpose.

(d) Exemption for food imported for personal consumption. The regulations in this subpart do not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is 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.

(e) Exemption for alcoholic beverages. (1) The regulations in this subpart do not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) 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.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) The regulations in this subpart do not apply with respect to food other than alcoholic beverages that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(f) Inapplicability to food that is transshipped or imported for further processing and export. The regulations in this subpart do not apply to food:

(1) That is transshipped through the United States to another country; or

(2) That is imported for future export and that is neither consumed nor distributed in the United States.

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) General. Except as specified in paragraph (b) of this section, for each food you import, 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 section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w)).

(b) Low-acid canned foods. With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid canned food

packaged in a hermetically sealed container, you must verify and document that the food was produced in accordance with part 113 of this chapter. With respect to all matters that are not controlled by part 113 of this chapter, you must have an FSVP as specified in paragraph (a) of this section.

(c) Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act. If you are required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import and you are in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in § 1.509.

(d) Importers whose customer is subject to section 418 of the Federal Food, Drug, and Cosmetic Act. If your customer is required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import, and you annually obtain from your customer written assurance that it is in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in §§ 1.509 and 1.510.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

Except with respect to the requirements in §§ 1.506(a), 1.509, 1.510, 1.511(c)(2), and 1.512(b)(5)~~(3) and (b)(6)~~, a qualified individual must develop your FSVP and perform each of the activities required under this subpart.

~~§ 1.504 What review of a food and foreign supplier's compliance status must I conduct?~~

~~Before importing a food from a foreign supplier, you must review the compliance status of the food and the foreign supplier, including whether they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the Federal Food,~~

~~Drug, and Cosmetic Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. You must document this review. You must continue to monitor and document the compliance status as long as you import the food from the foreign supplier.~~

§ 1.50~~4~~5 What hazard analysis must I conduct?

(a) Requirement for~~of~~ a hazard analysis. You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each food you import to determine whether there are any significant hazards. Your hazard analysis must be written. ~~Except as permitted under paragraph (d) and (e) of this section, for each food you import, you must determine the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur. You must document this determination and use it to determine appropriate verification activities in accordance with § 1.506.~~

(b) H~~Potential h~~azard identification~~s~~. (1) Your analysis~~evaluation~~ of the known or reasonably foreseeable hazards in~~that are reasonably likely to occur with~~ each food ~~you import~~ must ~~consider hazards that may occur naturally or may be unintentionally introduced,~~ includ~~e~~ing the following types of hazards:

(i~~1~~) Biological hazards, including microbiological hazards such as parasites, ~~and~~ environmental pathogens, and other pathogens~~microorganisms of public health significance~~;

(ii~~2~~) Chemical hazards, including radiological hazards, ~~substances such as~~ pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii~~3~~) Physical hazards.~~; and~~

~~(4) Radiological hazards.~~

(2) Your analysis must include hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced;

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) Hazard evaluation. (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to~~In evaluating the hazards~~ assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.~~set forth in paragraph (b) of this section,~~

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

(3) Your hazard evaluation~~you~~ must consider the effect of the following on the safety of the finished food for the intended consumer:

(i~~1~~) The formulation~~ingredients~~ of the food;

(ii~~2~~) The condition, function, and design of the foreign supplier's establishment and equipment;

(iii) Raw materials and ingredients;

(iv~~3~~) Transportation practices;

(v~~4~~) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi~~5~~) Packaging and labeling activities;

(vii~~6~~) Storage and distribution;

(viii~~7~~) Intended or reasonably foreseeable use;

(ix~~8~~) Sanitation, including employee hygiene; and

(x~~9~~) Any other relevant factors.

(d) Review of the foreign supplier's hazard analysis ~~developed by foreign supplier~~. If your foreign supplier has analyzed the known or reasonably foreseeable hazards~~conducted a hazard analysis~~ for the food to determine whether there are any significant hazards, you may meet your requirement to determine whether there are any significant hazards in a food~~identify the hazards that are reasonably likely to occur for a particular food~~ by reviewing and assessing~~evaluating~~ the hazard analysis conducted by the foreign supplier. ~~You must document the determination you make based on this review and evaluation~~.

(e) Microbiological hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to determine whether there are any significant~~conduct a hazard analysis regarding~~ microbiological hazards in~~that might be reasonably likely to occur with~~ such food.

(f) No significant hazards. If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no significant hazards, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter.

(g) Significant hazards controlled by you and/or your customer. If the preventive controls that you and/or your customer implement in accordance with subpart C of part 117 of

this chapter are adequate to significantly minimize or prevent all significant hazards in a food you import, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. If your customer controls one or more such hazards, you must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

§ 1.505 What risk evaluation must I conduct?

(a) Evaluation of food and supplier risks. (1) In determining the appropriate supplier verification and related activities that you must conduct, you must consider the following:

(i) The hazard analysis that you conduct in accordance with § 1.504, including the nature of the hazard.

(ii) The entity that will be applying controls for the hazards analyzed under § 1.504, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.

(iii) The foreign supplier's procedures, processes, and practices related to the safety of the food.

(iv) Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.

(v) The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.

(vi) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document your evaluation of risks.

(b) Reevaluation of risk factors. You must promptly reevaluate the risk factors specified in paragraph (a)(1) of this section associated with a food or foreign supplier when you become aware of new information about these factors. If you determine that it is appropriate to continue to import the food from the foreign supplier, you must document the reevaluation and your determination.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) Use~~List~~ of approved foreign suppliers. You must establish and follow~~maintain a~~ written procedures to ensure that you import foods only from foreign suppliers you have approved based on the risk evaluation you conduct under § 1.505 (or, when necessary and appropriate, on a temporary basis, from unapproved foreign suppliers whose foods you subject to adequate verification activities before using or distributing)~~list of foreign suppliers from which you are importing food~~. You must document your use of these procedures.

(b) Foreign supplier verification procedures. You must establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods you import.

(c) Purpose of supplier verification. ~~Except with respect to verification activities specified in paragraph (h) of this section concerning raw agricultural commodities that are fruits or vegetables and that are subject to part 112 of this chapter, y~~Your foreign supplier verification activities must provide adequate assurances that the foreign supplier produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 350g, 350h, 342, and 343(w)).~~hazards you have identified as reasonably likely to occur are adequately controlled.~~

~~(d) No hazards identified. If you conduct your hazard analysis in accordance with § 1.505 and determine that there are no hazards that are reasonably likely to occur with a food you import, you are only required to comply with paragraph (a) of this section with respect to this food. This paragraph does not apply if the food is a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter.~~

~~(e) Hazards controlled by you. For a hazard that you have identified as reasonably likely to occur with a food you import that you adequately control, you must document, at least annually, that you have established and are following procedures that adequately control the hazard.~~

~~(f) Hazards controlled by your customer. For a hazard that you have identified as reasonably likely to occur with a food you import that your customer adequately controls, you must document that your customer controls the hazard by obtaining written assurance, at least annually, from the customer that it has established and is following procedures (identified in the written assurance) that adequately control the hazard.~~

~~Option 1 for Requirements for Hazards Not Controlled by You or Your Customer~~

(d) Foreign supplier verification activities. (1) Except as provided in paragraphs (d)(2) and (4) of this section, you must conduct and document one or more of the supplier verification activities listed in paragraphs (d)(1)(i) through (iv) of this section for each foreign supplier before using or distributing the food and periodically thereafter. You must determine and document which verification activity or activities are appropriate, as well as the frequency with

which the activity or activities must be conducted, based on the risk evaluation you conduct for the food and foreign supplier under § 1.505.

(i) Onsite audit of the foreign supplier. (A) An onsite audit of a supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, including its implementation.

(C) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(ii) Sampling and testing of the food. (A) Sampling and testing of a food may be conducted by either the importer or the foreign supplier.

(B) You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

(iii) Review of the foreign supplier's relevant food safety records. You must retain documentation of each record review, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) Other appropriate activity. You may conduct other supplier verification activities that are appropriate based on the risk associated with the food and the foreign supplier. You must document each performance of such verification activity.

(2) When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you document your determination that, instead of such initial and annual onsite auditing, other supplier verification activities as set forth in paragraph (d)(1) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances in accordance with paragraph (c) of this section for the food and foreign supplier, based on the determination you made under § 1.505.

(3) Based on the risk evaluation you conduct, it might be necessary, under paragraph (d)(1) or (2) of this section, to conduct more than one supplier verification activity to address an individual hazard or risk factor or multiple hazards or risk factors.

(4) If a foreign supplier of a food is a farm that is not subject to the requirements in part 112 of this chapter in accordance with § 112.4 regarding the food being imported, the importer need not comply with paragraphs (d)(1) and (2) of this section if the importer:

(i) Documents, at the end of each calendar year, that the food provided by the foreign supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the foreign supplier is producing the food in compliance with the Federal Food, Drug, and Cosmetic Act.

(5) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. (i) Instead of an onsite audit conducted under paragraph (d)(1) or (2) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. You must document the inspection results on which you rely.

(ii) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(6) Review of results of verification activities. You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (d) of this section. If the results show that the risks for the food or foreign supplier identified in the determination you made under § 1.505 are not adequately controlled, you must take appropriate action in accordance with § 1.507(c).

(7) Independence of qualified individuals. A qualified individual who conducts any of the verification activities set forth in paragraph (d) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.

~~(g) Hazards controlled or verified by your foreign supplier. For a hazard that you have identified as reasonably likely to occur with a food that is not controlled by you or your~~

customer, you must conduct the verification activities in paragraph (g)(1) or paragraph (g)(2) of this section, depending on the type of hazard.

(1) Hazards controlled by your foreign supplier for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. For a hazard to be controlled by your foreign supplier at its establishment for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct and document the onsite auditing activities specified in paragraphs (g)(1)(i) and (g)(1)(ii) of this section for the hazard. When onsite auditing alone cannot provide adequate assurances that the hazard is adequately controlled, you must conduct one or more additional verification activities to provide such assurances.

(i) Initial onsite audit. You must conduct (and document) or obtain documentation of an onsite audit before importing the food from the foreign supplier.

(ii) Subsequent periodic onsite audits. You must conduct (and document) or obtain documentation of an onsite audit of the foreign supplier at least annually, unless more frequent onsite audits are necessary to adequately verify that the hazard is adequately controlled.

(2) Other hazards. For a hazard that you have identified as reasonably likely to occur with a food from a foreign supplier that is not specified in paragraph (g)(1) of this section, you must conduct one or more of the verification activities listed in paragraphs (g)(2)(i) through (g)(2)(iv) of this section before using or distributing the food and periodically thereafter. You must determine and document which verification activity or activities are appropriate to adequately verify that the hazard is adequately controlled. You must determine and document how frequently the verification activities must be conducted. In determining the appropriate

verification activities and how frequently they should be conducted, you must consider the risk presented by the hazard and the food and foreign supplier's compliance status as reviewed under § 1.504.

(i) Periodic onsite auditing. You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(ii) Periodic or lot-by-lot sampling and testing of the food. You conduct (and document) or obtain documentation (such as a certificate of analysis containing the results of the testing) from your foreign supplier of lot-by-lot or periodic sampling and testing of the food for the hazard.

(iii) Periodic review of the foreign supplier's food safety records. You periodically review (and document) or obtain documentation of a review of your foreign supplier's food safety records (such as records of your foreign supplier's audit of its supplier's hazard control activities).

(iv) Other appropriate procedure. You use any other procedure that you have established as being appropriate based on the risk associated with the hazard. You must document your use of any such procedure.

(3) Requirements of onsite auditing. An onsite audit conducted under this section must consider the FDA food safety regulations, if any, that apply to the food and foreign supplier and must include a review of the foreign supplier's written food safety plan, if any, for the hazard being audited and the supplier's implementation of such plan.

(4) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. Instead of an onsite audit conducted under paragraph (g) or (h) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or

~~the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.~~

~~(5) Review of results of verification activities. You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (g) or (h) of this section. If the results show that the hazards identified as reasonably likely to occur with a food are not adequately controlled, you must take appropriate action in accordance with § 1.507(c).~~

~~(6) Independence of qualified individuals conducting verification activities. A qualified individual who conducts any of the verification activities set forth in paragraphs (g)(1), (g)(2), and (h) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.~~

~~Option 2 for Requirements for Hazards Not Controlled by You or Your Customer~~

~~(g) Other hazards. (1) For a hazard that you have identified as reasonably likely to occur with a food from a foreign supplier and that is not controlled by you or your customer, you must conduct one or more of the verification activities listed in paragraphs (g)(1)(i) through (g)(1)(iv) of this section before using or distributing the food and periodically thereafter. You~~

must determine and document which verification activity or activities are appropriate to adequately verify that the hazard is adequately controlled. You must determine and document how frequently the verification activities must be conducted. In determining the appropriate verification activities and how frequently they should be conducted, you must consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier's compliance status as reviewed under § 1.504.

(i) Periodic onsite auditing. You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(ii) Periodic or lot-by-lot sampling and testing of the food. You conduct (and document) or obtain documentation (such as a certificate of analysis containing the results of the testing) from your foreign supplier of lot-by-lot or periodic sampling and testing of the food for the hazard.

(iii) Periodic review of the foreign supplier's food safety records. You periodically review (and document) or obtain documentation of a review of your foreign supplier's food safety records (such as records of your foreign supplier's audit of its supplier's hazard control activities).

(iv) Other appropriate procedure. You use any other procedure that you have established as being appropriate based on the risk associated with the hazard. You must document your use of any such procedure.

(2) Requirements of onsite auditing. An onsite audit conducted under this section must consider the FDA food safety regulations, if any, that apply to the food and foreign supplier and

must include a review of the foreign supplier's written food safety plan, if any, for the hazard being audited and the supplier's implementation of such plan.

(3) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. Instead of an onsite audit conducted under paragraph (g) or (h) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(4) Review of results of verification activities. You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (g) or (h) of this section. If the results show that the hazards identified as reasonably likely to occur with a food are not adequately controlled, you must take appropriate action in accordance with § 1.507(c).

(5) Independence of qualified individuals conducting verification activities. A qualified individual who conducts any of the verification activities set forth in paragraphs (g)(1) and (h) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.

~~Option 1 for Importers of Certain Produce~~

~~(h) Importers of certain produce. For a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter, in addition to the other requirements of this section, before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, you must conduct or obtain documentation of an onsite audit that examines the control of microbiological hazards associated with the fruit or vegetable. Such audit must provide adequate assurances that your foreign supplier is producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112 of this chapter. Such audits are subject to paragraphs (g)(3) through (g)(6) of this section. An audit conducted under this paragraph may be conducted in conjunction with an audit, if any, that is required under paragraph (g) of this section.~~

~~Option 2 for Importers of Certain Produce~~

~~(h) Importers of certain produce. For a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter, in addition to the other requirements of this section, before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, you must conduct one or more of the verification activities listed in paragraphs (g)(1)(i) through (g)(1)(iv) of this section to provide adequate assurances that your foreign supplier is producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112 of this chapter. An audit conducted under this paragraph is subject to paragraphs (g)(2) through (g)(5) of this section. You may conduct an activity under this paragraph in conjunction with an activity that you conduct in accordance with paragraph (g)(1)(i) through (g)(1)(iv) of this section.~~

§ 1.507 What investigations and corrective actions must I conduct under my FSVP?

(a) You must promptly conduct a review of any customer, consumer, or other complaint that you receive to determine whether the complaint relates to the adequacy of your FSVP.

(b) If you become aware that an article of food you import is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342 and 343(w)), either through review of a complaint or by other means, you must promptly investigate the cause or causes of such adulteration or misbranding. You must document any such investigation.

(c) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g or 350h), if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342 and 343(w)). This determination could be based on an investigation conducted under paragraph (b) of this section, the verification activities you conduct under § 1.506 or § 1.511(c), the FSVP reassessment you conduct under § 1.508, or otherwise. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(d) If you determine, by means other than your verification activities conducted under § 1.506 or § 1.511(c) or your FSVP reassessment conducted under § 1.508, that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under

section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(e) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§ 1.508 How must I reassess the effectiveness of my FSVP?

(a) Timing. (1) Except as specified in paragraph (a)(2) of this section, for each food you import, you must conduct a reassessment of your FSVP for the food, as described in paragraph (b) of this section, within 3 years of establishing the FSVP and within 3 years of the last reassessment.

(2) You must promptly reassess the effectiveness of your FSVP for a food you import when you become aware of new information about potential risks~~hazards~~ associated with the food or foreign supplier of the food.

(b) Reassessment and implementation of changes. In conducting a reassessment of your FSVP as required by paragraph (a) of this section, you must update your risk evaluation~~hazard analysis~~ for the food and foreign supplier in accordance with § 1.505. If the risks~~hazards~~ you previously identified ~~as reasonably likely to occur~~ change as a result of the reassessment, you must promptly determine whether the verification activities you conduct under § 1.506 or § 1.511(c) need to be changed to comply with that section, and you must promptly implement

any such changes. You must document each reassessment you conduct and any resulting changes to your FSVP.

§ 1.509 How must the importer be identified at entry?

(a) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of "importer" in § 1.500.

(b) You must obtain a Dun & Bradstreet Data Universal Numbering System (DUNS) number.

(c) You must ensure that, for each line entry of food product offered for importation into the United States, your name and DUNS number identifying you as the importer of the food is provided electronically when filing entry with U.S. Customs and Border Protection.

§ 1.510 How must I maintain records of my FSVP?

(a) Records of FSVP. You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(b) Record availability. You must maintain records required under this subpart, in English, and make them available promptly to an authorized FDA representative, upon request, for inspection and copying. You must maintain records at your place of business or at a reasonably accessible location; records are considered to be at a reasonably accessible location if they can be immediately retrieved from another location by computer or other electronic means. If requested in writing by FDA, you must send records to the Agency electronically rather than making the records available for review at your place of business.

(c) Record quality. All records must be legible and stored to prevent deterioration or loss.

(d) Record retention. (1) Except as specified in paragraph (d)(2) of this section, you must maintain records referenced in this subpart until at least 2 years after their use is discontinued (e.g., because you no longer import a particular food, you no longer use a particular foreign supplier, or you have changed your FSVP procedures).

~~Option 1~~

(2) You must maintain records required under §§ 1.502(d) and 1.504(g) (customer assurances), § 1.506(~~dg~~)(1)(i)(C), (d)(1)(ii)(B), (d)(1)(iii), and (d)(1)(iv)~~, (g)(2), and (h)~~ (certain verification activities), § 1.507 (investigations and corrective actions), § 1.508 (FSVP reassessments), § 1.511(b) (assurances from customers subject to certain dietary supplement current good manufacturing practice regulations, § 1.511(c)(5)(i)(C), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv) (certain verification activities for importers of~~food subject to~~ certain dietary supplements~~ current good manufacturing practice regulations~~), and § 1.513(b) (food imported from a country with an officially recognized or equivalent food safety system) for a period of at least 2 years after the records were created or obtained, except that you must maintain records of any changes to your FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.

~~Option 2~~

~~(2) You must maintain records required under § 1.506(g)(1) and (h) (certain verification activities), § 1.507 (investigations and corrective actions), § 1.508 (FSVP reassessments), § 1.511 (food subject to certain dietary supplement current good manufacturing practice regulations), and § 1.513(b) (food imported from a country with an officially recognized or~~

~~equivalent food safety system) for a period of at least 2 years after the records were created or obtained, except that you must maintain records of any changes to your FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.~~

§ 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

(a) Importers subject to certain dietary supplement current good manufacturing regulations. If you are required to establish specifications under § 111.70(b), (d), or (f) of this chapter with respect to a food you import and you are in compliance with the requirements of part 111 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ ~~1.506(a),~~ 1.509~~,~~ and 1.510, but you are not required to comply with the requirements in §§ 1.502 through 1.508 ~~(except § 1.506(a))~~. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) Importers whose customer is subject to certain dietary supplement current good manufacturing practice~~CGMP~~ regulations. If your customer is required to establish specifications under § 111.70(b), (d), or (f) of this chapter with respect to a food you import, your customer is in compliance with the requirements of part 111 of this chapter applicable for determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ ~~1.506(a),~~ 1.509~~,~~ and 1.510, but you are not required to comply with the requirements in §§ 1.502 through 1.508 ~~(except § 1.506(a))~~.

(c) Other importers of dietary supplements. (1) General. If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.5054(a)(2) through (a)(6) and (b), and 1.507 through 1.510, but you are not required to comply with the requirements in §§ 1.504 and 1.505(a)(1) and 1.506. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) Use of approved foreign suppliers. You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the risk evaluation you conduct under § 1.505 (or, when necessary and appropriate, on a temporary basis, from unapproved foreign suppliers whose foods you subject to adequate verification activities before using or distributing) You must document your use of these procedures. List of foreign suppliers. You must maintain a written list of foreign suppliers from which you are importing food.

(3) Foreign supplier verification procedures. You must establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods you import.

(4) Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that your supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required underthe requirements of part 111 of this chapter.

(5) Supplier verification activities. For each dietary supplement you import under paragraph (c) of this section, you must conduct one or more of the verification activities listed in paragraphs (c)(5)(i) through (c)(5)(iv) of this section before using or distributing the dietary

supplement and periodically thereafter. You must determine and document which verification activity or activities are appropriate to provide adequate assurances in accordance with paragraph (c)(4) of this section~~adequately verify that the foreign supplier is in compliance with the requirements of part 111 of this chapter~~. You must determine and document how frequently the verification activities must be conducted.

(i) Periodic onsite auditing. You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(A) An onsite audit of a supplier must be performed by a qualified auditor.

(B) The onsite audit must consider the requirements of part 111 of this chapter and must include a review of the foreign supplier's written food safety plan, if any, and the supplier's implementation of such plan.

(C) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(ii) Periodic or lot-by-lot sampling and testing of the food. ~~You conduct (and document) or obtain documentation (such as a certificate of analysis containing the results of the testing) from your foreign supplier of lot-by-lot or periodic sampling and testing of the dietary supplement.~~ (A) Sampling and testing of the dietary supplement may be conducted by you or the foreign supplier.

(B) You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the

date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

(iii) Periodic review of the foreign supplier's food safety records. You must retain documentation of each record review, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.~~You periodically review (and document) or obtain documentation of a review of your foreign supplier's food safety records.~~

(iv) Other appropriate activity. You may conduct other supplier verification activities that are appropriate based on the risks associated with the food and the foreign supplier. You must document each performance of such verification activity.~~Other appropriate procedure. You use any other procedure that you have established as being appropriate. You must document your use of any such procedure~~.

(6)~~ Requirements of onsite auditing. An onsite audit conducted under paragraph (c)(5)(i) of this section must consider the requirements of part 111 of this chapter and must include a review of the foreign supplier's written food safety plan, if any, and the supplier's implementation of such plan.~~

~~(7)~~ Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. Instead of an onsite audit conducted under paragraph (c)(5)(i) of this section, an importer may rely on the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been

required to be conducted. You must document the inspection results on which you rely. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(7~~8~~) Review of results of verification activities. You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5) of this section. If the results show that the foreign supplier does not meet the standard in paragraph (c)(4) of this section, you must take appropriate action in accordance with § 1.507(c).

(8~~9~~) Independence of qualified individuals conducting verification activities. A qualified individual who conducts any of the verification activities set forth in paragraph (c)(5) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.

§ 1.512 What FSVP may I have if I am a very small importer or I am importing food from a very small supplier?

(a) Eligibility. This section applies only if you a very small importer or the food you are importing is from a very small foreign supplier.

(b) Applicable requirements. (1) If this section applies and you choose to comply with the requirements in this section, you must document, at the end of each calendar year, that you meet the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. For the purpose of

determining whether you satisfy the definition of very small importer or the foreign supplier satisfies the definition of very small foreign supplier, the baseline year for calculating the adjustment for inflation is 2012. If you or the foreign supplier conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(2) Additional requirements. If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, ~~through~~ 1.5034, and ~~§~~ 1.509, but you are not required to comply with the requirements in §§ 1.5045 through 1.508 or § 1.510.

~~(3) List of foreign suppliers. You must maintain a written list of foreign suppliers from which you are importing food~~.

(34) Foreign supplier verification activities. For each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, 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 section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g or 350h), if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 343(w)). The written assurance must include a brief description of the processes and procedures that the foreign supplier is following to ensure the safety of the food.

(45) Corrective actions. You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as

those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5~~6~~) Records. (i) Availability. You must maintain records required under this subpart, in English, and make them available promptly to an authorized FDA representative, upon request, for inspection and copying. You must maintain records at your place of business or at a reasonably accessible location; records are considered to be at a reasonably accessible location if they can be immediately retrieved from another location by computer or other electronic means. If requested in writing by FDA, you must send records to the Agency electronically or by mail rather than making the records available for review at your place of business.

(ii) Record quality. All records must be legible and stored to prevent deterioration or loss.

(iii) Record retention. You must maintain records required under this subpart for a period of at least 2 years after the records were created or obtained.

§ 1.513 What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?

(a) General. If you meet the conditions and requirements of paragraph (b) of this section for a food you are importing, then you are not required to comply with the requirements in

§§ 1.503 through 1.508 ~~(except § 1.506(a))~~. You would still be required to comply with the requirements in §§ ~~1.506(a),~~ 1.509~~,~~ and 1.510.

(b) Conditions and requirements. (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being adequately controlled, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph.

§ 1.5134 What are some consequences of failing to comply with the requirements of this subpart?

(a) Refusal of admission. An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)(3)) if it appears that the importer of that food fails to comply with this subpart with respect to that food. If an article of food has not been sold or consigned to a person in the United States at the time

the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has designated a U.S. agent or representative as the importer for the purposes of the definition of "importer" in § 1.500.

(b) Prohibited act. The importation or offering for importation into the United States of an article of food by an importer without having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a), including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(zz)).