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

Guidance for Industry

Draft Guidance

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

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

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

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 purpose of this document is to provide guidance for industry on the requirements for a foreign supplier verification program (FSVP) in 21 CFR part 1, subpart L, that importers of human or animal food must establish and follow to ensure that each food they import into the United States meets applicable U.S. requirements and is not adulterated or (for human food) misbranded with respect to allergen labeling.

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

This guidance provides questions and answers to facilitate importers' understanding of the FSVP requirements. The pronouns "I," "me," and "you" are used in this guidance to refer to the importer. "Agency" and the pronouns "we" and "our" are used to refer to FDA. The term "food" includes food for humans and animals and has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(f)), except that, for the purposes of FSVP, "food" does not include pesticides as defined in 7 U.S.C. 136(u) (21 CFR 1.500). "Food" includes:

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

Thus, food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) are "food" for the purposes of FSVP.

This guidance uses acronyms and short titles as shown in Table 1 and Table 2.

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Table 1 – Acronyms

Reference	Acronym
Federal Food, Drug, and Cosmetic Act	FD&C Act
FDA Food Safety Modernization Act	FSMA
Foreign Supplier Verification Program regulation (21 CFR 1.500 through 1.514)	FSVP
Raw agricultural commodities	RACs
United States Department of Agriculture	USDA
U.S. Customs and Border Protection	CBP
Federal Meat Inspection Act	FMIA
Poultry Products Inspection Act	PPIA
Egg Products Inspection Act	EPIA
Food Safety Preventive Controls Alliance	FSPCA

Table 2 – Short Titles

Reference	Short Reference
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (21 CFR part 117)	preventive controls for human food regulation or part 117
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animal Food (21 CFR part 507)	preventive controls for animal food regulation or part 507
Preventive controls for human food regulation and for animal food regulation, collectively (21 CFR parts 117 and 507)	preventive controls regulations
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112)	produce safety regulation
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (21 CFR part 1 subpart M)	third-party certification regulation
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (21 CFR part 111)	dietary supplement regulation
Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed	low-acid canned foods regulation

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Containers (21 CFR part 113)	
Production, Storage, and Transportation of Shell Eggs (21 CFR part 118)	shell eggs regulation
Acidified Foods (21 CFR part 114)	acidified foods regulation
Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications (21 CFR part 106) and Infant Formula (21 CFR part 107)	infant formula regulations
Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007	RFR guidance

II. Background

The FD&C Act was amended by FSMA to add section 805 (21 U.S.C. 384a) to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying that:

- The food is produced in compliance with section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are RACs) of the FD&C Act (21 U.S.C. 350g and 350h), as appropriate;
- The food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and
- The food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling).

Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of foreign supplier verification programs. Section 805(b) of the FD&C Act requires FDA to issue guidance to assist importers in developing, implementing, and following an FSVP for each food they import.

FDA issued the final FSVP regulation for importers of food for humans and animals on November 27, 2015 (80 FR 74225). The FSVP regulation, codified in 21 CFR 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and 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

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- Importer identification for a food offered for entry into the United States.

The FSVP regulation aligns with key components of the food safety plans that facilities that manufacture, process, pack, or hold must establish and follow under the preventive controls requirements in FDA's preventive controls regulations. In particular, the FSVP regulation is consistent with the supply-chain program provisions of those regulations to the extent feasible and appropriate. The general FSVP framework, together with the modified requirements applicable to certain importers and foods, are intended to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade.

III. Questions and Answers

A. To what foods does the FSVP regulation apply? (21 CFR 1.501)

A.1 Q: Who must comply with the FSVP regulation?

A: The FSVP regulations apply to importers of food into the United States, as the term "importer" is defined in section 805(a)(2) of the FD&C Act and the FSVP regulation (21 CFR 1.500) (see 21 CFR 1.501(a)).

A.2 Q: How do I determine if I am an importer of a food for the purposes of the FSVP regulation (FSVP importer)?

A: You are the FSVP importer if you are the U.S. owner or consignee of an article of food that is being offered for import into the United States (21 CFR 1.500). If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the FSVP 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 the FSVP regulation.

A.3 Q: Must the FSVP importer be in the United States?

A: The FSVP importer must be located in the United States (21 CFR 1.500). This applies whether you are the U.S. owner or consignee of the food at the time of entry (see Question A.4) or the U.S. agent or representative of the foreign owner or consignee at the time of entry (see Questions A.11 and A.12). An FSVP importer could be a person who resides in the United States or maintains a place of business in the United States. It would not be sufficient to merely have a mailbox, answering service, or some other place in the United States where the importer is not physically present.

A.4 Q: What does "U.S. owner or consignee" mean?

A: "U.S. owner or consignee" means the person in the United States who, at the time of entry of an article of food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food (21 CFR 1.500). There is a variety of commercial arrangements regarding the importation of food. In some cases, one or more persons may have purchased the food (i.e., obtained it through payment of money or equivalent) or agreed in writing to purchase the food but do not own it at the time of entry. In addition, there may be cases in which, although ownership of an imported food has not transferred from the foreign owner at the time of the food's entry into the United States, there are one or more U.S. entities who have purchased the food or agreed in writing to purchase it.

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The FSVP importer must ensure that, for *each line entry of food product* offered for entry into the United States, the importer's name, email address, and unique facility identifier recognized as acceptable by FDA are provided electronically when filing entry with U.S. Customs and Border Protection (CBP) (21 CFR 1.509(a)).

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

A: In some cases there might be multiple entities that meet the "importer" definition for the same line of an entry of food offered for import into the United States. For example, a U.S. company might purchase olive oil manufactured in Italy and, at the time of entry, have entered into an agreement to re-sell the olive oil to a U.S. retail store after the product has entered the United States. In this case, both the U.S. purchaser and the retail store might meet the definition of importer. Alternatively, a foreign grower of lettuce might arrange for the importation of the lettuce into the United States under written agreements to sell the lettuce to multiple, unaffiliated U.S. buyers once the lettuce has entered this country.

When there are multiple entities that meet the "importer" definition, these entities will need to determine who will be responsible for meeting the FSVP requirements for the food (and, consequently, who should be identified as the importer of the food at entry). We expect that U.S. owners and consignees will address the responsibility for FSVP compliance in their contractual agreements when they have a direct commercial relationship. If there is an agreement between or among multiple U.S. owners or consignees of a food regarding responsibility for FSVP compliance and identification of the importer at entry, the entity identified as the FSVP importer at entry would be the entity that we would ordinarily prioritize for possible review under our risk-based FSVP compliance assessment program. When there are multiple unaffiliated U.S. owners or consignees for the same line of an entry of a food, we anticipate that each such entity will develop an FSVP for the food and foreign supplier. However, if one of the entities were willing to serve as the FSVP importer for this food from this foreign supplier, this would be permissible under the regulation. Similarly, if someone (e.g., one of multiple U.S. owners or consignees of a food) fraudulently or unintentionally identified a U.S. owner or consignee of a food as the FSVP importer (contrary to a written agreement regarding responsibility for FSVP compliance), we would take this into account in any enforcement action we take with respect to this food.

A.6 Q: What does it mean to have "agreed in writing to purchase" a food?

A: A person has agreed in writing to purchase a food (for the purposes of the definition of "U.S. owner or consignee") when he or she has entered into a written promise to purchase the food at a later date. Typically a buyer of a food issues a purchase order to a seller indicating the product to be purchased, the quantity, and the price. When the seller confirms acceptance of the purchase order in writing, there is a written agreement that the buyer will purchase the food. We regard agreements entered into electronically (e.g., through online submission and acceptance of a purchase order) as being "in writing."

A.7 Q: What is meant by "time of U.S. entry"?

A: Time of U.S. entry for the purposes of the definition of importer under the FSVP regulation is the time when the entry documentation for an imported food is submitted to CBP. (Time of

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entry for FSVP purposes is not necessarily the same as time of entry for CBP purposes under 19 CFR 141.68.)

A.8 Q: Would a retailer that places a purchase order with a U.S.-based food distributor be considered the “U.S. owner or consignee,” where the retailer does not specify the source of the food and the distributor purchases the food directly from a foreign supplier?

A: No. If the retailer does not direct the distributor to purchase the food from a particular source or sources, the retailer would not be the “U.S. owner or consignee.” For example, if a retailer places a purchase order for bell peppers from a U.S.-based distributor without specifying the source of the peppers, the retailer would not own the food, have purchased the food, or have agreed in writing to purchase the food at the time of entry. The retailer would have only placed an order directing the distributor to obtain peppers, leaving the decision about the source of the peppers to the distributor. At the time of entry, the distributor is the entity that purchased the peppers. Therefore, the distributor would meet the “U.S. owner or consignee” definition in 21 CFR 1.500.

A.9 Q: Would a retailer be the “U.S. owner or consignee” if the retailer agrees in writing, three days after the food arrives in the United States, to purchase the food at a warehouse of a U.S.-based distributor?

A: No. Agreeing in writing to purchase an imported food after the conclusion of the entry process does not cause the retailer to be the “U.S. owner or consignee.” The “U.S. owner or consignee” is the entity that owns the food, has purchased the food, or has agreed in writing to purchase the food *at the time of U.S. entry*.

A.10 Q: Would a U.S.-based distributor be the “U.S. owner or consignee” of a shipment of food if the distributor has a written agreement with the foreign producer to purchase the food, but the agreement allows for the distributor to reject the food if certain quality standards are not met?

A: Yes. In this situation, the distributor has a written agreement to purchase the food at the time of U.S. entry. The distributor therefore meets the “U.S. owner or consignee” definition, even if the condition regarding quality standards means that the distributor does not own the food unless the quality standards are satisfied.

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

A: The importer of a food for purposes of FSVP may be, but is not necessarily, the importer of record for CBP purposes. Under the FSVP regulation, the importer is the person who is responsible for verifying that the imported food was produced in accordance with applicable U.S. food safety requirements. In contrast the CBP importer of record of a food might be an express consignment operator with little to no knowledge of the safety regulations applicable to the products for which they obtain clearance from CBP.

A.12 Q: When is a U.S. agent or representative required under the FSVP regulation for importing a food?

A: A U.S. agent or representative of a foreign supplier of a food is a person in the United States (see Question A.3) who is designated by the foreign owner or consignee of a food as the owner or consignee’s agent or representative for purposes of meeting the requirements of the FSVP

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regulation, as confirmed in a signed statement of consent to serve as the FSVP importer (21 CFR 1.500). If there is no U.S. owner or consignee of an article of food at the time of entry, the foreign owner or consignee of the food must designate a U.S. agent or representative to serve as the importer of the food for FSVP purposes (21 CFR 1.509(b)). In this situation, the U.S. agent or representative is the importer of the food (under the definition of “importer” in 21 CFR 1.500) who is responsible for meeting the FSVP requirements. This requirement ensures that there is an entity located in the United States who is responsible for developing and implementing an FSVP for the food offered for entry.).

A.13 Q: Is the U.S. agent or representative for FSVP purposes the same as the U.S. agent for purposes of registration of a foreign food facility?

A: A U.S. agent or representative of a foreign owner or consignee for FSVP could be, but is not required to be, the same person as the U.S. agent of a foreign food facility named in the facility’s FDA registration under section 415 of the FD&C Act. Section 415(a)(1)(B) of the FD&C Act (21 U.S.C. 350d(a)(1)(B)) specifies that a foreign food facility must submit the name of the “United States agent” for the facility as part of the facility’s registration under that section. FDA’s regulation implementing the food facility requirements in section 415 of the FD&C Act requires that the registration for foreign facilities include the name of the U.S. agent for the facility (21 CFR 1.232). For food facility registration purposes, the U.S. agent is defined as a person (as defined in section 201(e) of the FD&C Act) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of food facility registration (21 CFR 1.227). The food facility regulation further specifies that the U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications (21 CFR 1.227).

In contrast, the U.S. agent or representative of a foreign owner or consignee for FSVP purposes is responsible for meeting the full breadth of applicable requirements under the FSVP regulation. These requirements include conducting a hazard analysis, performing supplier verification activities, and taking other steps to ensure the safety of imported food. These responsibilities are qualitatively different from serving as a communications link with a foreign facility. Therefore, a U.S. agent or representative for FSVP purposes serves a different role than a U.S. agent named in the FDA registration of a foreign food facility.

The U.S. agent of a foreign food facility may also serve as the U.S. agent or representative of that facility for FSVP purposes, provided that the person has signed a statement of consent to serve as the importer of the food for purposes of the FSVP regulation (21 CFR 1.500). It is up to the foreign owner or consignee of a food to determine which person (whether the foreign entity’s U.S. agent for registration purposes or some other person) will serve as its U.S. agent or representative for FSVP purposes (i.e., bear the responsibilities of the FSVP importer of the food).

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

A: No. If the foreign owner or consignee of a food designates you as the U.S. agent or representative for FSVP purposes, the designation is not valid unless you confirm in a signed statement that you have consented to serve as the FSVP importer (21 CFR 1.500). We may

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review the signed statement during a records review to verify the accuracy of the U.S. agent or representative designation. False representations to the U.S. government, including falsely identifying a U.S. agent or representative, may result in criminal prosecution of those involved.

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

A.15 Q: If I comply with the FSVP requirements for a food I import, is the food exempt from the prior notice requirements in 21 CFR part 1, subpart I?

A: No. Although both the FSVP and prior notice regulations help FDA ensure the safety of foods imported into the United States, each has a distinct purpose. FSVP focuses on ensuring that the food is safe before arrival at U.S. ports of entry. Under FSVP, the importer must perform risk-based foreign supplier verification activities to ensure that the foreign supplier produces the food using processes and procedures that provide the same level of public health protection as those required under the (1) preventive controls requirements in parts 117 and 507 or (2) the produce safety regulation, as applicable to the imported food, and that the food is not adulterated under section 402 of the FD&C Act or misbranded with respect to allergen labeling under section 403(w) of the FD&C Act. Prior notice is notification to FDA that an article of food is being imported or offered for import in advance of the arrival of the article of food. Advance notice of import shipments allows FDA, with the support of CBP, to target import examinations more effectively once food arrives at our ports of entry and help protect the nation's food supply.

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

A: The foreign supplier of a food is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature (21 CFR 1.500). Because of this, your foreign supplier might not be the entity from which you directly obtain the food you import. If you obtain a food from a foreign warehouse, distributor, broker, or other entity that does not perform any manufacturing/processing of a more-than-de minimis nature, the foreign supplier of the food would be the last entity in the foreign supply chain that conducts significant manufacturing/processing of the food. For example, if you import packaged dog food from a foreign distributor who obtains the dog food in its final packaging from the manufacturer, the foreign supplier would be the manufacturer of the dog food. Or if you obtain oranges from a packing house that only packs and holds the oranges (and does not perform manufacturing/processing on the oranges of more than a de minimis nature), the foreign suppliers would be the farms that grew the oranges.

A foreign supplier may or may not be a food facility that is required to register under section 415 of the FD&C Act. For example, an establishment that raises animals or grows food is included in the definition of foreign supplier but may not be required to register as a food facility with FDA (see 21 CFR part 1, subpart H).

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

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

Packing, cooling, and holding performed by a packing house (that only packs and holds produce and cools the produce incidental to packing and holding) would not make the packing house the foreign supplier, because these activities would not be considered manufacturing/processing but only packing and holding. Waxing, sorting, culling, conveying, and storing of raw agricultural commodities (RACs) would generally be considered packing or holding. Re-packing is a packing activity (i.e., the definition of packing includes re-packing), not a manufacturing/processing activity. For more information on activities related to RACs, see FDA's draft guidance on "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities"

(<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517567.htm>).

A.18 Q: What is an example of manufacturing/processing that is "de minimis"?

A: Adding labels is considered to be de minimis manufacturing/processing.

A.19 Q: Which foods that I import are subject to the FSVP requirements?

A: The FSVP regulation applies to all food (as defined in 21 CFR 1.500) imported or offered for import into the United States unless an exemption applies. The following foods are exempt from the FSVP regulation:

- Juice and fish and fishery products and ingredients for such products subject to HACCP regulations (see Question A.22)
- Food imported for research or evaluation (see Questions A.22 through A.27)
- Food imported for personal consumption (see Questions A.28 through A.30)
- Alcoholic beverages, alcoholic beverage ingredients, and certain non-alcohol foods (see Questions A.32 through A.34)
- Food that is transhipped through the United States (see Question A.36)
- Food that is imported for processing and export (see Question A.37)
- U.S. food returned (see Questions A.38 and A.39)
- Certain meat, poultry, and egg products (see Questions A.40 and A.41)

A.20 Q: Are food contact substances subject to the FSVP requirements?

A: Food contact substances are included in the definition of "food" for purposes of the FSVP regulation (21 CFR 1.500). However, for the reasons stated below, we intend to exercise enforcement discretion for importers of food contact substances with respect to the FSVP regulation.

A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food (section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)); 21 CFR 170.3(e)(3)). The term "food" is defined in section

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201(f)(3) of the FD&C Act to include articles used as components of food. In the preamble to the FSVP final rule, we stated that the definition of “food” for purposes of FSVP includes food contact substances that are considered “food” in section 201(f) of the FD&C Act (80 FR 74225 at 74233). Therefore, the FSVP regulation applies to importers of food contact substances that meet the definition of “food” in section 201(f).

After publishing the FSVP final rule, we issued a *Federal Register* notice (81 FR 57784, August 24, 2016) that, among other things, extended the compliance date for the importation of food contact substances by 2 years so that we could consider how best to address concerns raised about the feasibility of importers of food contact substances meeting the FSVP requirements. As a result of this extension, the earliest that an importer would be required to comply with FSVP for the importation of food contact substances would be May 28, 2019.

Upon consideration of comments and information provided by industry and other interested parties and the issues involved, we have concluded that, because of certain characteristics related to the nature of food contact substances, FDA’s premarket review/oversight of food contact substances, and the regulatory framework for such substances, it is appropriate to consider the exercise of our enforcement discretion to not require importers of food contact substances to meet FSVP requirements. Because by definition food contact substances are not intended to have a technical effect in food, food contact substances generally result in relatively low levels of migration to food. Consequently, consumer exposure to food contact substances is frequently less than exposure to other types of food substances. In addition, FDA has extensive premarket review processes for these substances under the food contact notification (FCN) process and the food additive petition process. Section 309 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) amended section 409 of the FD&C Act to establish the FCN process (codified in 21 CFR 170.100 through 170.106) as the primary method by which we regulate food additives that are food contact substances. Before FDAMA, many food additives that are now authorized through the FCN process required premarket approval by the Agency through the submission of food additive petitions and publication of regulations authorizing their intended use.

Both the FCN process and the food additive approval process require the notifier or petitioner to demonstrate that the intended use of the food contact substance is safe within the meaning of section 409(c)(3)(A) of the FD&C Act. If the information in the food additive petition or notification does not support the safety of the substance, FDA will act so that this use is not authorized: for food additive petitions, we can deny the petition; for FCNs, we can object to the notification within 120 days from the date of receipt of the notification so that it does not become effective (21 CFR 170.104)(c)). For an authorized use of a food contact substance, the food additive regulation or effective notification establishes, among other things, specifications (including purity or physical properties) for the substance and any limitations on the conditions of use. A substance is not authorized for use in contact with food in the United States unless it complies with all such criteria. Further, we note that food contact substances are not subject to the supply-chain program requirements in the human food preventive controls regulation. Under that regulation, the supply-chain program requirements only apply to hazards requiring a supply-chain applied control, and FDA has determined that there are no hazards associated with food

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contact substances that are hazards requiring a supply-chain applied control under 21 CFR 117.405(a)(1).

Given the foregoing, we intend to exercise enforcement discretion for these food contact substances with regard to the FSVP requirements. However, importers of food contact substances remain subject to the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a)). In addition, we will consider revising our exercise of enforcement discretion if, for example, new information becomes available regarding safety concerns associated with food contact substances.

A.21 Q: Are grains that are RACs subject to the FSVP requirements?

A: Grains that are RACs – including barley, dent- and flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds for oil extraction (e.g., cotton seed, flax seed, rapeseed, soybean, sunflower seed)) – are “food” subject to the FSVP regulation. However, we intend to exercise enforcement discretion with regard to the FSVP requirements for certain importers of grain RACs. This applies to the following importers of grain RACs: (1) Those that are solely engaged in the storage of grain intended for further distribution or processing; and (2) those that do not take physical possession of the grain they import, but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing. For more information regarding this exercise of enforcement discretion, see our guidance for industry on “Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities” which can be accessed at www.fda.gov/fsma.

A.22 Q: Under what circumstances are importers of juice and fish and fishery products and ingredients for such products exempt from the FSVP regulation?

A: The FSVP regulation does not apply to juice and fish and fishery products you import from a foreign supplier that is required to comply with, and is in compliance with, FDA’s hazard analysis and critical control point (HACCP) regulations for those foods (21 CFR parts 120 and 123, respectively). Instead, you must comply with the importer requirements of the juice and fish and fishery products regulations (21 CFR 120.14 and 123.12, respectively). (Among other things, you must implement written procedures for ensuring that these imported foods are processed in accordance with the HACCP regulations, including the use of “affirmative steps” such as obtaining continuing or lot-specific certificates from an appropriate foreign government inspection authority or competent third party, or regularly inspecting foreign processor facilities (see 21 CFR 120.14(a)(2)(ii) and 123.12(a)(2)(ii)).) In addition, the FSVP regulation does not apply with respect to raw materials or other ingredients you use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you comply with the relevant regulation when manufacturing or processing the juice or seafood product from the imported raw materials or other ingredients (see 21 CFR 1.501(b)).

For more information on application of the FSVP regulation and other FSMA regulations to juice and raw materials or other ingredients used in manufacturing or processing juice, see FDA’s guidance entitled “Juice HACCP and the FDA Food Safety Modernization Act” (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569777.pdf>). For more information on application of the FSVP regulation and other FSMA regulations to fish and fishery products and raw materials or other ingredients used

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in manufacturing or processing seafood, see FDA’s guidance entitled “Seafood HACCP and the FDA Food Safety Modernization Act”

(<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569798.pdf>).

A.23 Q: Under what circumstances is a food that I import for research or evaluation exempt from the FSVP regulation?

A: The FSVP regulation does not apply to food you import for research or evaluation use, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled with the statement, “Food for research or evaluation use”;
- The food is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and
- When filing entry for the food with CBP, the food is accompanied 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.

[FD&C Act section 805(f) and 21 CFR 1.501(c)]

You should take steps to ensure that the label statement “Food for research or evaluation use” is securely attached to the food so that it remains on the food until the food is used for research or evaluation. You should ensure that the label statement is not removed to facilitate sale or distribution of the food to the public.

A.24 Q: What does “research or evaluation” of an imported food mean?

A: Research or evaluation of a food for humans may involve analyzing food for characteristics such as protein or fat content, testing or observing physical characteristics such as color or texture, and sensory analysis or evaluation, such as organoleptic analyses for testing the quality of tea. It may also include research for marketing purposes. For animal food, research might involve palatability studies or studies to evaluate the impact of an ingredient or diet on animal production characteristics (e.g., growth, milk production, reproduction).

A.25 Q: What does a “small quantity” of a food that is consistent with a research or evaluation purpose mean?

A: The quantity of the imported food should be sufficient to perform the research, analysis, or quality assurance procedures, with no or very little food remaining after completion. The amount of food used in research or for evaluation can vary based on the type of food, the nature of the research or evaluation, and other factors such as the number of repetitions required for the research or evaluation process. For example, 10 pounds of a human food may be a small quantity for performing a laboratory analysis for pesticides (although 200 pounds of a food might be needed for similar research involving cattle) and 50 pounds of the food may be a small quantity for a mycotoxins analysis. On the other hand, only a few ounces of a color additive might be needed for research. If the entire amount of a food imported for the research is used during the course of the research, this would provide support for regarding the sample as a “small quantity” consistent with a research use.

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A.26 Q: Does the exemption for food for research or evaluation include food imported for consumption or distribution at trade shows?

A: Generally, no. Because food imported for consumption at trade shows typically is sold or distributed to the public generally (i.e., anyone who attends the trade show), exempting such food from the FSVP regulation would be inconsistent with the exemption provisions for food imported for research or evaluation stated in Question A.23 (see section 805(f) of the FD&C Act and 21 CFR 1.501(c)(1)). However, the exemption for research or evaluation would apply to food used in a defined study, conducted during a trade show, of a food involving a discrete set of test subjects who have agreed to participate in the study, because it does not appear that such food would be sold or distributed to the general public.

A.27 Q: Does the exemption for research or evaluation apply to food imported for use in in-home studies?

A: The exemption for research or evaluation may apply to food imported for use in in-home studies. The exemption may apply if the in-home study involves a discrete set of test subjects for the research or evaluation purposes. For example, the exemption may apply if the food is to be fed to pets as part of an in-home study of the pet food in accordance with contractual agreements with each pet owner. The food must be imported in a small quantity consistent with the research purpose and meet the other requirements for the exemption (see Question A.23).

A.28 Q: What electronic declaration must I submit for a food that will be used for research or evaluation?

A: When you import a food for research or evaluation, you must, when filing entry with CBP, provide an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public (21 CFR 1.501(c)(4)). You may do this using the affirmation of compliance code “RNE.” For additional information see Question I.11.

A.29 Q: Under what circumstances is a food I import for personal consumption exempt from the FSVP regulation?

A: The FSVP regulation does not apply to food you import for personal consumption, provided that the food is not intended for retail sale and is not sold or distributed to the public. Food is considered to be imported for personal consumption when 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 (FD&C Act section 805(f); 21 CFR 1.501(d)).

A.30 Q: What constitutes a “small quantity” of a food imported for personal consumption that is consistent with a non-commercial purpose?

A: The determination of the quantity of food that is consistent with a non-commercial purpose is made on a case-by-case basis and might vary depending on such factors as the type of food and its shelf life. Basically, the quantity of the imported food should not exceed the amount you can use for personal consumption within a reasonable period of time (e.g., on or before the expiration date). For example, a supply of a perishable food that exceeds what one person or household might consume in a relatively short period of time, such as 50 pounds of cheese, might suggest a commercial purpose and thus fall outside of the personal consumption exemption for FSVP. However, 50 pounds of a food with a long shelf life (e.g., cereal) might be consistent with a

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personal consumption purpose. In all cases, a food would not be subject to the exemption if it is sold or distributed to the public.

A.31 Q: How do I indicate at entry that a food is imported for personal consumption?

A: You may identify a food as intended for personal consumption by providing intended use code 210.000 for “Personal Importation” in the entry documentation. Alternatively, you may include a statement that a food is imported for personal consumption in the entry documentation or in response to an FDA request during the entry review.

A.32 Q: Under what circumstances is an alcoholic beverage I import exempt from the FSVP regulation?

A: The FSVP regulation does not apply to an alcoholic beverage you import from a foreign supplier that is a facility that meets the following two conditions:

- The foreign facility is 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 (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.)); and
- The facility is required to register with FDA as a food facility because it is engaged in manufacturing/processing one or more alcoholic beverages (under section 415 of the FD&C Act).

A.33 Q: How should I indicate at entry that I am importing an alcoholic beverage that is exempt from the FSVP regulation?

A: You may identify alcoholic beverages by providing the appropriate product code on the entry documents submitted to CBP.

A.34 Q: Does the FSVP regulation apply to food that is not an alcoholic beverage that I import from a foreign supplier that manufactures/processes alcoholic beverages?

A: The FSVP regulation does not apply to a food that is not an alcoholic beverage obtained from a foreign supplier that manufactures/processes alcoholic beverages and that meets the requirements in Answer A.32, provided the food:

- Is in prepackaged form that prevents any direct human contact with the food; and
- Constitutes not more than 5 percent of the overall sales of the foreign supplier’s facility, as determined by the Secretary of the Treasury (21 CFR 1.501(e)(2)).

For example, a non-alcoholic beverage from a foreign alcoholic beverage distillery is exempt from the FSVP regulation if it meets these requirements.

A.35 Q: Does the FSVP regulation apply to the ingredients that I import for use in making alcoholic beverages?

A: The FSVP regulation does not apply to ingredients that you import for use in alcoholic beverages provided that:

- You perform the manufacturing/processing, packing, or holding of the alcoholic beverages for which the ingredients were used;
- You are required to register as a food facility under section 415 of the FD&C Act; and

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- You are exempt from the preventive controls for human food regulation in accordance with 21 CFR 117.5(i) (21 CFR 1.501(e)(3); 21 CFR 117.5(i)).

For example, if you import hops from England that you use to make an English-style beer and you meet these requirements, the hops are exempt from the FSVP regulation.

A.36 Q: Under what circumstances is a food that I import for transshipment through the United States exempt from the FSVP regulation?

A: The FSVP regulation does not apply to a food that is transshipped through the United States to another country and is not sold or distributed to the public in the United States (21 CFR 1.501(f)(1)). Transshipment of a food involves shipment into and out of the United States without the food undergoing any processing or use in the manufacture of another food. Food offered for transshipment through the United States typically is declared to CBP using an in-transit entry type for “Transportation and Exportation” or “Immediate Exportation.” Examples of transshipment include (1) the transport of fresh produce from Mexico through the United States to Canada and (2) the shipment of grain from western Canada through the United States into eastern Canada.

A.37 Q: Under what circumstances is a food I import for processing and future export from the United States exempt from the FSVP regulations?

A: The FSVP regulations do not apply to a food imported for processing and future export and that is not sold or distributed to the public in the United States (21 CFR 1.501(f)(2)).

A.38 Q: If I import into the United States a food that was manufactured in the United States, exported, and then returned to the United States without further manufacturing/processing, am I subject to the FSVP requirements for that food?

A: Some food is produced in and exported from the United States and then brought back into the United States by the U.S. exporter of the food or some other entity, e.g., as a result of being rejected by the foreign purchaser. Such goods are sometimes referred to as “U.S. goods returned”. You are not subject to the FSVP regulation for a U.S. food returned (i.e., a food that was manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in the foreign country to which the food was exported) (21 CFR 1.501(g)). The exemption applies whether or not you, the importer, manufactured/processed, raised, or grew the food in the United States. However, even though the FSVP requirements do not apply to this food, if the food does not meet applicable U.S. regulatory requirements it cannot be sold or distributed in the United States. For example, if the U.S. food returned contains a color additive that causes the food to be adulterated under the FD&C Act, you may not sell or distribute the food in domestic U.S. commerce; you would need to re-export the food (in accordance with section 801(e) of the FD&C Act) or destroy it.

A.39 Q: How should I indicate at entry that I am importing “U.S. food returned” that is not subject to the FSVP regulation?

A: You may identify an entry of food as not subject to the FSVP regulation because it is “U.S. food returned” by ensuring that the United States is specified as the FDA Country of Production in the entry documentation.

A.40 Q: What meat, poultry, and egg products are exempt from the FSVP regulation?

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A: The FSVP regulation does not apply to certain meat, poultry, and egg products that at the time of U.S. entry are subject to regulation by the U.S. Department of Agriculture (USDA), as follows:

- Meat food products that at the time of importation are subject to the requirements of the USDA under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.). The FMIA regulates the inspection of the following species: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. In addition, under the FMIA, the USDA regulates fish of the order Siluriformes and products derived from these fish. Food from other animals (e.g., bison, rabbits, game animals, and all members of the deer family including elk (wapiti) and moose)) is not subject to the requirements of the FMIA at the time of importation and therefore would be subject to FSVP. In addition, products with 3 percent or less raw meat; less than 2 percent cooked meat or other portions of the carcass; or less than 30 percent fat, tallow or meat extract, alone or in combination; and closed-face sandwiches are not subject to the requirements of the FMIA at the time of importation and therefore would be subject to FSVP.
- Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.). The PPIA defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas, ratites, and squab. Products containing either less than 2 percent cooked poultry meat; or less than 10 percent cooked poultry skins, giblets, fat and poultry meat (limited to less than 2 percent); and closed-face sandwiches are not subject to the requirements of the PPIA at the time of importation and therefore would be subject to FSVP. In addition, food from all non-specified birds including wild turkeys, wild ducks, and wild geese is not subject to the requirements of the PPIA at the time of importation and therefore would be subject to FSVP.
- Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). Egg products are made from the shell eggs of domesticated chicken, turkey, duck, goose or guinea. USDA defines “egg product” to include dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. Note that egg products do not include shell eggs. Also, egg products do not include, among other foods: egg substitutes, cooked egg products, freeze-dried products, imitation egg products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies.

For more information on meat, poultry, and egg products subject to USDA regulation at the time of importation, see USDA’s Food Safety and Inspection Service Web site (<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/imported-food-products-containing-a-small-amount-of-meat-poultry-or-processed-egg-product-ingredients>).

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A.41 Q: Does the exemption for certain meat, poultry, and egg products apply to live animals?

A: The exemption in section 1.501(h) does not apply to the importation of live animals intended for consumption, i.e., the importer of the live animals is subject to the FSVP regulation. With respect to live animals that are eventually processed at slaughter and production plants inspected by USDA's FSIS or by States under cooperative agreements with FSIS, we generally expect that importers will determine that the live animals could not be consumed without application of an appropriate control in the supply or distribution chain. In that case, the importer would be required to comply with section 1.507(a)(1) (see Question G.1) and would not be required to conduct an evaluation of the food and foreign supplier under section 1.505 or supplier verification activities under section 1.506. The principal hazards for such live animals are chemical hazards (such as unlawful drug residues) and prions that cause bovine spongiform encephalopathy (BSE) in ruminant animals. FSIS and the Animal and Plant Health Inspection Service (APHIS) have comprehensive regulatory requirements that control these hazards, including HACCP requirements.

FSIS-regulated meat and poultry establishments are required to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from, for example, drug residues, and are also required to develop systems to guard against these hazards. In addition, FSIS oversees the requirements related to the identification and control of hazards, and collects samples of meat, poultry, and egg products and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, among other contaminants. Thus, when USDA-regulated establishments are in compliance with the USDA-administered HACCP requirements and other requirements, the hazards associated with the live animals processed at such establishments ordinarily are controlled and the animals ordinarily could not be consumed without such controls.

A.42 Q: Are substances that can be used for both food and non-food uses subject to the FSVP regulations?

A: A substance that can be used for both food and non-food uses is subject to the FSVP regulation if it is reasonably likely to be directed to a food use. Examples of substances that are capable of food and non-food use include the following:

- Dough strengtheners
- pH control agents
- Some seeds
- Food enzymes
- Color additives
- Carbon dioxide

B. What FSVP Must I Have? (21 CFR 1.502)

1. General

B.1 Q: What are the general requirements for an FSVP?

A: The FSVP regulation requires that, for each food you import that is subject to the FSVP regulation, you must develop, maintain, and follow an FSVP that provides adequate assurances

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that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the following, if applicable to the imported food:

- Section 418 of the FD&C Act regarding hazard analysis and risk-based preventive controls for certain foods and the implementing regulations in 21 CFR part 117, for human food, and 21 CFR part 507, for animal food; or
- Section 419 of the FD&C Act regarding standards for produce safety and the implementing regulation in 21 CFR part 112. (21 CFR 1.502(a))

You must also ensure that your foreign supplier is producing the food in compliance with section 402 of the FD&C Act regarding adulteration and section 403(w) of the FD&C Act regarding misbranding with respect to labeling of human food for the presence of major food allergens.

For requirements that apply in connection with low-acid food packaged in hermetically sealed containers (low-acid canned food or LACF), see 21 CFR 1.502(b) and Question B.8.

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

A: You must establish an FSVP for each food you import from each of your foreign suppliers. You do not need to establish a separate FSVP for different versions of the *same food* from a single foreign supplier when the differences in the foods do not result in different hazards requiring a control. For example, it might be appropriate for you to develop a single FSVP covering several different packaging sizes or formats for a particular food from a supplier, provided that the packaging differences do not pose different hazards that need to be controlled by the foreign supplier and addressed through different supplier verification activities. Similarly, you might include different flavor varieties of the same food in a single FSVP provided that the hazards and corresponding controls are the same. Examples of “foods” that you might address in a single FSVP (assuming any hazards requiring a control in the different versions of the food are the same) include different varieties of yogurt, cookies, potato chips, chocolate candies, or extruded dog or cat food.

However, if the use of different ingredients to make what is essentially the same food could result in different hazards requiring a control or a need for different types of controls, you should either establish separate FSVPs for these foods or create a single FSVP for the foods that separately addresses the differing hazards or controls required. For example, *Salmonella* is a reasonably foreseeable hazard in poultry meal used as ingredient in food for different animals (e.g., rodents, poultry, swine, cattle, sheep, and fish). You might develop separate FSVPs for poultry meal animal foods that are intended for different animals if the hazard to the animals is different (e.g., the *Salmonella* is of a serotype that is pathogenic to the animal species for which the animal food ingredient is intended). Alternatively, you might develop a single FSVP for poultry meal animal food from a particular supplier but separately address (within the FSVP) verification of the control of *Salmonella* where it is a hazard for different animal species. Another example is chocolate chip cookies made with walnuts and without walnuts. The presence of the allergen hazard in the cookies with walnuts (i.e., the walnuts) would mean that you should either have separate FSVPs for the two varieties of the cookies or separately address within a single FSVP the allergen hazard posed by the cookies with walnuts.

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Your FSVPs must be specific to *each foreign supplier* of a food. Thus, if you obtain a food from multiple foreign suppliers, you must have a separate FSVP for each supplier. This is appropriate because the FSVP regulation requires you to consider not just hazards inherent in the food you import, but also your foreign suppliers' processes and procedures as well as their compliance and performance history. In addition, you must conduct supplier verification activities that are tailored to the particular food and foreign supplier (see 21 CFR 1.505(a)(1) and 1.506(d)(1)(i)). However, FSVPs for different foreign suppliers might be very similar if the different suppliers have similar performance and compliance characteristics.

B.3 Q: May the corporate headquarters of my firm develop my FSVP records?

A: Yes. We expect that in many cases, corporate headquarters of a firm with multiple locations or branches would meet the definition of "importer" in 21 CFR 1.500 and could develop and implement FSVPs. Regardless of which entity in your corporate structure develops and implements the FSVPs, you would need to make the FSVP records available to FDA at your place of business within 24 hours upon Agency request (see 21 CFR 1.510(b)(2) and Question J.4).

B.4 Q: What constitutes "adequate assurances" that the foreign supplier produces food consistent with applicable food safety requirements?

A: You can obtain adequate assurances of foreign supplier compliance with the applicable food safety requirements stated in section 1.502(a) (see Question B.1) by conducting appropriate foreign supplier verification activities. The foreign supplier verification activities that importers may conduct are stated in section 1.506 and include onsite auditing of foreign suppliers, sampling and testing, review of supplier food safety records, and other measures determined to be appropriate. Your foreign supplier verification activities, and the frequency with which you conduct them, must reflect the evaluation of the foreign supplier's performance and the risk posed by the food that you conduct under section 1.505 (see Question F.9). If your foreign supplier is subject to the preventive controls requirements in parts 117 or 507 or the produce safety regulation, your FSVP must be capable of providing adequate assurances that your foreign supplier is producing the food in a manner that provides the same level of public health protection as is achieved through compliance with the applicable food safety regulations.

B.5 Q: How do I determine whether my potential foreign supplier uses processes and procedures that provide at least the "same level of public health protection" as those required under the preventive controls or produce safety requirements?

A: If your potential foreign supplier uses a process or procedure that varies in some way from the processes and procedures required under the preventive controls requirements in part 117 or part 507 or the produce safety regulation, you will need to determine whether the process or procedure that the supplier uses provides at least the same level of public health protection as those required under the specified FDA regulations. (Note that the preventive controls requirements for human food and animal food, which implement section 418 of the FD&C Act, are primarily located in subparts C and G of part 117 (for human food) and subparts C and E of part 507 (for animal food). Parts 117 and 507 include additional requirements that do not implement section 418 of the FD&C Act (i.e., requirements related to CGMPs for human food and animal food). The "same level of public health" provision in section 1.502(a) applies only to

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the requirements in parts 117 and 507 that implement section 418 of the FD&C Act; it does not apply to the CGMP requirements in parts 117 and 507.)

Because processes and procedures that provide the same level of protection might vary under different circumstances, you should make this determination on a case-by-case basis. Following are some general principles that you should use in determining whether the processes and procedures that a foreign supplier employs provides the same level of protection as is required under the preventive controls requirements in parts 117 or 507, or the produce safety regulation.¹ We also provide examples of types of alternative processes and procedures that might provide the same level of protection as those required under those regulations.

In general, to approve a foreign supplier who uses a process or procedure that differs from those required under the preventive controls requirements or produce safety regulation (as applicable), you should be able to show that the different method or approach that the foreign supplier uses adequately addresses the food safety concern that an applicable FDA requirement is intended to address. The preventive controls requirements in parts 117 and 507 consist primarily of “qualitative” requirements that allow manufacturers considerable flexibility to tailor their processes and procedures in a manner that is appropriate to the food and the facility, with management components that are appropriate to the food, the facility, and the nature of the preventive controls and their role in the facility’s food safety system. So there already is substantial flexibility under the preventive controls regulations for a foreign supplier to use a variety of processes and procedures, such as with respect to process controls, to ensure food safety and still act consistent with those requirements. The produce safety regulation also includes certain qualitative requirements (e.g., for design, construction, and workmanship of equipment and tools (21 CFR 112.123(a))) that allow for considerable flexibility in compliance.

If a foreign country has adopted more prescriptive, stringent, or restrictive requirements for a particular concern than those in a relevant FDA regulation, your supplier’s compliance with such requirements likely would provide assurance that the supplier’s process or procedure provides at least the same level of protection. At the other extreme, if a supplier has concluded that *no* process or procedure is needed to address a safety concern that is the focus of a particular provision of a relevant FDA regulation, you should obtain documentation supporting the supplier’s conclusion, perhaps due to unique circumstances (e.g., local growing conditions) in which the supplier operates.

You should have adequate scientific data or other information to enable you to conclude that your supplier’s use of an alternative process or procedure provides the same level of public health protection as an FDA requirement is intended to address. You can rely on your own scientific data or on data or other information available in scientific literature or developed by third parties, such as industry or trade associations or commodity boards. (When relying on scientific literature, it is not necessary that the information be published in a peer-reviewed

¹ These principles are discussed in more detail in FDA’s draft guidance entitled “Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507” which can be accessed at www.fda.gov/fsma.

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journal, although we encourage the use of peer-reviewed data and information to the extent it is available.) Any scientific analysis on which you rely should take into account (where appropriate) such factors as study design, sample size, weight of evidence (e.g., statistical significance), risk assessment methodology (if conducted), and range of relevant variables (e.g., animal species in which research was conducted). The conclusions on which you rely should be based on consideration of all available relevant data rather than a limited dataset selected to favor a desired outcome. In addition, any persons on whom you rely to make determinations about the same level of public health protection should have the appropriate education, training, or experience (or a combination of those characteristics) to make such decisions.

For quantitative regulatory requirements with specific numerical standards or criteria, any alternative measure should meet FDA-established quantitative metrics associated with public health protection to conclude that use of the measure provides the same level of public health protection. For example, if a requirement specifies a process such as a heat treatment to control a particular pathogen of public health significance, an alternative pathogen control process such as high-pressure processing might be appropriate if it results in an equivalent log reduction of pathogen levels. Another example is use of a surrogate or alternative indicator for a hazard or adverse health effect. For instance, you might conclude that a foreign farm's use of an alternative to generic *Escherichia coli* (*E. coli*) as an indicator of fecal contamination (in accordance with 21 CFR 112.49(a)) provides the same level of public health protection if that indicator is as sensitive to the presence and level of fecal pollution as generic *E. coli* (see discussion in the preamble to the produce safety final rule at 80 FR 74354 at 74416).

With respect to the preventive controls requirements in parts 117 and 507, a foreign supplier might use processes or procedures that are not strictly in accordance with a requirement of those regulations, but still provide at least the same level of public health protection as provided through compliance with the particular requirement. An example of this for the manufacture of human food might be a facility lacking a written hazard analysis describing how the facility determined which hazards require a control but having a HACCP plan identifying appropriate hazards along with controls and management components, and maintaining records documenting the facility's implementation of appropriate hazard controls.

With respect to the produce safety regulation, you might be able to conclude that your supplier of produce is producing the food in a manner that provides the same level of protection as production in accordance with the regulation, even though the supplier is not meeting a particular produce safety requirement. The produce safety regulation includes the following two sets of provisions that allow, under certain conditions, the use of measures that are different from those established in the regulation:

- Provisions to permit the use of alternatives to certain requirements related to the use of agricultural water (see 21 CFR 112.12 and 112.49).
- Provisions to permit requests for variances from one or more of the produce safety requirements (see 21 CFR 112.171 to 112.182).

Any alternatives that may be established or any variances that FDA may approve under these provisions may be relevant to your determination of whether your foreign supplier's processes

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and procedures provide the same level of public health protection as those required under the produce safety regulation.

The alternative and variance provisions of the produce safety regulation specify the conditions under which an alternative or variance may be used in lieu of a required measure. This information may be helpful in determining whether your foreign supplier's procedure or process provides the same level of public health protection as those required under the produce safety regulation.

Under 21 CFR 112.12, farms may use an *alternative to certain agricultural water requirements* if they have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement and would not increase the likelihood that the produce will be adulterated. The preamble to the produce safety final rule provides examples of potential alternatives to the requirements on microbial quality criterion (or criteria), microbial die-off rate (and accompanying maximum time interval), and frequency of testing of untreated surface water sources (80 FR 74354 at 74416-74417).² The preamble also states that the Agency expects alternative measures to be supported by a scientific analysis that is as robust and rigorous as the analysis the Agency conducted in adopting the corresponding requirement (80 FR 74354 at 74416). Section 112.12 also states that scientific data and information used to support an alternative may be developed by the farm, available in the scientific literature, or available to the farm through a third party, and requires the farm to document the data and information on which the farm relies. The preamble to the final rule states that although the scientific analysis on which the farm relies need not be published in a peer-reviewed journal, the Agency encourages the use of peer-reviewed data and information to the extent available (80 FR 74354 at 74417). If your foreign supplier uses a process or procedure that varies from those required under the produce safety regulation, you should determine whether the supplier has adequate scientific data or other information to support use of the alternative process or procedure.

Regarding *variances*, the produce safety regulation includes provisions under which States, tribes, or foreign countries may request a variance from the requirements of the produce safety regulation when the State, tribe, or foreign country determines that the variance is necessary in light of local growing conditions and the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated and to provide the same level of public health protection (21 CFR 112.171). Requests for variances must be submitted to FDA through a petition in accordance with 21 CFR 10.30 and must present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the food is not adulterated and will provide the same level of public health protection as the relevant produce safety requirements (21 CFR 112.172 and 112.173). FDA will publish a notice of requested variances in the *Federal Register* and interested parties will be able to submit comments and provide relevant information (21 CFR

² On March 20, 2017, FDA issued a statement that we are exploring ways to simplify the microbial quality and testing requirements for agricultural water set forth in the produce safety regulation while still protecting public health (see <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm>).

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112.176(b)). In addition, a different State, tribe, or foreign country may submit a request that the proposed variance be applied to its similarly situated persons (21 CFR 112.177(a)).

If your foreign supplier is growing produce in accordance with a variance approved by FDA (including meeting all relevant criteria for the variance, such as growing the produce within a geographic region covered by the variance), this would provide a basis for concluding that, with respect to the procedure, process, or practice covered by the variance, the supplier is producing the food in a manner that provides the same level of protection as under the corresponding produce safety requirement. We will make available to the public our responses to variance requests and a list of filed petitions requesting variances, including the status of each petition (see 21 CFR 112.176(c) and (d)).

As stated in the preamble to the FSVP final rule, you are not required to document each process or procedure of your foreign supplier that varies from those required under the preventive controls or produce safety regulations but that, in your determination, provides the same level of public health protection. However, when your supplier's use of such a process or procedure is relevant to your evaluation of the supplier's performance under section 1.505 or the performance of supplier verification activities under section 1.506, you must include information about the supplier's alternative processes and procedures in your documentation for these requirements. We believe that a supplier's use of a process or procedure that differs from those required under the preventive controls or produce safety regulations generally would be relevant to the importer's decision to approve the supplier and to the importer's determination of appropriate supplier verification activities. For example, if you approve a potential foreign supplier despite its use of processes or procedures that do not meet the preventive controls requirements in parts 117 or 507 or the requirements in the produce safety regulation, your documentation of supplier approval under section 1.505 should include information supporting your determination that the supplier's processes and procedures provide the same level of public health protection. Similarly, if results of an onsite audit of your supplier indicate non-compliance with preventive controls requirements in parts 117 or 507 or with the produce safety regulation, you should have documentation supporting your conclusion that the supplier's safety measures provide the same level of protection as those required under the relevant regulation.

B.6 Q: How should I design my FSVP to provide assurances that the food from a foreign supplier is not adulterated?

A: You must develop an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with section 402 (regarding adulteration) of the FD&C Act (21 CFR 1.502(a)). In determining whether the food you import is produced in compliance with section 402, you should consider whether the food is subject to FDA food safety regulations, violations of which may cause the food to be adulterated. Examples of such regulations include:

- Infant formula – 21 CFR part 107
- Acidified foods – 21 CFR part 114
- Shell eggs – 21 CFR part 118
- Bottled drinking water – 21 CFR part 129

The foreign supplier verification activities you conduct as part of your FSVP should be risk-based and focus only on those hazards that are known or reasonably foreseeable. If there are

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such hazards and they require a control, you should verify that the food is produced in compliance with safety standards for that hazard. For example, if you are purchasing cucumbers from a country, region, or grower with a history of pesticide residue violations for that food, we would expect you to address this potential adulteration and conduct verification activities to ensure that the cucumbers do not bear or contain pesticide chemical residues that cause the cucumbers to be adulterated. Conversely, if the cucumbers come from a country or region with no history of pesticide residue violations, we would not expect you to identify unsafe pesticide residues as a hazard that requires a control (unless new information came to light or questions about the use of pesticides or control of pesticide residues indicated an issue), and we would not expect you to conduct verification activities related to such a hazard. Similarly, when food additives and color additives pose known or reasonably foreseeable hazards requiring a control in a food, your FSVP for such food should provide assurances that these hazards are being controlled. For other types of hazards, such as *Salmonella*, the country or region in which the food is produced may not have any bearing on whether the hazard is known or reasonably foreseeable. For example, if you import dried milk powder or whey protein, you would likely determine that contamination with *Salmonella* is a known or reasonable foreseeable hazard and you would want to consider whether it requires a control. If the hazard does require a control, your verification activities should address whether your foreign supplier has controlled this hazard.

B.7 Q: How should I design my FSVP to provide assurances that a human food from a foreign supplier is not misbranded with respect to labeling for the presence of major food allergens?

A: As part of your FSVP, you should review the label of each human food you import to determine that it complies with the labeling requirements for major food allergens. Major food allergen means any of the following:

1. Milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
2. A food ingredient that contains protein derived from a food specified in paragraph 1 above, except the following:
 - a. Any highly refined oil derived from a food specified in paragraph 1 above and any ingredient derived from such highly refined oil.
 - b. A food ingredient that is exempt under section 403(w)(6) and (7) of the FD&C Act (section 201(qq) of the FD&C Act).

Food for humans (except for RACs) that is, or contains an ingredient that bears or contains, a major food allergen must meet the label and labeling requirements set forth in section 403(w) of the FD&C Act. Under section 403(w)(1), the food is misbranded (with respect to the labeling of food allergens) unless it meets one of the following criteria:

- The word “Contains”, followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under section 403(g) or (i); or
- The common or usual name of the major food allergen in the list of ingredients required under section 403(g) or (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when: (1) the common or usual name of the ingredient uses the name of the

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food source from which the major food allergen is derived; or (2) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of the food ingredient that is not a major food allergen.

You should also determine by inspection, audit, or communications with your foreign supplier whether the food contains a major food allergen that is not declared on the food label. When appropriate, you should verify that a supplier has not inadvertently omitted a required declaration of the presence of a food allergen (e.g., a candy bar containing peanuts that lacks the required declaration).

You can find additional information on food allergen labeling at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm>.

The requirement to provide assurances that a human food is not misbranded with respect to labeling for the presence of major food allergens under section 403(w) of the FD&C Act does not apply to food for animals. Therefore, if you are importing an animal food, you are not required to verify that the food is not misbranded under section 403(w).

2. Low-Acid Canned Food

B.8 Q: How does the FSVP regulation apply to a low-acid canned food?

A: For microbiological hazards in thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food or LACF) that you import, you are not required to meet the standard FSVP requirements. However, you must verify and document that your foreign supplier is producing the food in accordance with the LACF regulation in 21 CFR part 113 (see 21 CFR 1.502(b)(1)). The LACF regulation is designed to ensure control of microbiological hazards in an LACF. For hazards in an LACF other than microbiological hazards controlled by the low-acid canned food regulation (i.e., chemical and physical hazards), you must develop, maintain, and follow an FSVP in accordance with section 1.502(a).

In addition, you are not required to comply with the FSVP requirements with respect to microbiological hazards in raw materials or other ingredients that you import and use in the manufacturing or processing of an LACF, provided that you comply with the LACF regulation for the food that you manufacture or process from the imported raw materials or other ingredients (21 CFR 1.502(b)(2)). With respect to other hazards in such raw materials or other ingredients, you must have an FSVP.

An appropriate verification activity to determine that your foreign supplier is producing an LACF in compliance with the LACF regulation may be that you conduct an onsite audit or review and assess the results of an onsite audit or inspection conducted by another entity. However, an audit might not be necessary. Alternatively, for each entry of an LACF, you might conclude that it is appropriate to review the scheduled process and the processing and production records required under the LACF regulation and verify the integrity of the containers (e.g., cans are not swollen or leaking).

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Chemical and physical hazards are not controlled under the LACF regulation. For chemical and physical hazards requiring a control, a verification activity (e.g., onsite audit or sampling and testing) would be required as part of your FSVP (see 21 CFR 1.506(d)). You may verify control of all hazards you identify as requiring a control, including non-microbiological hazards, during a single onsite audit or inspection of the LACF facility, instead of conducting separate activities to verify control of the non-microbiological hazards and compliance with the LACF regulation.

For more information on application of the FSVP regulation and other FSMA regulations to LACF and raw materials or other ingredients used in manufacturing or processing LACF, see FDA's guidance entitled "Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act" (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569792.pdf>).

3. Importers Who Also Are Receiving Facilities Under the Preventive Controls Regulations

B.9 Q: What is a "receiving facility"?

A: A receiving facility is a facility that is subject to the hazard analysis and risk-based preventive controls requirements and the supply-chain program requirements of part 117 or 507 and that manufactures/processes a raw material or other ingredient that it receives from a supplier (21 CFR 117.3 and 507.3). (A "facility" is a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the registration requirements of 21 CFR part 1, subpart H.)

B.10 Q: Do I have to comply with all FSVP requirements if I am a receiving facility for a food I import?

A: Although you must identify yourself as the FSVP importer at entry (21 CFR 1.509), you are deemed to be in compliance with the other FSVP requirements for a food you import if you are a receiving facility and you are in compliance with any of the following requirements with respect to the food:

- You have implemented preventive controls for the hazards in the food in accordance with 21 CFR 117.135 or 507.34; or
- You are not required to implement a preventive control under 21 CFR 117.136 or 507.36 with respect to the food; or
- You are in compliance with the supply-chain program requirements of the preventive controls for human food regulation (21 CFR part 117, subpart G) or preventive controls for animal food regulation (21 CFR part 507, subpart E) (see 21 CFR 1.502(c)).

1. Receiving facility that has implemented preventive controls for the hazards in a food (21 CFR 1.502(c)(1)): You are deemed to be in compliance with most of the FSVP requirements if you implement a preventive control to significantly minimize or prevent the hazards in the raw material or other ingredient that you import for a food you manufacture/process. You also would not be required to have a supply-chain program for the raw material or other ingredient under the preventive controls regulations. For

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example, if you import a spice and irradiate the spice before including it as an ingredient in a frozen food you manufacture and the irradiation significantly minimizes or prevents the applicable hazards, you are deemed in compliance with most of the FSVP requirements under section 1.502(c)(1).

2. Receiving facility that is not required to implement a preventive control for a food (21 CFR 1.502(c)(2)): You are deemed to be in compliance with most of the FSVP requirements provided you are not required to implement a preventive control in accordance with 21 CFR 117.136 or 507.36. For example, if you import fresh produce and, after you cut and freeze the produce, you sell it to a customer who significantly minimizes or prevents the hazards in the produce before selling it, you are deemed in compliance with most FSVP requirements provided that you satisfy the requirements of 21 CFR 117.136 (e.g., disclose in documents accompanying the produce that it has not been processed to control the identified hazard(s)).
3. Receiving facility that has established and is following a supply-chain program for a raw material or other ingredient (21 CFR 1.502(c)(3)): You are deemed to be in compliance with most of the FSVP requirements. For example, if you are a U.S. receiving facility that imports fresh spinach and places it in 7-ounce packages for U.S. sale, and in accordance with subpart G of part 117 you adequately verify (using the results of an onsite audit) that your foreign supplier of the spinach is producing it consistent with the produce safety regulation, you are deemed in compliance with most of the FSVP requirements. For more information on compliance with the supply-chain program requirements in the preventive controls regulations, see FDA’s guidance for industry on “Supply-Chain Program for Human Food Products.”

In addition, if you are both (1) an importer of a raw material or ingredient and (2) a receiving facility that is a co-manufacturer of that raw material or other ingredient, we do not intend to take enforcement action against you under the FSVP regulation for failing to comply with certain supply-chain program requirements under certain circumstances set forth in FDA’s guidance for industry entitled “Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food” (see <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583490.pdf>). As discussed in the draft guidance, we are temporarily exercising our enforcement discretion with respect to certain supply-chain program requirements concerning supplier approval and verification to provide time for brand owners to revise their contracts with suppliers to allow brand owners to share certain information (e.g., audits of suppliers) with co-manufacturers, which will enable co-manufacturers to meet their supply-chain program requirements.

However, if you are domestic receiving facility that uses imported ingredients, you may choose to follow the FSVP regulation instead of the supply-chain program requirements in the preventive controls regulations. Under the preventive controls regulations, if you are a receiving facility that is in compliance with the FSVP requirements and you document the foreign supplier verification activities you conduct under 21 CFR 1.506(e) of the FSVP regulation for a raw material or other ingredient you import (providing assurance that hazards requiring a supply-

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chain-applied control have been significantly minimized or prevented), you are not required to conduct verification activities for that raw material or other ingredient under the supply-chain program requirements in the preventive controls regulations (21 CFR 1.506(e), 117.405(a)(2), and 507.105(a)(2)).

B.11 Q: What FSVP requirements will apply if I am a receiving facility that is in compliance with certain requirements under the preventive controls regulations for a raw material or other ingredient I import?

A: If you are a receiving facility that satisfies the requirements in 21 CFR 1.502(c)(1), (c)(2), or (c)(3), for each line entry of food offered for importation into the United States, you must provide your name, electronic mail address, and the unique facility identifier recognized as acceptable by FDA (see Questions I.1 and I.4). For more information on how to comply with this requirement, see FDA's fact sheet entitled "Foreign Supplier Verification Programs: What Do Manufacturers/Processors Covered by the PC Supply-Chain Program Need to Know About FSVP?" (<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM561213.pdf>).

C. Who Must Develop My FSVP and Perform FSVP Activities? (21 CFR 1.503)

1. Qualified Individual

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

A: A qualified individual as defined in 21 CFR 1.500 must develop your FSVP and perform each of the activities required under the FSVP regulation (21 CFR 1.503(a)).

C.2 Q: Who is a qualified individual?

A: A qualified individual is a person who has the education, training, or experience (or a combination of these) necessary to perform an activity required under the FSVP regulation, and can read and understand the language of any records that the person must review in performing this activity. (Note that the definition of qualified individual under the FSVP regulation differs from the definition of qualified individual under the preventive controls regulations (see 21 CFR 117.3 and 507.3).) A qualified individual may be, but is not required to be, an employee of the importer; you might also rely on non-employees such as a consultant or a third-party auditor. A government employee, including a foreign government employee, may be a qualified individual (21 CFR 1.500 and 1.503(a)).

C.3 Q: What kind of education, training, or experience should a qualified individual have?

A: A qualified individual should have education, training, or experience (or a combination of these) that enables the person to accurately and effectively conduct the assigned FSVP activity in a manner that ensures you meet the FSVP requirements for that activity. Because individuals may have different combinations of education, training, and experience that qualify them to perform a particular FSVP activity, we have not established specific courses, programs, certifications, or experiences that are required for a person to be a qualified individual. However, the Food Safety Preventive Controls Alliance (FSPCA), established by FDA and the Illinois Institute of Technology's Institute for Food Safety and Health, is developing a training curriculum for persons wishing to conduct certain activities under the FSVP regulation.

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For each FSVP activity, you must determine that the person you assign to conduct the activity has the necessary education, training, or experience (or a combination of these). For example, you may determine that an individual is qualified to conduct a hazard analysis of a food because the individual has:

- Taken courses or educational seminars that addressed the principles of hazard analysis,
- Taken science-related courses that provide information about specific hazards (e.g., microbiology courses that provide information on pathogens),
- Experience conducting hazard analyses, or
- A combination of these qualifications.

For activities related to assessing whether a foreign supplier uses processes and procedures that provide the same level of public health protection as the preventive controls requirements under section 418 of the FD&C Act (e.g., activities such as an onsite audit or a review of food safety records for a foreign supplier subject to section 418 of the FD&C Act), a qualified individual should have education, training, or experience (or a combination of these) in the development and application of risk-based preventive controls. The FSPCA courses on the development and application of preventive controls for human or animal food include a curriculum that FDA recognizes as providing adequate education and training to perform preventive controls activities. However, a person can use other means to obtain the education, training, or experience needed to conduct FSVP activities relating to verification of supplier implementation of preventive controls. An individual also may be qualified to assess a foreign supplier's compliance with preventive controls based on experience in developing and applying a food safety system (e.g., a HACCP plan).

C.4 Q: Does the education, training, or experience for a qualified individual have to be obtained in the United States?

A: No. The education, training, or experience that provides skills necessary to serve as a qualified individual does not have to be obtained in the United States. Education, training, or experience obtained in other countries may provide a person with qualifications to perform activities required under the FSVP regulation.

C.5 Q: What language skills must a qualified individual have?

A: A qualified individual must be able to read and understand the language of any records that the person must review in performing a required FSVP activity (21 CFR 1.503(a)). For example, if your foreign supplier located in Mexico keeps records in Spanish, a qualified individual who reviews the supplier's records written in Spanish must be able to read and understand Spanish.

C.6 Q: Are there any restrictions relating to conflict of interest of the qualified individuals?

A: Yes. See Question F.29 for a discussion of provisions concerning financial conflict of interest restrictions.

C.7 Q: Can a U.S. or foreign government employee be a qualified individual for conducting FSVP activities?

A: Yes. A U.S. or foreign government employee who is a qualified individual may conduct FSVP-related activities. For example, you may rely on the results of an audit or inspection of a foreign supplier conducted by the USDA's Agricultural Marketing Service or the U.S.

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Department of Defense as long as the audit or inspection considers applicable FDA food safety regulations and meets the other requirements for audits. You also may consider an employee of a foreign food safety authority who, as part of their responsibilities with that authority, has conducted an activity similar to the required FSVP activity to be a qualified individual for the purpose of conducting the FSVP activity. For example, a foreign government employee who is a microbiologist who has analyzed food samples for pathogens may be a qualified individual for analyzing samples collected as an FSVP verification activity.

2. Qualified Auditor

C.8 Q: Who is a qualified auditor?

A. A qualified auditor is a qualified individual who has technical expertise obtained through education, training, or experience, or a combination of these, necessary to perform the auditing function under certain provisions (21 CFR 1.506(e)(1)(i) or 1.511(c)(5)(i)(A)) of the FSVP regulation (21 CFR 1.500 and 1.503(a)). We believe a person would need experience in auditing (including by assisting or observing others in the performance of an audit) to meet the definition of a qualified auditor, as well as education, training, or experience (or a combination of these) in food safety processes and procedures. You or one of your employees might serve as a qualified auditor. A qualified auditor could also be a government official (see Question C.9), third-party auditor (see Question C.10), or another person as long as they have the education, training, or experience (or combination of these) needed to perform FSVP audits. However, you may not rely on an audit conducted by your foreign supplier or its employee (21 CFR 1.506(e)(2)(ii) and 1.511(c)(5)(ii)(B); see Question F.26).

C.9 Q: Can a U.S. or foreign government employee be a qualified auditor?

A. Yes, a government employee, including a foreign government employee, may be a qualified auditor (21 CFR 1.500). An importer may rely on the results of an audit conducted by an employee of the United States or a foreign country provided that person has the necessary education, training, or experience (or combination of these) and the onsite audit is conducted in accordance with 21 CFR 1.506(e)(1)(i) (for most foods) or 1.511(c)(5)(i)(A) (for dietary supplements). For example, a person who has performed food safety inspections or audits for a foreign authority may be a qualified auditor for purposes of conducting an onsite audit of your foreign supplier. However, it is important to note that the foreign inspection or audit usually must consider applicable FDA food safety regulations. This might be the case, for example, when a foreign export agency audits a facility that exports food to the United States for compliance with the produce safety regulation.

C.10 Q: Can a third-party auditor be a qualified auditor?

A. Yes, a third-party auditor, i.e., an auditor who is not employed by, and is independent from, you and your foreign supplier, can be a qualified auditor. A third-party auditor can be a public entity (i.e., an employee of the U.S. government or a foreign government) or a private entity.

A third-party auditor might be, but is not required to be, an audit agent of a certification body that is accredited in accordance with the regulation on Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (third-party certification regulation) in 21 CFR part 1, subpart M. A qualified auditor does not have to be formally

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accredited under FDA's third-party certification regulation or any other auditor accreditation or certification program as long as the person has the necessary education, training, or experience (or a combination of these) to conduct an audit.

C.11 Q: What kind of education, training, or experience should a qualified auditor have?

A: We have not established or approved specific courses, programs, or certifications that a qualified auditor must complete for you to be able to rely on them to meet your FSVP requirements. We expect a qualified auditor to have education, training, or experience (or a combination of these) that provides the person with knowledge and skills necessary to evaluate whether the equipment, processes, and procedures in a food facility or on a farm ensure that the hazards associated with the food are significantly minimized or prevented. For example, an individual who has previously conducted food safety inspections for a food safety authority may be a qualified auditor, provided that the person has the knowledge and experience to assess the applicable FDA regulations. A person should have at least some actual experience in auditing (including assisting in audits or observing audits) to meet the definition of a qualified auditor, i.e., the necessary technical expertise likely cannot be obtained solely through education and/or training that does not involve assisting or observing others in the performance of an audit.

We do not require that audits performed as a verification activity be conducted by auditors accredited in accordance with the third-party certification regulation. However, the requirements for competent audit agents (see 21 CFR 1.650) in FDA's third-party certification regulation (21 CFR part 1, subpart M) and FDA's draft guidance on "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff (Guidance on Accredited Third-Party Certification)" (see <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM455331.pdf>), add context for the qualified auditor standard. The requirements in 21 CFR 1.650 address how an accredited third-party certification body must ensure that its audit agents are competent and objective. Although an onsite audit that is solely conducted to meet FSVP requirements by an audit agent of a certification body that is accredited in accordance with the third-party certification regulation is not subject to the requirements in that regulation, the requirements for audit agents and the Guidance on Accredited Third-Party Certification related to competency are useful in determining appropriate education, training, or experience for a qualified auditor. For example, competency requirements for audit agents include that they:

- Have relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations;
- Be competent to conduct food safety audits; and
- Have completed annual food safety training.

The Guidance on Accredited Third-Party Certification further recommends education and/or experience for entry level auditors and lead auditors, as well as auditor skills such as observational, reasoning, analytical, and communication skills. Technical training may vary depending on the processes and products being audited. Training methods may include classroom training, annual food safety training, and joint audits with a qualified trainer to help the audit agent apply classroom learning.

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Provisions for auditor competency issued by the Global Food Safety Institute (GFSI) are also useful in determining the knowledge, experience, and skills for a qualified auditor (see Global Food Safety Initiative & The Consumer Goods Forum, “GFSI Food Safety Auditor Competencies, Edition 1,” 2013 (http://mygfsi.com/images/mygfsi/gfsifiles/information-kit/GFSI_Food_Safety_Auditor_Competencies_Edition_1_October_2013.pdf). The GFSI’s auditor competency model lists three main components for auditor competencies: (1) Auditing skills and knowledge; (2) technical skills and knowledge; and (3) behavior and systems thinking. Within each main component, GFSI provides details of specific tasks and the required auditor knowledge and skills to perform the specific tasks.

C.12 Q: When must I use a qualified auditor?

A: You must use a qualified auditor to conduct an onsite audit of a foreign supplier as a verification activity in accordance with section 1.506(e)(1)(i) or 1.511(c)(5)(i)(A) (21 CFR 1.503(b)). There must be documentation that the onsite audit was conducted by a qualified auditor, including when you rely on the results of an audit conducted by another entity (see 21 CFR 1.506(e)(1)(i), (e)(1)(iv)(B), and (e)(2) and 1.511(c)(6)(i)(A), (c)(5)(i)(D)(ii), and (c)(6)(ii)).

D. What Hazard Analysis Must I Conduct? (21 CFR 1.504)

D.1 Q: What is the purpose of the hazard analysis?

A: The purpose of your hazard analysis is to determine the food safety concerns that might be posed by a food you import into the United States. For each type of food you import, you must conduct a hazard analysis to identify potential food safety hazards that must be managed through controls. You must also assess the probability that the hazard you identify will occur in the absence of controls and assess the severity of the illness or injury to humans or animals from the hazard if the hazard were to occur.

D.2 Q: What basic requirements apply to a hazard analysis?

A: A hazard analysis must identify and evaluate, based on experience, illness data, scientific reports, and other information, the known or reasonably foreseeable hazards in each food you import to determine whether there are any hazards that require measures to control the hazard (e.g., a heat step that is lethal to a pathogen; sorting to remove physical hazards). A hazard analysis must be written, even if you determine that there are no hazards that require a control (21 CFR 1.504(a)). A qualified individual must conduct the hazard analysis.

D.3 Q: What types of hazards should I consider in the hazard analysis?

A: Your hazard analysis must consider known or reasonably foreseeable hazards in each food you import (21 CFR 1.504(b)(1)). Such hazards include:

- Biological hazards, including microbiological hazards such as parasites, viruses, environmental pathogens, and other pathogens;
- Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and, in animal food, nutrient deficiencies or toxicities; and
- Physical hazards, including stones, glass, and metal fragments.

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Your hazard analysis must include known or reasonably foreseeable hazards that:

- Occur naturally,
- May be unintentionally introduced, and
- May be intentionally introduced for purposes of economic gain (21 CFR 1.504(b)(2)).

D.4 Q: What does “known or reasonably foreseeable hazard” mean?

A: A known or reasonably foreseeable hazard means 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 (21 CFR 1.500).

D.5 Q: What does “hazard requiring a control” mean?

A: A “hazard requiring a control” 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 one or more controls or measures to significantly minimize or prevent the hazard in a food (21 CFR 1.500). This includes 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. The hazard analysis that is conducted 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 to humans or animals if the hazard were to occur.

The definition of “hazard requiring a control” is similar to (and was intended to align with) the definition of “hazard requiring a preventive control” in the regulations establishing preventive controls requirements for human and animal food. However, the definition of “hazard requiring a control” differs because it applies to all food covered by the FSVP regulation, which includes some foods that are not subject to the preventive controls requirements. Such foods include produce covered by the produce safety regulation (which requires the adoption of appropriate “measures” to minimize the risk of serious harm from the use of, or exposure to, covered produce (see 21 CFR 112.11)) and other foods (e.g., dietary supplements) not subject to “preventive controls” requirements under the preventive controls regulations (see also Response 20 in the preamble to the FSVP final rule (80 FR 74226 at 74237)).

D.6 Q: What are some examples of known or reasonably foreseeable hazards?

A: Examples of known or reasonably foreseeable biological hazards include bacterial pathogens, such as *Salmonella* in ready-to-eat produce, peanut butter, and pet food; *Listeria monocytogenes* in ready-to-eat produce, soft ripened cheeses, and raw cat and dog food; *Clostridium botulinum* in garlic packed in oils; and Shiga-toxin producing *Escherichia coli* (STEC) such as O157:H7 in produce, raw milk, and some cheeses made from raw milk).

Examples of known or reasonably foreseeable chemical hazards include:

- Pesticide residues on produce or grains;
- Drug residues in milk;
- Heavy metals in or on produce or grains;
- Environmental contaminants (e.g., dioxins);
- Natural toxins (e.g., mycotoxins in grains, histamine in some aged cheeses);

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- Radiological hazards (e.g., in foods from areas after a nuclear accident);
- Unapproved food and color additives;
- Food allergens in human food (e.g., milk, egg, fish (bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, pecans, walnuts), wheat, peanuts, and soybeans);
- Nutrient deficiencies or toxicities in animal food (e.g., inadequate thiamine in cat food, excessive vitamin D in dog food, excessive copper in food for sheep); and
- Substances associated with a food intolerance (e.g., sulfites).

Examples of known or reasonably foreseeable physical hazards include:

- Hard or sharp physical hazards (e.g., glass, metal, plastic, wood, and stones); and
- Choking hazards (e.g., trinkets imbedded in food).

Additional examples of known or reasonably foreseeable hazards are provided in FDA’s draft guidance for industry on “Hazard Analysis and Risk-Based Preventive Controls for Human Food” (Preventive Controls for Human Food draft guidance) (Chapter 3, Potential Hazards Associated with the Manufacturing, Processing, Packing, or Holding of Human Food) on FDA’s Web page at [“Hazard Analysis and Risk-Based Preventive Controls for Human Food”](#).

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

A: You must conduct a hazard analysis for each type of food you import that is subject to the FSVP regulation. “Type of food” refers to foods that are similar and for which the same hazards are known or reasonably foreseeable. For example, Brie, Camembert, and Mozzarella are soft-ripened cheeses that are subject to the same hazards. Thus, a hazard analysis for soft-ripened cheeses may cover all three of these cheeses, provided you specify in the hazard analysis the specific soft-ripened cheeses you are importing that are covered by the hazard analysis. Similarly, if you import three different flavors of pet treats, such as baked dog biscuits, that are subject to the same hazard (e.g., *Salmonella*), your hazard analysis may cover the three pet treats as a “type of food.” However, it would not be appropriate to use the same hazard analysis for foods that, though similar, have different hazards requiring control (unless you clearly identify in your hazard analysis what those differences are). For example, if two foods are grown, harvested, and packed under the same conditions, and one food is susceptible to a certain microbiological hazard but the other food is not, it would not be appropriate to use the same hazard analysis for both foods. Also, a food that is packaged in multiple size containers or with different labels may be considered a “type of food” (provided that the foods have the same known or reasonably foreseeable hazards).

D.8 Q: Must I conduct a hazard analysis for an acidified food I import?

A: Yes. You must conduct a hazard analysis for an acidified food you import. However, for microbiological hazards, you can consider the processor’s current scheduled process established in accordance with the acidified foods regulation in 21 CFR part 114. If you determine that the microbiological hazards associated with the acidified food are addressed by controls in the supplier’s scheduled process, you may consider this when determining what supplier verification activities are appropriate. For example, you may determine that reviewing your foreign supplier’s processing records and reports to ensure that the food is processed according to a validated scheduled process is an appropriate supplier verification activity. You

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would also need to determine if there are any chemical or physical hazards associated with the acidified food.

D.9 Q: What is meant by a hazard that is intentionally introduced in a food for purposes of economic gain?

A: Your hazard analysis must address agents that are intentionally introduced for purposes of economic gain (economically motivated adulteration). Economic gain may be the primary motivation for someone who intentionally introduces an adulterant into a food, but the adulterant may or may not present a food safety concern. Your FSVP need not consider adulterants that do not pose a safety concern (i.e., those that only affect the quality of the food). For example, water may be mixed with a fruit juice or corn syrup added to honey to fraudulently enhance economic value. Although such actions may violate certain provisions of the FD&C Act, they may not pose safety concerns and therefore you would not need to consider them as part of your hazard analysis under the FSVP regulation. However, an example of economically motivated adulteration that caused a food safety concern is the addition of melamine to milk used in infant formula and wheat gluten used in pet food to enhance perceived quality, protein content, or both, which unintentionally resulted in deaths of humans and animals. Sudan dyes, considered to be carcinogens, have been added to spices such as chili powder to enhance color. We believe that reasonably foreseeable hazards intentionally introduced for economic gain that will need controls will be rare under the FSVP regulation. You should consider the potential for such hazards in foods that have a history of known or attempted economically motivated adulteration.

D.10 Q: Does my FSVP need to address hazards that are intentionally introduced to cause wide scale public health harm?

A: You are not required under the FSVP regulation to consider (in your hazard analysis) hazards that are intentionally introduced to cause wide scale public health harm. If you are a food facility that manufactures/processes, packs, or holds food for human consumption in the United States and you are required to register with FDA under section 415 of the FD&C Act, you are subject to FDA's regulation (in 21 CFR part 121) on intentional adulteration (unless you are exempt under 21 CFR 121.5, such as the exemption for animal food facilities). The intentional adulteration regulation requires food facilities to have food defense plans to address potential adulteration intended to cause wide scale public harm. The methods used to identify hazards related to economically motivated adulteration and the controls to significantly minimize or prevent these hazards are different from the methods used to identify vulnerabilities related to adulteration intended to cause wide scale public health harm and the mitigation strategies to significantly minimize or prevent such harm. However, you should consider warning letters or other enforcement action taken by FDA against foreign suppliers for violations of the intentional adulteration regulation in your evaluation of potential suppliers under section 1.505 (see Question E.5).

D.11 Q: How can I determine whether a hazard that may be intentionally introduced in a food for purposes of economic gain is known or reasonably foreseeable and requires a control?

A: An important step to take is to review information to determine if there are reported incidences associated with the type of food you import. In addition, the qualified individual who conducts your hazard analysis may have knowledge and experience to determine the likelihood

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that a food may be adulterated for economic gain. Food safety hazards that have been associated with intentional adulteration for economic gain include:

- Melamine added to milk used in infant formula;
- Melamine added to ingredients used as a protein source in animal food such as dog treats;
- Sudan red dyes, which are known carcinogens, used to color paprika, chili powders, and curries;
- Di(2-ethylhexyl) phthalate (DEHP) added as a substitute for vegetable oil in an emulsifier or clouding agent, or for a flavoring; and
- Corn adulterated with aflatoxin mixed with other corn to reduce the level of aflatoxin in the mixed lot.

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

A: For your hazard analysis for a RAC that is a fruit or vegetable and is “covered produce” (as defined in 21 CFR 112.3) subject to the produce safety regulation, you are not required to determine whether there are any biological hazards requiring a control. The biological hazards in such fruits or vegetables require a control, and the produce safety regulation establishes requirements to significantly minimize or prevent these hazards. Under the FSVP regulation, you must determine whether there are any other types of known or reasonably foreseeable hazards (i.e., non-biological hazards) requiring a control in such fruits or vegetables (e.g., chemical hazards such as pesticide residues and physical hazards such as stones and other field debris) (21 CFR 1.504(e)).

D.13 Q: How must I evaluate the risk posed by a RAC that is a fruit or vegetable?

A: Your evaluation of the risk posed by a RAC that is a fruit or vegetable that is “covered produce” must consider the biological hazards requiring a control that are addressed in the produce safety regulation and the chemical and physical hazards requiring a control that you identified in the hazard analysis you conducted under the FSVP regulation (see 21 CFR 1.504(e) and 1.505(a)(1)). Therefore, even though you are not required to conduct a hazard analysis regarding the biological hazards in fruits and vegetables, you must take into account the risks posed by these hazards (as addressed under the produce safety regulation) in approving foreign suppliers of such produce and determining appropriate supplier verification activities.

D.14 Q: May I rely on a hazard analysis conducted by another entity?

A: Yes. You may rely on a hazard analysis conducted by another entity provided it was conducted by a qualified individual (21 CFR 1.504(d)). Your foreign supplier who has conducted a hazard analysis under the preventive controls regulation is likely to be a good source for a hazard analysis for the food you import from them. Alternatively, you might rely on a hazard analysis of a food conducted by another entity, such as a consolidator of a RAC or a trade association that conducted a hazard analysis on behalf of its members. If you rely on a hazard analysis conducted by another entity, you must review and assess that hazard analysis and document your review and assessment, including documenting that the hazard analysis was conducted by a qualified individual (21 CFR 1.504(d)).

D.15 Q: Where can I find guidance and other information that may be useful for conducting a hazard analysis?

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A: FDA's Preventive Controls for Human Food draft guidance (Chapter 2, Conducting a Hazard Analysis) provides information on conducting a hazard analysis for a human food. In addition, the Food Safety Preventive Controls Alliance (FSPCA), in collaboration with FDA, developed training and technical assistance programs to help industry comply with the preventive controls requirements in parts 117 and 507, including conducting a hazard analysis. The [FSPCA's training manual on preventive controls for human food](#), which is available to download at no charge, provides useful information on hazards associated with food and on conducting a hazard analysis. Information relating to the FSPCA preventive controls training and assistance may be found on FDA's web page at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm284406.htm>. The following also may provide information for your hazard analysis:

- FDA's [Bad Bug Book](#) provides information relating to microorganisms that are of public health significance, including foodborne pathogens such as *Salmonella*, *Listeria monocytogenes*, *Clostridium botulinum*, *E. coli* O157:H7, and *Staphylococcus aureus*.
- Your foreign supplier.
- Trade associations.
- FDA information relating to administrative and enforcement actions (e.g., import alerts, recall notices, warning letters, and untitled letters).
- [Food Fraud and "Economically Motivated Adulteration" re Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#) (Congressional Research Service)
- ["Economically Motivated Adulteration \(EMA\) of Food: Common Characteristics of EMA Incidents"](#) (Everstine, K., J. Spink, and S. Kennedy, "Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents," *Journal of Food Protection*, 76:723-735, 2013).

D.16 Q: What evaluation must I include in my hazard analysis?

A: Your hazard analysis must include an evaluation of the probability that the known or reasonably foreseeable hazards you identified will occur in the absence of controls. You must also assess the severity of the illness or injury if the hazard were to occur (21 CFR 1.504(c)(1)). For a ready-to-eat food, you must include an evaluation of environmental pathogens when the food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure that would significantly minimize the pathogen (e.g., a formulation that is lethal to the pathogen) (21 CFR 1.504(c)(2)). Your hazard evaluation also must consider the effect of each of the following on the safety of the finished food for the intended consumer or animal species:

- The formulation of the food (e.g., is the formulation balanced for the animal species so that it does not result in nutrient deficiencies or toxicities, does the formulation of the food result in pH, water activity, or other conditions that favor or prevent the growth of a pathogen identified in the hazard analysis);
- The condition, function, and design of the establishment and equipment of a typical entity that manufacturers/processes, grows, or harvests this type of food (e.g., is the equipment generally used to manufacture/process the type of food difficult to clean or prone to wear or damage that could result in an increased risk of hazards being introduced into the food);

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- Raw materials and other ingredients (e.g., are there hazards that may be introduced by the ingredients and raw materials);
- Transportation practices (e.g., do the transportation practices influence the potential for contamination or growth of pathogens);
- Harvesting, raising, manufacturing, processing, and packing procedures (e.g., is there a step that may introduce pathogens; is there a “kill” step during processing);
- Packaging and labeling activities (e.g., are allergens identified on the label; are refrigeration instructions provided on the label, when applicable);
- Storage and distribution (e.g., does the food require specific storage conditions; does bulk shipment of the food increase the potential for contamination during shipment);
- Intended or reasonably foreseeable use (e.g., is a food that is labeled with cooking instructions likely to be consumed without cooking or is an animal food reasonably expected to be fed to the intended species);
- Sanitation, including employee hygiene (e.g., does the equipment or do the employee sanitation procedures provide for potential cross contamination between raw and cooked product); and
- Any other relevant factors (e.g., are there weather-related hazards such as aflatoxins that fluctuate year-to-year; has the food been associated with adulteration for economic gain) (21 CFR 1.504(c)(3)).

Although you must at least consider the potential effect of each of these factors on the safety of the finished food, if the factor is not relevant with respect to a particular food, the consideration might be brief.

D.17 Q: Where can I find information about the condition, function, and design of the nature of the establishment and equipment of a typical entity that manufactures/processes, grows, or harvests a type of food?

A: You can obtain information about the nature of establishments that produce a particular food and the equipment from an inspection or audit, trade journals and other publications, academic literature, and materials obtained directly from your potential foreign suppliers.

D.18 Q: What records relating to the hazard analysis must I establish and maintain?

A: For each food you import, you should document and maintain records of:

- Your determination of the hazards, if any, that are known or reasonably foreseeable in each food,
- Your assessment of the probability that each known or reasonably foreseeable hazard will occur in the absence of controls,
- Your assessment of the severity of the illness or injury if the hazard were to occur, and
- Your review and assessment of any hazard analysis performed by another entity, including documenting that the hazard analysis was conducted by a qualified individual. While you do not necessarily need a complete copy of the written hazard analysis, you must establish and maintain records that allow FDA to see what hazards were identified and evaluated under 21 CFR 1.504, as well as that the original hazard analysis was conducted by a qualified individual.

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D.19 Q: If, based on my hazard analysis for a food, I determine there are no hazards requiring a control, must I conduct foreign supplier activities?

A: If you conduct a hazard analysis and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification activities and you are not required to conduct foreign supplier verification activities (21 CFR 1.504(f)). However, this does not apply if the food is a RAC that is a fruit or vegetable that is “covered produce” (as defined in 21 CFR 112.3) subject to the requirements of the produce safety regulation (because FDA has determined that there are biological hazards associated with “covered produce” that require controls). Thus, such fruit and vegetables are subject to the FSVP requirements to conduct an evaluation for foreign supplier approval and verification and to conduct foreign supplier verification activities.

D.20 Q: Are there foods for which there is not likely to be a hazard that is known or reasonably foreseeable or no hazards requiring a control?

A: Although unlikely, it is possible that your hazard analysis may determine that there are no hazards that are known or reasonably foreseeable in a food. For example, depending on the circumstances, foods such as salt, food additives, certain food-grade chemicals, chewing gum, and vegetable oils (including vegetable oils used as ingredients in animal food) may not be associated with a known or reasonably foreseeable hazard. You would still need to conduct a hazard analysis and document your conclusion that a food has no hazards that are known or reasonably foreseeable.

There are some types of food products for which you may determine that there are no hazards requiring a control. Some human foods that might not have hazards requiring a control include many crackers, most bread, dried pasta, many cookies, many types of candy (e.g., hard candy, fudge, maple candy, taffy and toffee), molasses, sugar, syrup, soft drinks, and jams, jellies, and preserves from acid fruits. (However, some crackers, bread, pasta, and cookies contain allergens (such as milk, eggs, soy, and nuts) which would require labeling in accordance with section 403(w) of the FD&C Act, and the manufacture of such foods may require controls related to food allergens.) Examples of animal foods that might not have hazards requiring a control include alfalfa cubes, vegetable oils, and molasses. You would need to document any conclusion that a particular food has no hazards that require a control.

D.21 Q: How often must I conduct a hazard analysis for a food that I import?

A: You must reevaluate the risk posed by a food (which involves consideration of the hazard analysis) when you become aware of new information about potential hazards, or at least every 3 years (21 CFR 1.505(c)).

E. What evaluation for foreign supplier approval and verification must I conduct? (21 CFR 1.505)

E.1 Q: What must I consider when approving a foreign supplier and determining the appropriate supplier verification activities that must be conducted for the foreign supplier?

A: When approving a foreign supplier and determining the appropriate supplier verification activities, you must, under 21 CFR 1.505(a)(1), evaluate the foreign supplier’s performance and the risk posed by a food by considering the following factors:

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- The hazard analysis of the food, including the nature of the hazard requiring a control.
- The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.
- Foreign supplier performance, including:
 - The foreign supplier's procedures, processes, and practices related to the safety of the food;
 - Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (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, and information relevant to the supplier's compliance with those laws and regulations);
 - The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

You must document your evaluation of the risk posed by a food and the foreign supplier's performance (21 CFR 1.505(a)(2)). Your documentation should explain how your consideration of these factors provided a basis for approving your foreign supplier.

E.2 Q: How should I consider the hazard analysis for a food I import in deciding whether to approve a foreign supplier or determining appropriate verification activities?

A: You will use the hazard analysis you conduct (or review and assess) to determine whether there are any hazards requiring a control in a food you want to import and, if so, provide details on the nature of any such hazards. To conclude that a hazard requires a control, you would have evaluated the hazard to assess the probability that the hazard will occur in the absence of a control and the severity of the illness or injury if the hazard were to occur. The outcome of this hazard probability and severity assessment impacts the type of verification activity you use (as well as the frequency of conducting the activity). For example, when the hazard is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals (SAHCODHA), the default verification activity is to conduct an annual onsite audit before initially importing the food from the supplier and at least annually thereafter (see 21 CFR 1.506(d)(2) and Question F.10). The determination of supplier verification activities and the frequency of conducting those activities should be risk-based, i.e., the greater the risk presented by the hazard, the more robust the verification activity, and the greater the frequency of the verification.

To conclude that a hazard requires a control, you also would have evaluated environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a

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formulation lethal to the pathogen) that would significantly minimize the pathogen. For example, if you are purchasing a cheese to be used as an ingredient in a ready-to-eat food, because *Listeria monocytogenes* is a SAHCODHA hazard in the cheese, you should conduct an annual onsite audit (unless you make an adequate written determination that an annual audit is not necessary) to verify that your supplier controls *Listeria monocytogenes* when it manufactures the cheese, for example by using a “kill step” such as pasteurization of the milk used to make the cheese and sanitation controls to significantly minimize contamination from *Listeria monocytogenes* in the environment. If you expect that a sanitation control will be applied to address the *Listeria monocytogenes*, you could also ask to review the cheese producer’s written procedures for the environmental monitoring it does to verify the sanitation controls. You also could periodically verify your supplier’s controls by sampling and testing the cheese for *Listeria monocytogenes*.

For all hazards that require a control, we recommend that you use the outcome of your hazard analysis to help you determine the extent of what you do to consider foreign supplier performance as required by section 1.505(a)(1)(iii). The greater the risk presented by the hazard, the more stringently you should assess supplier performance as a mechanism to reduce the risk presented by the hazard.

E.3 Q: How should I consider the entity or entities that will be significantly minimizing or preventing a hazard or verifying that a hazard has been significantly minimized or prevented?

A: The entity that is expected to control a hazard in a food (or verify control of a hazard) can be relevant to selecting an appropriate supplier verification activity. Depending on the circumstances, you, the foreign supplier, a supplier to the foreign supplier, or some other entity might be controlling the hazards in a food.

In the following example, you obtain a seasoning mix from a foreign supplier (Supplier X). Supplier X made the seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z). You identify *Salmonella* as a hazard in the seasoning mix, and you learn from Supplier X (your direct supplier) that he does not apply a control for *Salmonella* in the blending operation. Instead, Establishment Y applies a process control for *Salmonella* in the milk powder and Establishment Z applies a process control for *Salmonella* in the spice blend. Although Supplier X is your “foreign supplier” (as defined in 21 CFR 1.500), Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, would be subject to the supply-chain program provisions of the preventive controls regulation (and therefore would have conducted appropriate supplier verification activities, such as auditing its suppliers or sampling and testing the milk and the spices, to ensure that they have used proper controls). You would have several options for conducting supplier verification activities for Establishment Y and Z because they are entities controlling the *Salmonella* hazard. You could conduct the appropriate supplier verification activities with respect to Establishments Y and Z yourself. You could rely on documentation provided to you by Supplier X regarding Supplier X’s supplier verification activities for Establishments Y and Z. You could rely on documentation from Supplier X for some supplier verification activities with respect to Establishments Y and Z and conduct additional supplier verification activities for Establishments Y and Z yourself. You also would determine an appropriate supplier verification activity and associated frequency for Supplier X.

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For another example, if you receive oranges from a foreign consolidator of oranges (but that consolidator is not the “foreign supplier” as defined under 21 CFR 1.500 because they do not engage in further manufacturing/processing of the oranges of a more than de minimis nature), you would need to obtain and review the results of audits showing that the farms from which the consolidator obtained the oranges significantly minimized or prevented the hazards in the oranges (i.e., by growing and harvesting the fruit consistent with the produce safety regulation).

In determining whether to approve a foreign supplier that relies on its supplier to control the hazards, we recommend you consider the robustness of the foreign supplier’s approval process and supplier verification activities. The further removed you are from the entity applying the control for a hazard, the more challenging it may be to adequately verify that control has been applied appropriately and the more likely you will have to rely on information provided to you by other entities in the supply chain. Although section 1.506 gives you the flexibility to rely on information provided to you by another entity, that flexibility does not affect your overall responsibility for obtaining assurance that the hazards in the food you import are being controlled.

E.4 Q: What information about the food safety-related procedures, processes, and practices of a potential foreign supplier should I consider and how should I evaluate it?

A: Understanding a potential supplier’s procedures, processes, and practices related to the safety of the food the supplier provides can help you understand the supplier’s strengths and weaknesses.

You must consider whether a potential foreign supplier employs adequate food safety procedures, processes, and practices (21 CFR 1.505(a)(1)(iii)(A)). You might obtain relevant information by doing the following:

- Conducting a survey or administering a supplier “pre-assessment” questionnaire to obtain information about the supplier’s operations, covering topics such as product information (e.g., regulatory compliance information and allergen information) and the supplier’s food safety programs (e.g., a HACCP plan, a sanitation control program, and an allergen control program);
- Asking the supplier to provide documents such as a food safety plan or HACCP plan (if applicable) and third-party food safety and CGMP audit results;
- Conducting a pre-approval site visit to assess food safety programs and process capabilities; or
- Adopting a system with defined metrics to evaluate supplier performance, including compliance with specifications, third-party audit scores, number of recalls, mock recall performance, material rejections/complaints, and issue response time (e.g., the supplier’s timeframe for resolving a food safety issue).

E.5 Q: What information about applicable FDA food safety regulations and a potential foreign supplier’s compliance with those regulations should I consider and how should I evaluate it?

A: You should determine what FDA food safety regulations a potential foreign supplier is subject to, such as the requirements for preventive controls in parts 117 or 507, produce safety, dietary supplement CGMP, LACF, acidified foods, infant formula, or BSE. Having an understanding of applicable FDA food safety regulations and information relevant to a foreign

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supplier's compliance with those regulations can help you determine whether the supplier has a demonstrable history of supplying acceptable products and meeting all industry and regulatory requirements.

In evaluating the supplier's compliance with the applicable regulations, you should consider whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (e.g., mandatory recall). You should at least consider such compliance-related information that is publicly available (including at FDA's Web site) or that you have obtained by other means. FDA has searchable online databases for compliance-related documents such as warning letters, import alerts, import refusals, recall notices, inspections, and notices of suspensions of facility registrations. For FDA information relevant to foreign supplier compliance with FDA regulations, see FDA's [Supplier Evaluation Resources Web page](#).

In addition to information available from FDA, you might also ask your potential supplier to provide documentation of any recent food safety-related inspections.

You should use this compliance-related information to inform your decisions about whether you will approve a supplier, the type of verification activity you would use if you do approve the supplier, and the frequency of conducting the verification activity. Being subject to an FDA enforcement action such as a warning letter or an import alert should not necessarily disqualify a foreign supplier. However, you should consider carefully the actions a foreign supplier has taken as a result of regulatory compliance issues along with how they impact your approval of that supplier and your verification activities. When the potential foreign supplier is in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States (see Section M of this document), you may consider the company's compliance with the relevant laws and regulations of that country rather than its compliance with applicable FDA food safety regulations.

E.6 Q: What information about a potential foreign supplier's food safety history should I consider and how should I evaluate it?

A: Before you became subject to the FSVP requirements, you may already have established a relationship with your foreign suppliers and have information related to audits and sampling and testing that provides a history of how the suppliers have met your specifications. If so, you already may be aware of past problems with foods provided by a supplier and the steps the supplier took to address such problems. You may consider such prior relationships as part of your consideration of a supplier's food safety history. Likewise, as time goes on and you conduct appropriate supplier verification activities to meet your FSVP requirements, you would consider this same type of information for other foreign suppliers you approve.

You should focus your consideration of a foreign supplier's food safety history on the hazard that the supplier is controlling because that is the most relevant information. However, you should also consider other information about the supplier, e.g., information about recalls or regulatory actions. For example, if you are obtaining a product from a supplier that is controlling a microbial hazard (e.g., *Salmonella* in a spice blend) and food from this supplier has been associated with a chemical hazard (e.g., excess sulfites in another spice blend it produces), you should consider whether you should implement verification activities related to control of sulfites

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to prevent excess sulfites in the spice blend you receive for a period of time adequate to demonstrate that problems that could lead to excess sulfite levels have been resolved. As an example involving animal food, if you import sheep feed and you become aware that the sheep feed from your supplier has been associated with high levels of copper, you should consider whether you should implement verification activities, such as sample testing and verification of label controls, to provide assurances that the sheep feed you receive does not contain a toxic level of copper if fed to sheep.

E.7 Q: What other factors might be appropriate to consider in deciding whether to approve a foreign supplier or determining appropriate supplier verification activities?

A: You must consider any other factors as appropriate and necessary, such as storage and transportation practices, in approving suppliers and determining appropriate supplier verification activities (21 CFR 1.505(a)(1)(iv)). For example, if you import a food that supports the growth of mold that could produce mycotoxins, you may need to ensure that temperature and moisture are controlled during transport and storage. You should consider the procedures that the supplier uses to control factors impacting mold growth during the time the supplier stores the food. As another example, you might receive a food that needs temperature control during transportation to ensure its safety. You should consider whether the foreign supplier is subject to the regulation on sanitary transportation of human and animal food.

As another example, if you are obtaining a food from a foreign facility owned by your corporate parent, you may consider your knowledge of corporate-wide food safety procedures, processes, and practices in determining an appropriate supplier verification activity and the frequency with which it is conducted.

E.8 Q: How must I approve a foreign supplier?

A: You must approve a foreign supplier on the basis of your evaluation of the hazards in the food and the foreign supplier's performance, including its food safety procedures, processes, and practices, its record of compliance with FDA food safety regulations, and its food safety history (21 CFR 1.505(b)). Before approving a foreign supplier, you should have reasonable assurance, based on your consideration of the supplier's performance under section 1.505(a)(1), that the supplier is controlling the hazards in the food you import or verifying that the hazards have been controlled by its ingredient suppliers.

You must document your approval of each foreign supplier (21 CFR 1.505(b)). You could do so by maintaining a paper list of approved suppliers or an electronic system that can generate a list of approved suppliers as needed.

E.9 Q: May I have another entity approve my foreign suppliers?

A: No. Only you as the FSVP importer may approve your suppliers. You can rely on information provided to you by others when you are considering a foreign supplier (see 21 CFR 1.505(d) and Question E.11), but only you can approve a supplier.

E.10 Q: When must I reevaluate the risk posed by a food and the foreign supplier's performance?

A: You must promptly reevaluate the concerns associated with the factors related to the food and foreign supplier discussed in Question E.1 when you become aware of new information about the factors (21 CFR 1.505(c)(1)). Examples of such new information include the following:

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- A hazard previously unknown in a food you import is the cause of a foodborne illness outbreak.
- One of your foreign suppliers opens a new facility it will use to process a food you import from the supplier.
- Your supplier verification activities reveal that your foreign supplier has failed to control a hazard.
- One of your suppliers receives a warning letter from FDA regarding significant violations of one of the preventive controls requirements.

Because we post on our Web site FDA warning letters, import alerts, and inspection classifications, as well as information on foodborne illness outbreaks and food recalls, we believe that you should maintain an awareness of relevant new information in these documents about the foods you import and your suppliers by frequently checking for new information that we post. In addition, you might learn of any significant safety or compliance problems from your supplier.

If you determine that the concerns associated with a food you import or the foreign supplier have changed, you must promptly determine whether it is appropriate to continue to import the food from the foreign supplier and whether you need to change your supplier verification activities (21 CFR 1.505(c)(1)). For example, if you learn that a particular microbiological hazard not previously associated with a food you import has been found in the food, you should revise your FSVP to address the hazard. An example of an emerging microbiological hazard in pet food is *Listeria monocytogenes*. Prior to the expansion of raw, fresh, and frozen pet food into the market, there was little known association of animal food with *Listeria monocytogenes*, but data now available from FDA recalls and the Reportable Food Registry show that *Listeria monocytogenes* has been associated with raw, fresh, and frozen pet food. Another example might be that FDA has placed your foreign supplier on an import alert. If this occurs, you should promptly reevaluate your foreign supplier to determine the relevance of the situation to the food you import from the supplier and whether you need to obtain the food from a different supplier, either permanently or until you complete your reevaluation.

You must document changes to your hazard analysis, your reevaluation of the food and foreign supplier, and any subsequent actions you take (21 CFR 1.505(c)(1)).

If you have not reevaluated the concerns associated with a food and the foreign supplier at the end of any 3-year period, you must reevaluate those concerns and take other appropriate actions, if necessary (21 CFR 1.505(c)(2)). This means that you must reevaluate the food and foreign supplier at least every 3 years even if you do not become aware of new information about the risks posed by a food or about the performance of the foreign supplier. You must document your reevaluation and any subsequent actions you take (21 CFR 1.502(c)(2)).

E.11 Q: May I review another entity's evaluation or reevaluation of the risk posed by a food and the foreign supplier's performance rather than conduct my own evaluation or reevaluation?

A: Yes. If another entity (other than your foreign supplier) has, using a qualified individual, performed the evaluation or reevaluation of the risk posed by a food and the foreign supplier's performance, you may meet the requirements for conducting the evaluation or reevaluation by

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reviewing and assessing the evaluation or reevaluation conducted by that entity (21 CFR 1.505(d)). (If your employee or someone you have engaged to perform an evaluation or reevaluation on your behalf (e.g., a consultant) has conducted the evaluation or reevaluation, you do not need to review and assess it because your employee or consultant would not constitute “another entity” whose actions you must review and assess.) In reviewing and assessing an evaluation or reevaluation, you should consider whether information provided in the entity’s evaluation or reevaluation affects your approval of the foreign supplier. For example, if the evaluation or reevaluation provides information about your supplier’s noncompliance with food safety requirements, you should assess the impact of that information on your approval of the foreign supplier. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual (21 CFR 1.505(d)).

E.12 Q: Under what circumstances am I not required to conduct a food and foreign supplier evaluation or conduct foreign supplier verification activities?

A: You are not required to evaluate a food and foreign supplier under section 1.505(a), or to conduct foreign supplier verification activities under section 1.506, if you are importing a food that cannot be consumed without application of a control in accordance with 21 CFR 1.507(a)(1). This also applies if you are importing a food for which the hazards are controlled by your customer or a subsequent entity in U.S. distribution and you are following the applicable requirements in 21 CFR 1.507(a)(2)-(5). (See 21 CFR 1.507 and section G of this document for questions relating to section 1.507.)

In addition, the food and foreign supplier evaluation requirements do not apply to the following:

- Certain importers subject to section 418 of the FD&C Act (see 21 CFR 1.502(c));
- Certain importers of dietary supplements (see 21 CFR 1.511); and
- Very small importers and importers from certain small suppliers are not required to follow 21 CFR 1.505 (see 21 CFR 1.512).

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

F.1 Q: What foreign supplier verification and related activities must I conduct under my FSVP before importing a food from a foreign supplier?

A: You will need to conduct the following supplier verification and related activities in accordance with section 1.506:

- Establish and follow written procedures to ensure that you use approved suppliers (or, when necessary and appropriate, unapproved suppliers on a temporary basis when you subject foods from such suppliers to adequate verification activities before importing the food);
- Establish and follow written procedures for ensuring that appropriate foreign supplier verification activities are conducted;
- Determine and conduct appropriate foreign supplier verification activities, such as onsite auditing, sampling and testing, and review of supplier food safety records; and
- Review and assess the results of verification activities and, if necessary, take appropriate corrective action.

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For some of these activities, you may rely on other entities to perform the activity provided that you review and assess documentation of the performance of these activities (see 21 CFR 1.506(a)(2), (d)(3), and (e)(3)).

F.2 Q: What must I do to ensure that I am obtaining food from foreign suppliers I have approved?

A: You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under section 1.505 and document your use of these procedures (21 CFR 1.506(a)(1)). You have flexibility to design written procedures that are tailored to your facility and operations. The goal of the written procedures is to ensure that you can accurately identify approved foreign suppliers and incorporate changes in such suppliers on a timely and accurate basis (e.g., addition of new approved suppliers, deletion of suppliers no longer deemed approved). Procedures to ensure that foods are only received from approved suppliers allow consistent implementation of the supplier program by personnel who order foods, receive foods, and conduct supplier verification activities. Such procedures also can help with training for applicable personnel.

The use of written procedures is particularly important in light of the flexibility to rely on an entity other than you (such as an entity in the supply chain between you and the supplier) to ensure that you receive food from approved suppliers (see 21 CFR 1.506(a)(2)). Although such an entity can do this as a service to you, a written procedure is appropriate to ensure a robust and meaningful verification. If you purchase food from a broker or distributor, you must approve the suppliers of the foods you buy from the broker/distributor, but the broker/distributor could document that written procedures are being followed to ensure that the foods provided to you only come from suppliers you have approved. The broker/distributor would provide this documentation to you (e.g., in documents accompanying the shipment) for you to review and assess. Thus, if you rely on a broker/distributor to ensure that the foods provided to you only come from suppliers you have approved, you and the broker/distributor you buy from should agree on the written procedures for how the broker/distributor will document that foods are received only from suppliers approved by you. For example, the broker/distributor could have a checklist that the broker/distributor's employee dates and initials after reviewing the invoice from the supplier, and send a copy of that dated checklist to you together with the invoice for the food. You could use an electronic system or specific supply-chain management software to document receipt of the food and review of the checklist from the broker/distributor at the time of receipt.

When necessary and appropriate, you may use an unapproved foreign supplier on a temporary basis (following written procedures that you have established), provided you subject the food from the supplier to adequate verification activities before importing the food (see 21 CFR 1.506(a)(1) and Question F.4).

F.3 Q: What procedure or mechanism should I use to ensure that I am obtaining food from approved suppliers?

A: We do not require that importers follow any specific procedures or mechanisms. However, you may find it beneficial to use a procedure or mechanism for ensuring you obtain food from approved suppliers that you can readily integrate into your current operations. For example, you

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might be able to use your existing records system, either paper or electronic, to identify foreign suppliers and to flag orders from foreign suppliers that are not approved suppliers. You may also want to include an additional procedure or mechanism to check shipping records to verify that the foreign supplier of the food was an approved supplier.

One approach to a written procedure for ensuring you receive foods only from approved foreign suppliers is to use an actual “approved supplier list.” For example, you might establish a paper system (e.g., a receiving log) under which you check the origin of the purchased food and refer to a list of approved suppliers to verify that the food is received from an approved supplier (e.g., put a check mark by the supplier’s name on the receiving document if the supplier is an approved supplier). The receiving log might include information such as the foreign supplier number (if any), the date and time the shipment was received, and the signature or initials of the receiving clerk.

Another approach to a written procedure for ensuring that you receive foods only from approved suppliers is use of a computer program that links inputs on foods received with the list of approved suppliers for that food and flags discrepancies. You could either use your existing receiving record system or modify your existing system to record information regarding receipt from approved suppliers.

How you document use of the written procedures for receiving food from approved suppliers depends on what your procedures are and how you implement them. For example, if you put a check mark on the receiving document if the supplier is an approved supplier, then the receiving document would be your documentation. If you use a computerized system, you can generate records such as a list of foods received and documentation that the supplier of the food was an approved supplier. If you receive documentation from another entity that has documented the receipt of food from suppliers you have approved, you would review that documentation to verify that it is correct and document your assessment (e.g., with a notation on the documentation you received or in a computerized receiving log).

F.4 Q: Under what circumstances may I import food from a foreign supplier that I have not approved?

A: In certain circumstances you may import food from an unapproved foreign supplier on a temporary basis when you subject the food from such supplier to adequate verification activities before importing (21 CFR 1.506(a)(1)). For example, unexpected circumstances may arise that make it impossible for you to obtain a particular food from an approved supplier. Examples of such circumstances could include the following:

- An environmental incident (e.g., an earthquake) or weather-related crisis (e.g., a tornado or severe drought or flooding in the area where the supplier is located).
- A major equipment breakdown at the facility of a sole supplier of a food.
- The emergence of a contamination problem at your supplier’s facility.
- Your supplier ceases operations without giving you advance notification.

For an unapproved foreign supplier that you plan to use on a temporary basis, we recommend that you conduct at least a minimal review of the supplier. For example, we suggest that you

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review FDA's Web site to determine whether the potential supplier has received a warning letter or is listed on an import alert.

In addition, if you need to use an unapproved supplier under unexpected circumstances, you must subject the food to adequate verification activities before importing it. For example, if you are importing black pepper and your supplier controls *Salmonella*, you could sample and test each shipment of food from the unapproved supplier for *Salmonella* using a statistically-based sampling plan. Alternatively, you could obtain and review records of the process the unapproved supplier uses to kill *Salmonella* in the black pepper. You should document any activities you conduct to verify that hazards in the food are controlled by the temporary supplier.

You should use an unapproved foreign supplier only on a temporary basis until you are able to evaluate and approve that foreign supplier or a different foreign supplier under section 1.505, or until the problem with your previously approved supplier has been corrected and, as appropriate, you reevaluate your approval of that supplier. An appropriate time period for use of an unapproved supplier on a temporary basis might vary, depending on the circumstances, from a few weeks to a few months. For example, if your approved foreign supplier ceases operations and you intend to continue to use a temporary foreign supplier, you should promptly evaluate the new supplier and revise your FSVP accordingly. If you are considering multiple new foreign suppliers to replace your approved foreign supplier, you may need some additional time to evaluate and approve the additional suppliers. Another example is that you expect to be able to obtain the food from the approved foreign supplier in a few weeks, but you subsequently determine that, because of an equipment breakdown or a weather-related incident, it may take several months or an indefinite period of time before you can import the food from the approved supplier. In that circumstance, you may determine that you want to use your temporary supplier or another supplier on a more permanent basis. If that occurs, you should promptly evaluate and approve the new foreign supplier and revise your FSVP to reflect this. Having multiple suppliers approved for each food you import can reduce the use of temporary suppliers when one supplier becomes unavailable.

F.5 Q: May I rely on someone else to establish and implement procedures to ensure that I am importing food from approved foreign suppliers?

A: Yes, provided you review and assess documentation of the procedures and their use. Under section 1.506(a)(2), you may rely on an entity other than your foreign supplier to establish the procedures to ensure use of approved suppliers as well as to implement and document use of these procedures as long as you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment. For example, you might rely on a consolidator or distributor to implement a system to ensure that you import food from your approved foreign suppliers. However, you must review the consolidator or distributor's procedures and subsequent documentation of receipt of food from approved suppliers (perhaps provided when you receive the food from the consolidator or distributor).

F.6 Q: What written procedures must I have for conducting foreign supplier verification procedures?

A: You must establish and follow adequate written procedures for ensuring that you conduct appropriate foreign supplier verification activities with respect to the foods you import (21 CFR 1.506(b)). You should adopt general procedures establishing the approach you will take to

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determine the appropriate foreign supplier verification activities. Your procedures should address how you will consider and evaluate the risk posed by a food (based on the hazard analysis), the entities that control or verify control of hazards in the food and the factors related to the performance of the foreign supplier in deciding what verification activity or activities are appropriate and the frequency with which the activities will be conducted (21 CFR 1.505; 21 CFR 1.506(a)).

Your procedures might address, among other things, the following:

- General principles about supplier verification activities that are appropriate for certain types of food or certain types of hazards in foods. For example, you may explain your reason for conducting audits of foreign suppliers of foods that do not have a SAHCODHA hazard, your basis for the frequency of the sampling and testing you will conduct as your supplier verification activity for the supplier of a particular food, or the types of food safety records you will review for supplier verification.
- The effect that the entity that controls the hazard or verifies the application of controls has on your determination of appropriate supplier verification activities.
- Aspects of the supplier's performance (including its procedures, processes, and practices and its food safety history (e.g., record of compliance with FDA food safety regulations, record of response to safety problems in the food it supplies)) that may affect your determination of appropriate verification activities and frequency of performance.
- Circumstances under which verification activities other than or in addition to annual onsite auditing might be appropriate when there is a SAHCODHA hazard in a food.

You must maintain documentation of these procedures in accordance with the recordkeeping requirements in section 1.510 (21 CFR 1.506(b)).

F.7 Q: What must my foreign supplier verification activities be designed to do?

A: Your foreign supplier verification activities must be designed to verify that the hazards requiring a control in the food you import are significantly minimized or prevented (21 CFR 1.506(c)). Foreign suppliers that are subject to preventive controls requirements (either for human food in part 117 or animal food in part 507) must generally develop and implement a food safety plan that will significantly minimize or prevent hazards associated with the food manufactured, processed, packed or held by the facility and to document they are following their plan. Suppliers subject to the produce safety regulation must follow the procedures set forth in that regulation to significantly minimize or prevent biological hazards in covered produce.

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

A: Depending on the evaluation of the food and foreign supplier conducted under section 1.505, you may conduct foreign supplier verification activities from among the following:

- Onsite audits as specified in section 1.506(e)(1)(i);
- Sampling and testing of a food as specified in section 1.506(e)(1)(ii);
- Review of the foreign supplier's relevant food safety records as specified in section 1.506(e)(1)(iii); and
- Other appropriate supplier verification activities as specified in section 1.506(e)(1)(iv). (21 CFR 1.506(d)(1)(ii)).

These activities are discussed in Questions F.15 through F.24.

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Some supplier verification activities are performed with varying frequency. For example, an importer may decide to conduct testing on every lot for a new supplier until the importer has adequate assurance that the supplier is controlling a hazard. In addition, an importer may decide to increase from periodic testing to testing every lot if a supplier has had a contamination issue until the testing shows that the supplier has resolved the issue and can consistently provide product that is not contaminated.

F.9 Q: How must I determine what foreign supplier verification activities to conduct?

A: With certain exceptions, before importing a food from a foreign supplier, you must determine and document which verification activity or activities (from among those listed in section 1.506(d)(1)(ii)), as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with section 1.506(c) (21 CFR 1.506(d)(1)(i)). Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce harvests or packs the produce and controls the hazard or verifies control of the hazard, or when the foreign supplier's raw material supplier controls a hazard). Based on the determination you made (or reviewed and assessed) under section 1.506(d), you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in section 1.506(e)(1)(i) through (e)(1)(iv) for each foreign supplier before using or distributing the food in the United States and periodically thereafter (21 CFR 1.506(e)(1)).

The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under section 1.505 (21 CFR 1.506(d)(1)(i)). Therefore, in deciding what foreign supplier verification activities you need to conduct, you need to consider:

- The hazards requiring a control in the food;
- The entities that will be applying or verifying control of the hazards;
- The foreign supplier's processes, procedures, and practices related to the safety of the food;
- Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety;
- The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems; and
- Any other factors as appropriate and necessary, such as storage and transportation practices.

In documenting your determination of appropriate supplier verification activities and frequency of performance, you should explain why you decided that the particular supplier verification activities you chose were appropriate. For example, when considering the significance of the hazard in a food, you should consider whether the hazard is likely to be present at high

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concentrations that would easily be detected by testing, or whether the concentration is expected to be so low that testing is unlikely to be reliable in detecting the hazard.

The place at which controls are applied (e.g., at the supplier or the supplier's supplier) might also affect verification procedures. For example, a milling company might have an aflatoxin control program for the dried corn it receives. A baking mix company might conduct verification activities at the miller to ensure that aflatoxin is controlled. If you import a cornbread muffin mix from the baking mix company, you might verify the documentation from that company on its verification program for the miller.

Another example of the importance of where controls are applied or verified is when growing, harvesting, and packing operations for a fruit or vegetable are performed by different entities. Harvesting and packing operations include controls such as those on worker hygiene, quality of water used during harvesting and packing operations, and establishing and following water-change schedules for recirculated water. If you receive fruit from a supply chain that includes a separate grower, harvester, and packer, the grower is your foreign supplier. However, in addition to verifying that the grower produced the fruit consistent with the produce safety regulation, you will need to obtain assurances that hazards associated with harvesting and packing are being significantly minimized or prevented. For verification activities related to the harvester, you might review the harvester's records, such as records of training for harvest workers and records of agricultural water quality used in harvest operations. For verification activities related to the packer, you might review the packer's records, such as records of agricultural water quality used in packing operations and water-change schedules for recirculated water used in packing operations. You can rely on other entities, such as distributors, brokers, aggregators, and harvesters, to determine, conduct, and document verification activities for the grower, harvester, and packer, provided that you review and assess the determinations and verification activity results (see 21 CFR 1.506(d)(3) and (e)(2) and Questions F.13 and F.26).

Knowledge of your foreign supplier's food safety procedures, processes, and practices might also influence your verification procedures. For example, your hazard analysis may have determined that monensin is a hazard requiring a control because your foreign supplier is a medicated feed facility that manufactures food for multiple animal species (including horses) and that also uses the drug monensin in some of the animals' diets. Monensin is an approved new animal drug for cattle and poultry but is highly toxic to horses. Your supplier verification activities should include obtaining verification that the foreign supplier is manufacturing horse feed that is not contaminated with monensin.

A foreign supplier's compliance history, whether positive or negative, could play a significant role in determining appropriate verification measures. A supplier's recent receipt of an FDA warning letter or inclusion on an import alert might warrant taking extra precaution to verify that the supplier has adequate controls in place. On the other hand, a foreign supplier whose recent FDA inspections have found no significant non-compliance might require less extensive verification.

An importer's relationship with its foreign supplier is another important factor. If you have many years of positive food safety experience with a particular supplier, you might conclude that

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you can conduct less extensive verification. For example, if you are importing sweet potatoes from a country or region with a history of pesticide violations but you routinely conduct testing that verifies your foreign supplier does not send shipments of sweet potatoes with unlawful pesticide chemical residues, you may determine that less frequent testing is sufficient.

F.10 Q: What supplier verification activities must I conduct when a food I import has a SAHCODHA hazard?

A. Under section 1.506(d)(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 (a SAHCODHA hazard), you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter. Alternatively, you may make an adequate written determination that, instead of initial and annual onsite auditing, other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is significantly minimizing or preventing the hazard, based on the determination made under section 1.505.

We believe that annual onsite auditing of the foreign supplier is appropriate when there is a SAHCODHA hazard in a food. Onsite audits provide a comprehensive assessment of an entire food production operation and an opportunity to review food safety plans and written procedures, as well as to observe the implementation of food safety procedures and review records related to the past application of control measures, including laboratory test results. Audits also provide the opportunity to interview employees to assess their understanding of the food safety measures for which they are responsible. Many audits are tabulated and scored for compliance with food safety standards. Therefore, audits provide a particularly robust evaluation of a supplier, which is appropriate in light of the greater risk associated with the presence of a SAHCODHA hazard in a food.

By “annual” onsite auditing, we mean once every 365 days. The goal is to conduct this activity with sufficient frequency to provide assurance that a hazard requiring a control has been significantly minimized or prevented, and we believe this goal can be met by conducting an audit every year, i.e., every 365 days. Nevertheless, we realize there may be practical reasons which preclude meeting this timeframe, e.g., a third-party auditor needs to delay a previously scheduled audit. In assessing your compliance with the default requirement to conduct an onsite audit at least annually (in circumstances in which that requirement applies), we will take such practical timing considerations into account.

Under some circumstances it might be reasonable for you to determine that annual onsite auditing of a foreign supplier is not necessary even though there is a SAHCODHA hazard in a food. However, in most of these circumstances we recommend that your supplier verification activities include some frequency of onsite auditing, such as every 2 or 3 years. For example, you might determine that because of your supplier’s excellent compliance and performance history (e.g., based on your own experience of several years with the supplier or as documented in audits, inspections, test results, and FDA compliance information) annual audits are not needed to ensure the safety of food from the supplier. Instead, you might conclude that adequate verification can be achieved through auditing the supplier every other year combined with

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sampling and testing for the hazard each quarter in the intervening year or periodically reviewing your supplier's food safety records relating to controlling the hazard.

A different verification approach might be appropriate in a situation in which you are part of a larger corporation and obtain roasted peanuts from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as you. You could determine that the food safety requirements established by the parent company and applied at the subsidiary provide the needed assurance that *Salmonella* in raw peanuts is adequately controlled. You could support your decision by documenting this determination, including the supplier's procedures in effect at the supplier and the corporation's activities to verify that the subsidiary operates in accordance with corporate food safety policies to ensure that hazards are adequately controlled.

If you determine that it is appropriate to conduct an activity or activities other than annual onsite auditing, you will need to maintain documentation that the activity or activities provide adequate assurances of safety, and this documentation must be available for FDA review during any inspection or upon Agency request for records under section 1.510(b).

F.11 Q: How do I determine whether a hazard is a SAHCODHA hazard?

A: All SAHCODHA hazards require a control, but not every hazard requiring a control is a SAHCODHA hazard (i.e., has the potential to result in serious adverse health consequences or death to humans or animals). Examples of SAHCODHA hazards include pathogens or their toxins in ready-to-eat foods, undeclared food allergens, and nutrient deficiencies and toxicities in animal food (e.g., inadequate thiamine in cat food, excess copper in a sheep mineral premix). For additional information on hazards requiring a control in human food, see the Preventive Controls for Human Food draft guidance (Chapter 3, Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food). SAHCODHA hazards generally are those for which a recall of a food posing such a hazard is designated as "Class I" under 21 CFR 7.3(m)(1). The Agency's weekly ["FDA Enforcement Report"](#) provides information about foods that have been the subject of a Class I recall and the reasons for the recall. While these examples can be helpful in understanding information about foods that have been the subject of Class I recalls, they should not be used as a substitute for evaluating the facts of your particular situation in order to determine whether there is a reasonable probability that exposure to the hazard in a food you import will result in serious adverse health consequences or death

Information about SAHCODHA hazards can also be found in FDA's guidance for industry entitled ["Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007"](#) (RFR guidance). The RFR guidance provides recommendations to industry on compliance with the statutory requirements for reportable foods under section 417 of the FD&C Act. Under section 417(a)(2), a "reportable food" is an article of food (other than dietary supplements and infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. The RFR guidance and the annual reports of the RFR provide examples of food considered to have SAHCODHA hazards.

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F.12 Q: Should I conduct more than one supplier verification activity for a particular food from a particular foreign supplier?

A: In some cases you may determine that more than one supplier verification activity is warranted for a particular food from a particular foreign supplier. For example, when the identified hazard requiring a control in a food is a pesticide that is not a SAHCODHA hazard, you may determine that the appropriate foreign supplier verification activities are to review the foreign supplier's food safety plan and to sample and test some of the shipments you import for pesticides.

F.13 Q: May I rely on someone else to determine what foreign supplier verification activities I must conduct?

A: Yes, you may rely on a determination of appropriate foreign supplier verification activities made by another entity (i.e., other than you, your employee, or a person performing the activity on your behalf, such as a consultant) if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate (21 CFR 1.506(d)(3)). However, you may not rely on your foreign supplier to determine appropriate supplier verification activities for the food you import from that supplier. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

Other entities on which you might rely to determine appropriate supplier verification activities could include a produce packinghouse or consolidator that determines appropriate verification activities for the farms supplying the produce that you in turn import from the packinghouse or consolidator. Another example might be relying on a determination of appropriate supplier verification activities by the distributor of a packaged food product.

F.14 Q: What foreign supplier verification activities must I conduct?

A: Based on the determination you made (or reviewed and assessed) in accordance with section 1.506(d), you must conduct (and document) or obtain documentation of one or more supplier verification activities (onsite auditing, sampling and testing, review of foreign supplier food safety records, or some other mechanism determined to be appropriate) for each foreign supplier before importing the food and periodically thereafter (21 CFR 1.506(e)(1)).

F.15 Q: When onsite auditing is appropriate, who can conduct the audit?

A: An onsite audit of a foreign supplier must be performed by a qualified auditor, as defined in section 1.500 (21 CFR 1.506(e)(1)(i)(A)). (See section III.C of this guidance for a discussion of qualified auditors.) As long as the person conducting the audit is a qualified auditor under sections 1.500 and 1.503(b), an audit for FSVP purposes might be conducted by, among others, the following:

- An employee of the importer.
- A consultant to the importer.
- A government employee (including a foreign government employee) (e.g., report of an audit of an LACF manufacturer conducted by a foreign authority who has regulatory oversight of the LACF industry).
- A third party, such as a person that is accredited to conduct food facility audits under an international food safety auditing system or a person who is accredited under FDA's

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third-party certification regulation in accordance with 21 CFR part 1 subpart M. Although formal accreditation is not required, any third-party auditor conducting an onsite audit on which you wish to rely must have the necessary expertise specified in section 1.503(b).

However, you may not rely on an onsite audit of your foreign supplier conducted by the supplier itself (see 21 CFR 1.506(e)(2)(ii) and Question F.26).

You may have your own employee (if he or she is a qualified auditor as defined in section 1.500) audit your foreign supplier (a “second-party audit”). Alternatively, you might rely on the results of an audit of your supplier conducted by an independent third party, including a third-party audit conducted at the supplier’s request, provided the audit is conducted by a qualified auditor. Both second- and third-party audits allow first-hand review of the critical food safety programs in place at a supplier’s establishment and can help you obtain a sense of how effective programs are by diligently reviewing program records, observing activities, and interviewing workers. You can also rely on an audit conducted by a qualified auditor who is a government employee, including a foreign government employee, provided that the audit meets the other requirements applicable FDA food safety regulations. For example, it might be appropriate to rely on an audit conducted by a foreign government employee as required for certification by an export agency that a facility meets U.S. standards if that audit is conducted in accordance with all FSVP audit requirements.

There are several widely used national and international auditing schemes to assess food safety practices in manufacturing facilities and on farms. You could rely on the results of audits conducted in accordance with such schemes provided that the audits consider the farm or facility’s compliance with applicable FDA regulations, review the supplier’s food safety plan (if any) and its implementation, and otherwise meet the requirements for onsite audits in section 1.506(e)(1)(i). Before relying on the results of a third-party onsite audit, you should determine whether the auditing scheme used can help you conclude whether the supplier uses processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety provisions of the FD&C Act (and the implementing regulations), as well as provide adequate assurances that the food is not adulterated or misbranded with respect to allergen labeling.

If an onsite audit of a foreign supplier is conducted solely to meet FSVP requirements by an audit agent of a certification body accredited in accordance with 21 CFR part 1, subpart M (the third-party certification regulation), the audit is not subject to that regulation (21 CFR 1.506(e)(1)(i)(C)).

F.16 Q: How must an onsite audit of a foreign supplier be conducted?

A: If the food is subject to one or more FDA food safety regulations (such as the preventive controls for human food regulation or the produce safety regulation), 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, and its implementation (21 CFR 1.506(e)(1)(i)(B)). Because FDA food safety regulations vary in scope and detail, the parameters and key components of an onsite audit

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conducted under section 1.506(e)(1)(i) would necessarily vary depending on what regulations applied to the foreign supplier.

If your foreign supplier is required under the preventive controls requirements in parts 117 or 507 to have a food safety plan, the onsite audit would focus on that plan and assess the implementation of the preventive controls applied by the supplier to address the known or reasonably foreseeable hazards that the importer has determined require a control. For example, before you obtain roasted peanuts for which you had identified *Salmonella* as a hazard from a foreign supplier subject to the preventive controls requirements for human food, you would audit the supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier's roasting process adequately controlled *Salmonella*. Because the supplier was subject to the preventive controls requirements, the audit would include a review of the supplier's food safety plan. The auditor would review whether the roasting process had been validated to significantly minimize *Salmonella* in peanuts and would examine whether the supplier had implemented the roasting procedures in accordance with the food safety plan (e.g., through observing the establishment's procedures and reviewing records).

A similar approach would be used if you obtained dog treats for which you had identified *Salmonella* as a hazard from a foreign supplier subject to the animal food preventive controls requirements. You would audit the foreign supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier's thermal process (or sanitation controls if the product is exposed to the environment after a thermal process step) adequately controlled *Salmonella*. Because the supplier was subject to the preventive controls requirements for animal food, the audit would include a review of the supplier's food safety plan. The auditor would review whether the thermal processing had been validated to significantly minimize the *Salmonella* in the dog treats and would examine whether the supplier had implemented the thermal processing in accordance with the food safety plan (e.g., through observing the establishment's procedures and reviewing records).

Farms are not required under the produce safety regulation to have a food safety plan. However, in some cases, a foreign supplier (such as a large farming operation) might voluntarily elect to establish a food safety plan. In that case, the onsite audit of the supplier would need to include a review of the foreign supplier's written plan, and its implementation of the plan, to ensure that identified hazards are being adequately controlled.

An audit of your foreign supplier should include both records review and observation of practices to obtain a complete picture of the safety of your supplier's operations. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year than an audit focused only on the state of the facility at the time of the audit. An audit of a manufacturing/processing facility should address process, allergen (for human food), sanitation, and supply-chain applied controls, if applicable, as well as CGMPs (if applicable) and the specific hazards identified in your hazard analysis of the food.

F.17 Q: What documentation of an onsite audit must I have?

A: 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

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significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor (21 CFR 1.506(e)(1)(i)(D)). You are not required to maintain a copy of the entire audit report.

We consider a “significant deficiency” to be a deficiency that may result in food that would pose a risk to public health or otherwise be adulterated. If the supplier takes a corrective action in response to auditor identification of such a deficiency, you will need to retain documentation of the corrective action (21 CFR 1.506(e)(1)(i)(D)).

You can document that an audit was conducted by a qualified auditor by describing any certification or applicable training and auditing experience (e.g., “more than a dozen audits of food facilities”) of the auditor. Alternatively, a copy of the auditor’s resume might provide sufficient information to document that the auditor is qualified. When the auditor is accredited under FDA’s accredited third-party certification regulation, you can meet this requirement by documenting the name of the accredited auditor as appearing on the registry of accredited third-party certification bodies available at FDA’s Web site (see 21 CFR 1.690).

F.18 Q: When may I substitute inspection results for the results of an onsite audit?

A: Some suppliers might be routinely inspected by FDA or other government agencies. Under section 1.506(e)(1)(i)(E), you may substitute two particular types of inspection results for an onsite audit, provided that the relevant inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted. The first type is the written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies in the United States (21 CFR 1.506(e)(1)(i)(E)(I)).

For an inspection conducted by one of these entities, an “appropriate” inspection conducted for compliance “with applicable FDA regulations” means that the inspection must be sufficiently relevant to compliance with applicable FDA food safety regulations to credibly substitute for an onsite audit. For example, inspection by the USDA to determine whether a farm satisfies the requirements of the produce safety regulation could constitute an appropriate inspection that could substitute for an audit, but an inspection by the USDA to determine whether a farm satisfies the requirements of the National Organic Program could not. Another example might involve an FDA inspection of an animal food facility to ensure compliance with regulations for BSE. If the hazard being controlled by the facility is associated with BSE, the inspection could be substituted for an onsite audit. However, if the inspection focused on another regulation, such as implementation of medicated feed CGMP requirements, and did not assess compliance with the BSE regulations, it would not be appropriate to substitute the inspection for an audit to verify that the BSE hazard was being controlled.

The written results of an inspection on which you rely would depend on the nature of the inspection and how the entity conducting the inspection reports its results.

You may also substitute for an onsite audit the written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially

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recognized as comparable or determined to be equivalent to that of the United States, provided the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country (21 CFR 1.506(e)(1)(i)(E)(2) (see also section III.M of this guidance for a discussion of findings of comparability under the systems recognition process and equivalence determinations). Under FDA's systems recognition initiative, the Agency reviews a country's food safety system to determine whether it provides a similar, though not necessarily identical, system of protections as the U.S. food safety system and whether the country's food safety authority provides similar oversight and monitoring activities for food produced under its jurisdiction.

FDA maintains on its Web site a list of countries whose food safety systems we have officially recognized as comparable to the U.S. system or determined to be equivalent to the U.S. system (see Section III.M of this document). In addition, the Web site provides information on the types of food covered under each systems recognition arrangement or equivalence agreement.

Some countries issue certifications or recognitions to facilities for compliance with certain requirements such as for HACCP systems. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit because HACCP requirements are not identical to preventive controls requirements, and it would not be clear what basis was used to issue a HACCP certificate. However, you could consider whether such a certificate could be part of your justification for conducting an audit on a less frequent basis than annually or conducting another supplier verification activity in lieu of an annual onsite audit.

F.19 Q: When might sampling and testing of food be an appropriate supplier verification activity?

A: Testing of in-process materials, environmental samples, or the food produced by the supplier may be an appropriate supplier verification approach if such testing provides meaningful results relating to control of a hazard requiring a control. Depending on the circumstances, you, your foreign supplier, or another entity might conduct the sampling and testing. For example, you might ask your supplier to conduct sampling and testing and provide the results in a certificate of analysis (COA).

Any testing on which you rely should use scientifically-based sampling plans that provide reasonable assurance that the hazard in the food has been adequately controlled and address known limitations of sampling and testing foods as a verification activity. For example, hazards may not be homogeneously distributed throughout a product lot, food components may interfere with the method of analysis, and the method of analysis may not be sensitive enough to detect a hazard that is present at low concentrations. To address such limitations, we recommend that you obtain samples that are representative of the lot, use a testing method that has been shown to provide reliable results when the analyte of interest is within the food matrix you will be testing, and use a method that has a sensitivity appropriate to detect that hazard.

You can perform sampling and testing on a periodic or lot-by-lot basis. We recommend that you establish the frequency of testing for a food by testing on a relatively frequent basis (e.g.,

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monthly) until the supplier establishes a good history of supplying the food, after which time you could sample and test less frequently, such as quarterly.

As an example of use of sampling and testing as a verification method, if you import a packaged mix of food seasonings, you might conduct your own periodic *Salmonella* testing or use a contracted laboratory to test samples of the seasoning mix on a monthly basis. This monthly testing could be conducted until a good history is established for the seasoning mix supplier, after which time you might determine it would be appropriate to test less frequently, such as quarterly.

Alternatively, you might determine that it is appropriate to obtain documentation (such as a COA) of lot-by-lot or periodic testing of the food that is conducted before the food is distributed by the foreign supplier. We recommend that a COA document that major analytical parameters for a specific food or lot in a specific shipment have been met (see, e.g., Grocery Manufacturers Association, “Food Supply Chain Handbook” (http://www.gmaonline.org/downloads/technical-guidance-and-tools/GMA_SupplyChain2.pdf), April 16, 2008). The testing might be performed by the supplier’s in-house laboratory or contracted to an outside testing laboratory.

Whether you conduct sampling and testing yourself or rely on testing performed by others, you should only rely on the results of testing that was conducted by a laboratory that employs scientifically valid laboratory methods and procedures that can provide reliable, accurate test results.

F.20 Q: What documentation of sampling and testing must I have?

A: You must retain documentation of each sampling and testing of the food (21 CFR 1.506(e)(1)(ii)). Your documentation must include:

- 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 date of the report of the testing,
- Results of the testing,
- Corrective actions taken in response to detection of hazards,
- Information identifying the laboratory that conducted the testing (e.g., name and address), and
- Documentation that the testing was conducted by a qualified individual (21 CFR 1.506(e)(1)(ii)).

If any of this information is included in the laboratory report or COA you receive from the laboratory that performs the test, you may use the report or certificate as documentation of that information (i.e., you need not create a duplicate record of the information on the laboratory report).

F.21 Q: Should I use an accredited laboratory to conduct the testing?

A: A laboratory conducting the tests on which you rely might be, but is not required to be, accredited. Using an accredited laboratory (e.g., a laboratory accredited in accordance with

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section 422 of the FD&C Act or to International Organization for Standardization (ISO) Standard 17025) is one way to have confidence that a laboratory will provide reliable, accurate test results.

F.22 Q: What are food safety records and when might review of my foreign supplier's food safety records be an appropriate supplier verification activity?

A: Food safety records are records documenting that the food safety procedures the supplier has established to control hazards are being followed and are adequately controlling the hazards.

Such records might include:

- A supplier's control log for a particular process that verifies the process was conducted effectively;
- Records of a foreign supplier's audit of its supplier's hazard control activities; and/or
- Records of environmental monitoring or product testing.

In general, relevant food safety records are any records that will provide sufficient documentation that your supplier is following the procedures it has established to control a hazard and that the hazard has been controlled. Relevant food safety records relate to a particular lot of a food you imported, such as the record created when a process control measure was applied. For example, if you import fresh vegetables and you determine through periodic testing for pesticides (performed as part of your supplier verification) that the supplier provided vegetables with a pesticide level in excess of the approved tolerance for that pesticide, you might determine that it would be appropriate to obtain a copy of the pesticide application records from the farm that grows the vegetables for a period of time to verify that the supplier has resolved problems that could lead to excess pesticide levels.

Relevant food safety records also could include, when applicable, records demonstrating that your foreign supplier has verified control of a hazard by its own supplier. Such records could relate more broadly to the supplier's food safety procedures, such as records of your supplier's audit of its supplier's food safety activities. For example, if you manufacture deli salads and obtain chopped fresh vegetables from your supplier, you could obtain a copy of your supplier's records documenting their audits of the farms growing the vegetables, provided the audits meet the requirements for onsite audits under the FSVP regulation.

As an example of relying on supplier food safety records, if your foreign supplier controls vegetative pathogens (e.g., *E. coli* O157:H7, *Salmonella*) in a food through pasteurization, to verify that the supplier controlled these hazards you might review such records as the supplier's pasteurization log, validation of process (if applicable), finished product testing log, and corrective action log. If your supplier takes steps to prevent the contamination of a food with metal fragments, you might review the supplier's procedures for metal detection, metal detection log, metal detector calibration log, and corrective action log.

Here is an example of using relevant food safety records when the hazard requiring a control is *Salmonella* that could contaminate black pepper and your foreign supplier (Supplier A) provides you with a spice mix containing black pepper that has been steam-treated by Supplier A's own supplier, Establishment B, to control *Salmonella*. One relevant food safety record could be the applicable audit record resulting from an onsite audit of Establishment B. You could either

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obtain applicable audit records directly from Establishment B or you could obtain the records from Supplier A. The applicable audit records could include copies of audit procedures, dates, conclusions of the audits, and any corrective actions taken in response to significant deficiencies identified during the audit of Establishment B. If Supplier A conducts additional verification activities such as periodic testing of the steam-treated black pepper, you could also ask Supplier A to provide records of those activities for your review. Likewise, if you want to see documentation of the applicable parameters for the steam treatment that Establishment B delivered to a lot of black pepper, you could obtain these records either directly from Establishment B or from Supplier A.

F.23 Q: What documentation of supplier food safety record review must I have?

A: You must retain documentation of each record review, including the date(s) of your review of the records, the general nature of the records reviewed, the conclusions of the 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 (21 CFR 1.506(e)(1)(iii)).

You do not need to retain a list of every document you review, but the documentation you retain should at least generally describe the types of records you reviewed. Your documentation of the conclusions of your review should address the basis for your conclusions. For example, if you determined that the supplier's analysis of a sample of finished poultry food was positive for *Salmonella enteritidis* and the supplier took appropriate corrective action (e.g., reprocessed or destroyed the food), you may document this situation to support your conclusion that the supplier takes appropriate corrective actions for significant deficiencies.

F.24 Q: What other foreign supplier verification activities might be appropriate?

A: You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on your foreign supplier's performance and the risk associated with the food (21 CFR 1.506(e)(1)(iv)). This means that you may specify and design risk-based activities (other than onsite auditing, sampling and testing, and review of relevant food safety records) that can provide effective supplier verification. For example, you could develop and use a fact-specific questionnaire or consider information applicable to a supplier's certification to a widely recognized auditing scheme, and rely on such activities alone or in combination with other supplier verification activities (e.g., periodic sampling and testing of the food) if they provide adequate assurance that hazards are being controlled.

As with the other supplier verification activities, you will need to document your determination that use of an alternative verification activity is appropriate based on your evaluation of the food and the foreign supplier, and document your performance of the alternative activity. Your documentation must include a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual (21 CFR 1.506(e)(1)(iv)(B)). Your documentation of other appropriate supplier verification activities would partly depend on the nature of the activity. For example, if you use a fact-specific questionnaire, you should maintain a record of the completed questionnaire applied to a particular foreign supplier. If you considered information applicable to a supplier's

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certification to an auditing scheme, you should maintain a record of the information you considered.

F.25 Q: What verification activities may be appropriate for hazards related to transportation of food?

A: Your hazard analysis of a food you import might determine that there is a hazard requiring a control that relates to transportation of the food (see 21 CFR 1.504(c)(iv)). Examples of foods for which a hazard needs to be controlled during transportation include the following:

- Produce shipped in open or porous containers or crates: A pathogen (e.g., *Salmonella*, *Listeria monocytogenes*) may be introduced into the produce if the transportation vehicle is not properly cleaned and sanitized before loading.
- Soft ripened cheeses: *Listeria monocytogenes* may proliferate if the cheese is not transported in a vehicle that maintains appropriate refrigeration temperatures.

If you determine there is a hazard requiring a control in a food you import that relates to transportation practices, you will need to conduct verification activities to provide assurance that the hazard is being significantly minimized or prevented by the foreign supplier or other responsible entity (21 CFR 1.506(d)(1)(i)). This verification is in addition to verification of your foreign supplier.

If your foreign supplier is subject to the requirements of the regulation on sanitary transportation of human and animal food (sanitary transportation regulation) (21 CFR 1.900-1.934), your verification activities may include obtaining written assurance from the foreign supplier that your supplier is complying with the sanitary transportation of human and animal food regulation when it ships the food. The sanitary transportation regulation requires shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food (including animal food) to use sanitary transportation practices to ensure the safety of the food they transport. Under the sanitary transportation regulation, vehicles and transportation equipment used in transportation operations must be designed, maintained, and stored to prevent the food they transport from becoming unsafe (i.e., adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act) during transportation operations. Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations (21 CFR 1.906). In addition to being a factor in the verification activities you conduct, if your foreign supplier is subject to the requirements of the sanitary transportation regulation (because it meets the definition of shipper in the rule), you should consider your foreign supplier's compliance with the regulation as part of your evaluation for foreign supplier approval and verification (21 CFR 1.505(a)(1)(B)).

If you determine that there is a hazard requiring a control that relates to transportation practices but your foreign supplier is not subject to the sanitary transportation regulation because your supplier is not a shipper under the rule (see 21 CFR 1.904), your verification activities could include obtaining written assurance directly from the actual foreign shipper that it is complying with the sanitary transportation regulation, if applicable, when it ships the food. If the sanitary

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transportation regulation does not apply to the foreign shipper (e.g., because the food is transported to the United States by cargo ship and the foreign shipper did not arrange for transport by rail or motor vehicle within the United States), you could obtain written assurance from the transporting entity that the food is imported in a manner that significantly minimizes or prevents the hazard (e.g., the entity monitors and records the temperatures of a refrigerated unit to ensure that the required temperature is maintained during transport of the food).

F.26 Q: May I rely on the results of foreign supplier verification activities conducted by others?

A: Yes. You are not required to conduct required supplier verification activities yourself, i.e., an employee of your company is not required to conduct the actual onsite audit, food testing, record review, or other verification activity. You may hire a third party to conduct verification activities and review and assess documentation of these activities.

In addition, you may rely on the results of verification activities performed by other entities provided that you review and assess the results of these activities in accordance with section 1.506(e)(3) (21 CFR 1.506(e)(2)(i)). For example, you may rely on the results of verification activities conducted by third parties whose services were obtained by the foreign supplier (such as when a foreign supplier arranges for a third-party audit of its facility) (21 CFR 1.506(e)(2)).

However, you may not rely on the foreign supplier (or its employees) to perform supplier verification activities regarding its own operations, except with respect to sampling and testing of food (21 CFR 1.506(e)(2)(ii)).

F.27 Q: What review and assessment of the results of foreign supplier verification activities must I conduct?

A: You must promptly review and assess the results of the verification activities you conduct (or obtain documentation of), or that are conducted by other entities in accordance with section 1.506(e)(2) (21 CFR 1.506(e)(3)). You should have a qualified individual with expertise in the activity reviewed (e.g., auditing, sampling and testing) consider the documentation of the activity and assess whether the results and findings provide adequate assurance that the hazards requiring a control are being significantly minimized or prevented and that the foreign supplier is producing food consistent with applicable U.S. standards. For example, rather than conducting or obtaining your own audit of your supplier, your supplier might provide you with the results of an appropriate third-party audit that the supplier obtains for several of its customers, as long as you have a qualified individual review the audit results and ensure that the audit meets the FSVP requirements.

You must document your review and assessment of the results of verification activities. You have flexibility in how you document your review and assessment; for example, you might have appropriate staff (a qualified individual) date and sign the documentation received from another entity, or you could attach a signed, dated statement from appropriate staff stating that he/she had reviewed and assessed the documentation.

F.28 Q: What if the results of supplier verification activities suggest that a hazard is not being controlled?

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A: If the results of verification activities do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with section 1.508(a) (21 CFR 1.506(e)(3)). For example, if your verification activity for a frozen ice cream novelty includes sampling and testing for *Listeria monocytogenes* before the ice cream product is shipped from your foreign supplier and your sample results are positive for *Listeria monocytogenes*, you may choose to cancel the shipment and follow up with your foreign supplier to address the food safety issue. You may choose to discontinue use of the foreign supplier, either permanently or until you can assure the safety of future lots of the product.

You are not required to retain (at your place of business) documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with section 1.510(b) (21 CFR 1.506(e)(3)).

F.29 Q: What requirements apply to the independence of persons conducting foreign supplier verification activities?

- A: There must not be any financial conflicts of interests that influence the results of the verification activities conducted, and payment must not be related to the results of the activity (21 CFR 1.506(e)(4)). For example, if a qualified individual has a financial conflict of interest that influences the results of verification activities, the qualified individual would be precluded from being able to independently conduct verification activities under the FSVP regulation. You can avoid this possibility when conducting supplier verification activities by only using individuals or firms that do not have conflicts of interest.

In addition, payment to a qualified individual must not be related to the results of the verification activity. For example, you may not give a qualified auditor who conducts an onsite audit or a qualified individual who reviews supplier food safety records greater compensation for determining that the foreign supplier is in compliance with applicable FDA requirements. Also, you may not reduce the compensation of a qualified auditor or qualified individual or assess financial penalties because the person identified areas of supplier non-compliance. Similarly, your foreign supplier may not make such payments.

To ensure that a qualified auditor or qualified individual who conducts a supplier verification activity on your behalf does not have a financial conflict of interest with your foreign supplier, you may want to request that the person provide you with a written, signed, no-conflict-of-interest statement.

Section 1.506(e)(4) does not prohibit an employee of your foreign supplier from conducting sampling and testing so that the supplier could provide you with the results; as previously stated, it is common for suppliers to provide COAs for tests conducted on specific lots of product along with a shipment of food. In addition, section 1.506(e)(4) does not prohibit you from relying on the results of an audit of your supplier that your supplier gives you when the audit was conducted by a third-party qualified auditor.

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G. What Requirements Apply When I Import a Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation? (21 CFR 1.507)

G.1 Q: What FSVP requirements apply when I import a food that cannot be consumed without application of an appropriate control for the hazard?

A: If you import a food that cannot be consumed without application of an appropriate control for the hazard, you must:

- Conduct a hazard analysis (21 CFR 1.504), the results of which should indicate that there is a hazard requiring a control, and
- Document your determination that the type of food cannot be consumed without application of an appropriate control (21 CFR 1.507(a)(1))
- Meet other standard FSVP requirements (e.g., develop an FSVP, use a qualified individual, maintain records).

You are not required to:

- Conduct an evaluation of the food and foreign supplier (21 CFR 1.505), or
- Conduct foreign supplier verification activities (21 CFR 1.506).

G.2 Q: What are examples of foods that cannot be consumed without application of the appropriate control by an entity in the distribution chain?

A: We believe there are few foods that fit into this category. For example, raw cocoa beans and coffee beans cannot be consumed without roasting. The roasting process kills pathogens that may be in the cocoa and coffee beans. Also, some imported grains for human consumption (e.g., some wheat, rice, corn) must be processed or cooked before they are consumed.

G.3 Q: What FSVP requirements apply when I rely on my customer or a subsequent entity in the distribution chain to ensure that the identified hazard will be adequately controlled?

A: You must disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”.

You are not required to (1) conduct an evaluation of the food and foreign supplier (section 1.505) or (2) conduct foreign supplier verification activities (section 1.506).

Note that the FSVP regulation also requires that you obtain an annual assurance from your customer that the food will be processed in accordance with applicable food safety requirements (21 CFR 1.507(a)(2)(ii), (a)(3)(ii), and (a)(4)(ii)). However, FDA has delayed the compliance date for these assurance requirements by 2 years to address feasibility concerns with these requirements (see 81 FR 57784 at 57787).

G.4. Q: What are some examples of relying on my customer or an entity in the distribution chain subsequent to my customer to ensure that the identified hazard will be adequately controlled?

A: Examples of relying on your customer to ensure control of an identified hazard would be (1) your customer significantly minimizes or prevents the hazards in imported spices that it obtains from you when your customer makes a soup product in accordance with the preventive controls requirements in part 117, and (2) your customer applies a kill-step to control the

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Salmonella in animal-derived protein ingredients such as meat meal or poultry meal used to make pet food. An example of relying on an entity in the distribution chain subsequent to your customer to control a hazard is when you import fresh vegetables, sell them to a distributor, and the distributor sells them to a soup manufacturer who controls the hazards in the vegetables when it manufactures the soup.

G.5. Q: What language must I use in my disclosure statement?

A: For biological hazards, if you specify the “identified hazard” using a general term (e.g., “microbial pathogens”) rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*), we will consider that to be in compliance with the disclosure requirement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food accompanied by such a disclosure statement is subject to the CGMP requirements, the preventive controls requirements for human or animal food, or both the CGMP and preventive controls requirements, that facility is responsible for taking appropriate steps to ensure that biological hazards applicable to the food are controlled before the food reaches the consumer.

For chemical and physical hazards, an importer that does not control chemical and physical hazards but instead relies on its customers to do so would be subject to the disclosure requirements in section 1.507. We expect such an importer to describe the identified chemical or physical hazard using a specific term (e.g., “mycotoxins,” “aflatoxin,” “stones”) that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring only to physical or chemical hazards without specificity would not provide a customer with sufficient information to address the hazard.

You should not use descriptive terms characterizing the food (such as “unpasteurized”) or specific cooking instructions (such as “must be cooked at 350 degrees for 30 minutes for food safety”) as the sole means of communicating that a food must be processed for safety without specifying in some way the identified hazard that is to be controlled. We would not consider use of such terms or instructions to be consistent with the disclosure statement requirement.

Note that we also address the disclosure statement requirements in 21 CFR 1.507 in our draft guidance for industry entitled “Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act” (see <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM526490.pdf>).

G.6 Q: What “documents accompanying the food, in accordance with the practice of the trade,” may I use to provide the disclosure statement?

A: The document that is appropriate for placement of the disclosure could vary depending on the particular food, the type of document used, and how likely it is for the staff who receive the food (or others who need to know that the food has not been processed to control an identified hazard) to see the statement. Examples of documents accompanying the food include labels, labeling, bills of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that the customer is likely to read. In addition, documents

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accompanying the food could include labels or labeling on bulk food that is in transit for further processing.

It would not be sufficient to reference a Web site in a document of the trade without including the disclosure statement in the document of the trade. However, you may use labeling that includes a disclosure statement such as “not processed to control microbial pathogens” and directs the recipient to a Web site for additional information about those microbial pathogens.

We do not recommend use of documents such as contractual agreements, letters of guarantee, specifications, and terms and conditions to communicate the information required in the disclosure statement. Such documents generally are not specific to a particular shipment and some of these documents may not be available to the customer’s food safety manager or other appropriate employees.

G.9 Q: May I establish a system (other than one using disclosures and customer assurances) that ensures control, at a subsequent distribution step, of the hazards in a food?

A: Yes. For a food you distribute, you may establish a system that ensures control of the hazards in the food at a subsequent distribution step. You must document your establishment and implementation of the system. For example, if you routinely import a food for which a hazard requiring a control has been identified and you always distribute the food to one or more manufacturers/processors with whom you have an established, documented relationship that ensures you and they are aware of their responsibility to control the hazard, your existing documentation that your customer is aware of the specific hazard and that your customer is controlling the hazard may be used in lieu of documents accompanying each shipment that state, “not processed to control [identified hazard]” (as required under 21 CFR 1.507(a)(2)-(4)).

H. What Corrective Actions Must I Take Under My FSVP? (21 CFR 1.508)

H.1 Q: When must I take corrective actions under my FSVP?

A: 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 FD&C Act (21 U.S.C. 350g or 350h), if either is applicable, and the implementing regulations, or
- Produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act (21 U.S.C. 342 and 343(w)). (Section 403(w), regarding misbranding due to failure to provide labeling for the presence of major food allergens, does not apply to animal food.)

H.2 Q: What sources of information can help me determine if I need to take corrective actions?

A: Your determination that you need to take corrective actions could be based on:

- The foreign supplier verification activities you conduct under 21 CFR 1.506 or 1.511(c).
- A reevaluation of the foreign supplier’s performance and the risks posed by the food that you conduct under 21 CFR 1.505(c) or (d).

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- Reviewing consumer, customer, or other complaints related to food safety.
- Monitoring FDA compliance action information (e.g., import alerts, warning letters).
- Any other relevant information you obtain (21 CFR 1.508(a)).

H.3 Q: What are examples of corrective actions that I may need to take?

A: The appropriate corrective actions will depend on the circumstances, but could include:

- Notifying the foreign supplier of the problem and requesting documentation of corrective actions taken by the foreign supplier.
- Assisting the foreign supplier's efforts to correct and prevent recurrence of the problem.
- Conducting (by yourself or with your foreign supplier) a recall of an adulterated or misbranded food.
- Revising your FSVP.
- Discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding are adequately addressed.

You must document any corrective actions you take (21 CFR 1.508(a)).

H.4 Q: Must I physically visit my foreign supplier to determine or assess the corrective actions that are conducted?

A: The FSVP regulation does not specifically require you to visit your foreign supplier's establishment as part of the corrective action that you conduct. In some cases, reviewing food safety records or conducting laboratory testing might be adequate. However, depending on the situation requiring corrective action and the risk from the food if the corrective actions are not adequate, you may determine that a visit to the foreign supplier's establishment is necessary for you to reliably determine the adequacy and implementation of the foreign supplier's corrective actions. Alternatively, you might want to obtain the results of an audit of the supplier to verify corrective actions.

H.5 Q: Will actions taken by my foreign supplier to be removed from an import alert be considered a sufficient corrective action for FSVP?

A: Actions taken by your foreign supplier to be removed from an import alert might be appropriate corrective actions to meet FSVP requirements (in section 1.508(a)) provided that those actions correct the underlying problem that precipitated the need for corrective actions under that provision. However, you may also need to consider additional corrective actions, such as revising your FSVP.

H.6 Q: Under what circumstances must I investigate to determine whether my FSVP is adequate?

A: If you determine, by means other than your supplier verification activities or a reevaluation of the food and foreign supplier that your foreign supplier does not produce food using processes or procedures that provide the same level of public health protection as those required under the preventive controls requirements in parts 117 or 507 or the produce safety regulation (if applicable), or produces food that is adulterated or misbranded with respect to allergen labeling, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP (21 CFR 1.508(b)). For example, you might initially discover through a customer complaint or a news report about a foodborne illness outbreak that your

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foreign supplier had manufactured and distributed a cheese product that was contaminated with *Listeria monocytogenes*. You would need to investigate to determine whether you should make any changes to your FSVP for the cheese from this foreign supplier, such as reevaluating your supplier or conducting different verification activities. You must document any investigations, corrective actions, and changes to your FSVP that you undertake (21 CFR 1.508(b)).

H.7 Q: Does taking corrective action under this section exempt me from having to comply with other regulatory requirements, such as product recall requirements?

A: No. Taking corrective action or conducting investigations in accordance with section 1.508 does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls in 21 CFR part 7, subpart C (21 CFR 1.508(c)).

I. How Must the FSVP Importer Be Identified at Entry? (21 CFR 1.509)

I.1 Q: How will the procedures for importing food change as a result of the FSVP regulation?

A: The FSVP regulation does not change the procedures for importing food into the United States. In particular, we will not seek to verify an importer's compliance with FSVP at the time food is offered for import into the United States. However, for each line entry of food product offered for importation into the United States, the FSVP importer must ensure that it is identified at entry with its name, email address, and unique facility identifier (UFI) recognized as acceptable by FDA (21 CFR 1.509(a)). Currently, the DUNS number, derived from Dun & Bradstreet's (D&B's) Data Universal Numbering System (DUNS), is the UFI that FDA recognizes as acceptable.

I.2 Q: What is a line entry of food product?

A: The term entry refers to the information or documentation that an "importer of record" (as defined by CBP) must file with CBP. A line entry of a food product offered for importation into the United States represents a portion of a shipment that is listed as a separate item on an import entry document. A line entry is sometimes referred to as an import line or a line of an entry. (Note that the FSVP regulation did not change the definition of a line entry for CBP purposes or the CBP requirement to split multiple types of products into separate lines.)

I.3 Q: Why is FSVP importer identification information required for each food offered for entry?

A: The FSVP importer of a food is responsible for meeting the FSVP requirements with respect to the importation of that food. Obtaining the importer's name, email address, and UFI will enable FDA to identify the responsible FSVP importer and effectively implement, monitor compliance with, and enforce the FSVP requirements.

I.4 Q: What is an acceptable UFI?

A: We currently recognize an FSVP importer's DUNS number as an acceptable UFI for identifying the importer at entry. For more information on acceptable UFIs, see the guidance for industry entitled "Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation" (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm>). If you are unable to provide a DUNS number to identify yourself at entry, you

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may contact FDA's Division of Import Operations at 1-301-796-0356 or via email at FDImportsInquiry@fda.hhs.gov.

I.5 Q: How may I obtain a DUNS number?

A: You may obtain a DUNS number by contacting D&B at 866-705-5711 or via email to govt@dnb.com (or visit D&B's Web site). You should be able to obtain your DUNS number free of charge (though for expedited service, charges may apply). Although a DUNS number may be obtained within a few business days, in some circumstances it could take up to 45 days or more.

I.6 Q: What if I have multiple DUNS numbers and multiple U.S. locations?

A: If you have multiple DUNS numbers and multiple U.S. locations, you might choose to provide the DUNS number that applies to the location at which you maintain your FSVP records, because FDA investigators will conduct records reviews at the location identified by your DUNS number. For example, if you maintain your FSVP records at your corporate headquarters, you might choose to provide the DUNS number for your headquarters when you identify yourself at entry as the FSVP importer. However, because the FSVP regulation permits you to store records offsite if they can be retrieved and provided to us within 24 hours of request (see 21 CFR 1.510(b)(2)), you may instead provide the DUNS number for another of your locations. For example, if a qualified individual who performs most or all of your FSVP activities works at one of your locations other than where you keep your records, you might choose to provide the DUNS number for your office in which the qualified individual is located.

I.7 Q: What email address should I provide at entry?

A: As the FSVP importer, you should provide the email address that will ensure that you receive FSVP-related communications from FDA.

I.8 Q: Why must I provide an email address?

A: FDA plans to use email addresses to facilitate communications between FDA and importers. We might use the email address to notify you that you have been identified as the FSVP importer and, if applicable, request confirmation that you have agreed, in writing, to serve as the FSVP importer (see Question I.9). We may also use your email address to communicate with you on issues relating to the food offered for importation, including information that may help facilitate our entry review of the food.

I.9 Q: What are the requirements when there is no U.S. owner or consignee at the time of entry?

A: If there is no U.S. owner or consignee of the food at the time of entry, the foreign owner or consignee must designate a U.S. agent or representative as the importer of the food responsible for compliance with the FSVP requirements (21 CFR 1.509(b)). The designated agent must be a person who resides in the United States or maintains a place of business in the United States. It would not be sufficient to merely have a mailbox, answering service, or some other place in the United States where the agent is not physically present. Note that in order to validly designate a U.S. agent or representative for the purpose of meeting the definition of FSVP importer, the U.S. agent or representative's role must be confirmed in a signed statement of consent to serve as the importer under the FSVP regulation. (We recommend that both the foreign owner or consignee

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and its U.S. agent or representative retain a copy of the statement of consent.) At any time, FDA may request to see the signed statement of consent.

I.10 Q: Who must provide the FSVP importer identification information to CBP?

A: As the FSVP importer, you are responsible for ensuring that the required information identifying you as the importer is provided to CBP for each line of an entry of imported food. If you do not provide the importer identification information to CBP, some other entity must do so. The “importer of record” (as defined by CBP for purposes of CBP requirements) typically provides required entry information to the filer/broker for submission to CBP. (Note that the FSVP importer may be, but is not required to be, the “importer of record” as defined by CBP.) If you are not involved in the entry process for food for which you are the FSVP importer, you should contact the person or entity from which you obtained the food to ensure that they provide your FSVP importer identification information to the filer/broker filing the entry submission for your food.

I.11 Q: How may I transmit the required importer identification information at entry?

A: We describe the process for providing information on importer identification in a guidance for industry entitled “Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Program Regulation” (<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>). Information in that guidance is set forth below because we intend to withdraw that guidance when it is no longer needed to assist importers during the phase-in of FSVP compliance dates.

When a food product under FDA oversight is offered for entry into the United States, the CBP Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:

- An entity role code “FSV,” which will send a signal to the ACE system indicating the entry line is subject to the FSVP regulation; or
- One of two Affirmation of Compliance codes indicating the article of food and importer are not subject to the FSVP regulation at the time of entry or FDA has provided guidance that the Agency intends to exercise enforcement discretion for the relevant shipment with respect to the FSVP regulation.

Transmission of entity role code “FSV” will trigger a request for the FSVP importer’s name, email address, and DUNS number as the UFI recognized as acceptable by FDA.

If the food entry line is (1) exempt from the requirements of the FSVP regulation, (2) not yet subject to the regulation based on the applicable compliance date, or (3) FDA has provided guidance that the Agency intends to exercise enforcement discretion for the relevant shipment with respect to the FSVP regulation, the filer should transmit the applicable Affirmation of Compliance code, either “FSV” or “RNE.” The “RNE” code should be used when designating that the food is exempt from the FSVP regulation in accordance with 21 CFR 1.501(c) because it will be used for research or evaluation. A filer is required to submit an “RNE” Affirmation of Compliance code for foods that are imported for research or evaluation because the final FSVP regulation specifically requires that a food be accompanied, when filing entry with CBP, by an electronic declaration that the food will be used for research or evaluation purposes and will not

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be sold or distributed to the public in order to qualify for this exemption (21 CFR 1.501(c)(4)). By selecting the “RNE” Affirmation of Compliance code, filers would be providing such a declaration.

If one of these codes is not transmitted for an imported food product under FDA oversight, the entry line will be rejected. Similar to all rejections in the ACE system, the rejection will generate an error message to the filer. Once an error message is received, the filer can make the appropriate adjustments to the entry submission and retransmit the entry line.

Although we expect all FSVP importers to provide their UFI starting on the applicable compliance date, we recognize that this is a new requirement and there may be factors that prevent importers from doing so. Therefore, for FSVP importers temporarily unable to obtain a DUNS number, we intend to allow filers to transmit the value “UNK” (to represent “unknown”) in the UFI field for the FSVP importer. This temporary allowance will permit articles of food offered for import into the United States to be processed through the ACE system even if an importer has not yet provided a DUNS number. We will communicate with importers when we intend to discontinue use of the “UNK” value.

During the time that FDA and CBP allow use of the “UNK” value for the UFI field, we intend to contact those FSVP importers for whom “UNK” was transmitted in place of the UFI. We will provide additional information to help ensure that FSVP importers understand this FSVP requirement and take the appropriate steps to obtain a UFI.

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

J.1 Q: What are the general requirements for maintaining FSVP records?

A: You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records to support your FSVP for each food from a particular foreign supplier (21 CFR 1.510(a)(1)). We recommend (but do not require) storing all your original records in an electronic format so that the records could be quickly retrieved and are easily searchable. For example, human and animal food labels can be saved into a PDF and submitted to FDA if we request to review your records (see Question J.5).

You must sign and date your FSVP records upon initial completion and upon any modification of the FSVP (21 CFR 1.510(a)(2)). For example, when you complete a hazard analysis, you must sign and date the analysis. If you modify the hazard analysis based on a reevaluation conducted in accordance with 21 CFR 1.505(c), you must sign and date the modified hazard analysis. Additional examples of FSVP records that must be signed and dated upon initial completion and any modification are records documenting the approval of foreign suppliers, determination of appropriate foreign supplier verification activities, and performance of supplier verification activities.

All required FSVP records must be legible and stored to prevent deterioration or loss (21 CFR 1.510(a)(3)).

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J.2 Q: May I use existing records that provide information required for FSVP?

A: If you have records that you maintain to comply with other Federal, State, or local government regulations or for your own business purposes, you do not need to duplicate those records to meet FSVP requirements if the records contain all of the information required for FSVP. If your existing records contain some, but not all, of the information required for FSVP, you may supplement your existing records as necessary to include all of the information required for FSVP (21 CFR 1.510(e)(1)). For example, if you maintain business records documenting that you addressed a food safety problem with a foreign supplier, you may use them to help demonstrate that you took corrective actions in accordance with 21 CFR 1.508.

You also are not required to maintain FSVP information in one set of records. For example, you may keep your tax records at a corporate headquarters and keep records of corrective actions at a local office. However, you must make all necessary records promptly available to an FDA representative, upon request, for inspection and copying (21 CFR 1.510(b)(1)) (see Question J.5).

J.3 Q: How long must I retain my FSVP records?

A: You must retain required FSVP records for a period of at least 2 years after you created or obtained the records (with certain exceptions discussed below) (21 CFR 1.510(c)(1)). For example, if you take a corrective action after determining that a food you import was adulterated (e.g., you work with the foreign supplier to ensure that the problem is corrected before you import additional shipments of the food), you must retain documentation of the corrective action you took for at least 2 years.

You must retain records relating to your FSVP processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after you discontinue using the process or procedure (21 CFR 1.510(c)(2)). We would consider a process or procedure discontinued if, among other things, you no longer import a particular food, you no longer obtain food from a particular foreign supplier, you reevaluated the foreign supplier's performance and the risks associated with a food, or you changed your supplier verification activities for a particular food and supplier. For example:

- If you rely on the results of a particular onsite audit of your foreign supplier for 2 years (e.g., when the hazard for a food is not a SAHCODHA hazard), you must retain documentation of the audit results for at least 2 years after you no longer rely on those results in meeting your verification activity requirements.
- If you import produce, but stop importing all tomatoes, you must retain your FSVP records relating to tomatoes for 2 years after you stop importing them.
- If you change your foreign supplier of tomatoes from Farm X to Farm Y, you must retain your records specific to Farm X for 2 years after you stop using Farm X as your supplier.
- If you become aware of new information about your supplier that causes you to reevaluate the risk posed by a food and the foreign supplier's performance, you must retain the previous food and supplier evaluation for 2 years after you perform the reevaluation.
- If your reevaluation of foreign supplier performance causes you to change your supplier verification activities from annually reviewing the supplier's food safety records to annually conducting an onsite audit of the supplier, you must retain records of your previous determination of appropriate supplier verification activities (i.e., review of your supplier's

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food safety records) for 2 years after you determined that a different supplier verification activity (i.e., annual onsite audit) is appropriate.

J.4 Q: Must I store my FSVP records at my place of business?

A: You are not required to store FSVP records onsite at your place of business, provided that you can retrieve the records and provide them to FDA within 24 hours of our request for official review (21 CFR 1.510(b)(2)). We recognize that some importers, particularly those that import food into the United States through multiple ports, may prefer to develop and maintain FSVP records at a single location, such as a corporate headquarters. We also recognize that some FSVP records may be maintained by other entities in your supply chain. Storing records at corporate headquarters or at multiple locations is acceptable provided you can meet the requirement to make FSVP records available to FDA within 24 hours.

J.5 Q: When must I make my FSVP records available to FDA?

A: When requested, you must make all required FSVP records available promptly to an authorized FDA representative for inspection and copying (21 CFR 1.510(b)(1)). When an FDA representative makes this request at your place of business, we expect you to provide the requested onsite records while FDA is at your place of business. We consider electronic records to be available onsite if they are accessible from your onsite location. You must provide records stored offsite within 24 hours of FDA's request for the records (21 CFR 1.510(b)(2)).

If requested in writing by FDA, you must send your FSVP records to the Agency electronically, or by another means that delivers the records promptly, rather than making the records available for review at your place of business (21 CFR 1.510(b)(3)). We will generally expect you to deliver the FSVP records within 72 hours. If there are circumstances that will cause you to need additional time, you should contact us to discuss an appropriate timeframe for delivery.

We might request that you submit some or (less likely) all of your FSVP records. For example, we might request that you send us all of your records for one or more FSVPs for particular foods and their foreign suppliers, or we might request records of significant portions of one or more FSVPs, such as records relating to hazard analysis, determination of appropriate supplier verification activities, or corrective actions. If sending records electronically, you may send an email with attached PDF files through the FDA Unified Registration and Listing System (FURLS) portal system available on FDA's Web site. To use this portal, you will need to have an active account and password in FURLS or create an account in the Online Account Administration (OAA) system. During the OAA account creation process, users can select which FURLS systems they will need to access. After you create your account and log onto OAA, you can view your account profile information and all the FURLS systems you have access to from the Account Management page. If you already have a FURLS account, to use it to submit FSVP records you will need to log into your account and check the FSVP box. For additional information and to create a FURLS account, go to the FDA industry Systems Main page at <http://www.access.fda.gov>. Online help instructions are available at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm114181.htm>.

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As an alternative to use of the FURLS portal, you might submit paper copies of records to the Agency using the U.S. Postal Service or commercial delivery providers such as FedEx or UPS/DHL global mail.

J.6 Q: Do I need to maintain my records in English?

A: You do not need to maintain your FSVP records in English. However, if you maintain records in a language other than English, you must, upon FDA request, provide an English translation of the records within a reasonable time (21 CFR 1.510(b)(1)). What constitutes a “reasonable time” will vary depending on factors such as the number, length, and complexity of the records requested. For example, if we request your FSVP for one food you import, you should be able to provide an English translation of those records in less time than if we request your FSVP records for ten foods you import. We suggest you discuss with us the amount of time you need to obtain an English translation of the requested records when the situation arises.

J.7 Q: What requirements apply to my FSVP records maintained in electronic form?

A: An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system (21 CFR 11.3(b)(6)). Records that you establish or maintain to satisfy FSVP requirements and that meet this definition are exempt from the requirements for electronic records and signatures in 21 CFR part 11 (21 CFR 1.510(d)). This exemption does not apply to electronic records that satisfy FSVP requirements but are also required under other applicable statutory provisions or regulations.

J.8 Q: Will FDA release my FSVP records to the public?

A: All FSVP records that we obtain will be subject to the disclosure requirements in 21 CFR part 20 (21 CFR 1.510(f)). We expect that many FSVP records we obtain will contain confidential commercial information and trade secrets that will be exempt from public disclosure in accordance with 21 CFR part 20. We will keep such information confidential.

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

K.1 Q: Why are there modified FSVP requirements for foods that are subject to certain provisions of the dietary supplement CGMP regulation?

A: The modified provisions reflect the dietary supplement CGMP regulation in 21 CFR part 111. In addition, the CGMP regulation already requires appropriate supplier “verification” tailored to dietary supplements in certain circumstances. Specifically, the dietary supplement CGMP regulation requires a dietary supplement manufacturer to establish specifications for each component used in the manufacturing of a dietary supplement so that they are identified properly, have the appropriate purity, strength, and composition, and do not contain contaminants that adulterate or can lead to adulteration of the dietary supplement (see 21 CFR 111.70(b)). Also, a dietary supplement manufacturer is required to establish specifications for dietary supplement labels and for packaging that comes into contact with dietary supplements; packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of

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the dietary supplements (21 CFR 111.70(d)). Under 21 CFR 111.73, a dietary supplement manufacturer must determine whether these (and other) specifications are met; 21 CFR 111.75 describes the steps that manufacturers must take to determine whether the specifications are met. We believe that compliance by the importer (or its customer) with these specification and verification provisions in the dietary supplement CGMP regulation provides adequate assurances that the foreign supplier of the dietary supplement or dietary supplement component produced it in compliance with the FD&C Act. Therefore, imposing additional supplier verification requirements under the FSVP regulation in these circumstances would be redundant and unnecessary.

K.2 Q: What is a dietary supplement?

A: As defined in section 201(ff) of the FD&C Act, the term “dietary supplement”

1. means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- a. a vitamin;
- b. a mineral;
- c. an herb or other botanical;
- d. an amino acid;
- e. a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- f. a concentrate, metabolite, constituent, extract, or combination of any ingredient that is a vitamin, a mineral, an herb or other botanical, an amino acid a dietary substance for use by man to supplement the diet by increasing the total dietary intake;

2. means a product that:

- a. is intended for ingestion in a form described in section 411(c)(1)(B)(i) of the FD&C Act; or complies with section 411(c)(1)(B)(ii) of the FD&C Act;
- b. is not represented for use as a conventional food or as a sole item of a meal or the diet; and
- c. is labeled as a dietary supplement; and

3. does

(A) include an article that is approved as a new drug under section 505 of the FD&C Act or licensed as a biologic under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f) of the FD&C Act; and

(B) not include—

(i) an article that is approved as a new drug under section 505 of the FD&C Act, certified as an antibiotic under section 507 of the FD&C Act, or licensed as a biologic under section 351 of the PHS Act, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food

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unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act.

K.3 Q: What is a dietary supplement component?

A: A dietary supplement component is any substance that is intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished product (see 21 CFR 111.3). Dietary supplement components may include both dietary ingredients and other ingredients.

K.4 Q: Are products that would be dietary supplements if marketed for humans subject to the modified FSVP requirements for dietary supplements when the products are intended for use for animals?

A: No. Products for animals are not considered "dietary supplements" (as that term is defined in section 201(ff) of the FD&C Act). Consequently, products for animals are not subject to the modified provisions for dietary supplements and dietary supplement components in section 1.511 of the FSVP regulation but instead are subject to the standard FSVP requirements.

K.5 Q: When am I eligible for the modified FSVP requirements regarding specifications for dietary supplement components and labels and/or packaging?

A: Certain modified FSVP requirements, stated in section 1.511(a) and (b), apply to you if you or your customer (i.e., an entity that manufactures, processes, or packages a dietary supplement or dietary supplement component you import) is subject to and in compliance with the following dietary supplement CGMP requirements:

- For components (including dietary ingredients) that are used in the manufacture of a dietary supplement, you or your customer must establish an identity specification and specifications to ensure the purity, strength and composition of dietary supplements manufactured using the component, and establish limits on the types of contamination that could result in adulteration of the finished batch of the dietary supplement (21 CFR 111.70(b)).
- For labels and/or for packaging that may come into contact with dietary supplements, you or your customer must establish specifications for the labels and packaging; packaging that may contact dietary supplements must be safe and suitable for its intended use and must not affect the safety or quality of the dietary supplement (21 CFR 111.70(d)).

In addition to establishing specifications under section 111.70(b) or (d), to be eligible for the modified FSVP requirements, you or your customer must determine that the established component, label, and/or packaging specifications have been met in accordance with 21 CFR 111.73 and 111.75.

K.6 Q: What FSVP requirements apply if I am an importer subject to and in compliance with the specified dietary supplement CGMP provisions requiring that I establish certain specifications and verify they are met?

A: If you establish specifications for a dietary supplement or dietary supplement component under section 111.70(b) or (d) and ensure that they are met in accordance with sections 111.73 and 111.75, the FSVP requirements that apply to you are as follows:

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- Identify yourself at entry as the importer of the food (21 CFR 1.509); and
- Use a qualified individual (to ensure identification at entry) (21 CFR 1.503).

K.7 Q: What FSVP requirements apply to me if my customer is subject to and in compliance with the specified dietary supplement CGMP provisions requiring that I establish certain specifications and verify they are met?

A: If your customer establishes specifications for a dietary supplement or dietary supplement component under section 111.70(b) or (d) and ensures that they are met in accordance with sections 111.73 and 111.75, the FSVP requirements that apply to you are as follows:

- Annually obtain from the customer written assurance that it is in compliance with the applicable CGMP requirements (21 CFR 1.511(b));
- Use a qualified individual (21 CFR 1.503);
- Identify yourself as the importer of the food at entry (21 CFR 1.509); and
- Maintain applicable FSVP records (i.e., written customer assurances) (21 CFR 1.510).

K.8 Q: What is acceptable “written assurance” that my customer is in compliance with the above-discussed CGMP specification requirements for a dietary supplement or dietary supplement component I import?

A: Examples of acceptable “written assurance” include a letter on your customer’s company letterhead or a report of an audit of the customer. The letter, report, or other form of annual written assurance from your customer should:

- Identify the customer and the dietary supplement or dietary supplement component you import;
- State whether specifications under 21 CFR 111.70(b) or (d) are required to be established for the food; and
- Provide a statement or information to assure that the customer is in compliance with the requirements of 21 CFR 111.73 and 111.75 applicable to determining whether those specifications are met.

K.9 Q: What FSVP requirements apply under section 1.511(c) if I am importing a dietary supplement other than in accordance with section 1.511(a) or (b)?

A: If you import a dietary supplement and neither section 1.511(a) nor (b) applies (e.g., you import a finished dietary supplement), you must comply with the FSVP requirements relating to:

- Use of a qualified individual to develop the FSVP and perform each required FSVP activity (21 CFR 1.503);
- Conducting an evaluation for foreign supplier approval and verification (21 CFR 1.505(a)(1)(ii) through (a)(1)(iv), (a)(2), and (b) through (d));
- Use of approved foreign suppliers (21 CFR 1.511(c)(2));
- Foreign supplier verification procedures (21 CFR 1.511(c)(3));
- Determination of appropriate foreign supplier verification activities (21 CFR 1.511(c)(4));
- Performance of foreign supplier verification activities (21 CFR 1.511(c)(5));
- Taking corrective actions (21 CFR 1.508);
- Identifying the importer of the food at entry (21 CFR 1.509); and
- Maintaining applicable FSVP records (21 CFR 1.510).

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These requirements, set forth in section 1.511(c), apply to importers of dietary supplements (not dietary supplement components). The dietary supplements included under this provision include finished dietary supplements (i.e., dietary supplements ready for retail sale without any additional manufacturing, processing, or labeling) and dietary supplements imported for labeling and/or packaging other than in accordance with sections 111.70(d), 111.73, and 111.75 (for example, when labeling and packaging of the imported dietary supplement are performed by an entity subsequent to the importer's customer in U.S. distribution).

K.10 Q: What evaluation for foreign supplier approval and verification must I conduct?

A. When approving a foreign supplier of a dietary supplement and determining the appropriate supplier verification activities, you must, under 21 CFR 1.505(a)(1)(ii) through (a)(1)(iv), evaluate the following:

- The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.
- Foreign supplier performance, including:
 - The foreign supplier's procedures, processes, and practices related to the safety of the food;
 - Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (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, and information relevant to the supplier's compliance with those laws and regulations);
 - The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

For guidance on how to evaluate these factors, see Questions E.3 through E.7.

You must document the evaluation you conduct under section 1.505.

Your approval of a foreign supplier must be based on the evaluation you conduct under section 1.505 (21 CFR 1.505(b)). For guidance on approval of suppliers, see Question E.8.

You must promptly reevaluate the concerns associated with foreign supplier performance and the other factors specified in section 1.505(a)(1)(ii)-(iv) when you become aware of new information about the factors (21 CFR 1.505(c)(1)). For guidance on reevaluation of foreign suppliers, see Question E.10.

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If another entity (other than your foreign supplier) has, using a qualified individual, performed the supplier evaluation or reevaluation of discussed above, you may meet the requirements for conducting the evaluation or reevaluation by reviewing and assessing the evaluation or reevaluation conducted by that entity (21 CFR 1.505(d)). For guidance on review and assessment of another entity's evaluation or reevaluation of your dietary supplement supplier, see Question E.11.

K.11 Q: What must I do to ensure that I am receiving dietary supplements from foreign suppliers that I have approved?

A: You must establish and follow written procedures to ensure that you import dietary supplements only from foreign suppliers you have approved based on the evaluation conducted under section 1.505(a)(1)(ii)-(a)(1)(iv) and document your use of these procedures (21 CFR 1.511(c)(2)(i)). For guidance on meeting these requirements, see Questions F.2 and F.3.

K.12 Q: Under what circumstances may I import dietary supplements from a foreign supplier that I have not approved?

A: In certain circumstances you may import dietary supplements from an unapproved foreign supplier on a temporary basis as long as you subject the dietary supplements to adequate verification activities (21 CFR 1.511(c)(2)(i)). For example, unexpected circumstances may arise that make it impossible for you to obtain a particular food from an approved supplier. For guidance on importing food from unapproved suppliers, see Question F.4.

K.13 Q: May I rely on someone else to establish and implement procedures to ensure that I am importing dietary supplements from approved foreign suppliers?

A: Yes, provided you review and assess the procedures and documentation of use of the procedures. Under section 1.511(c)(2)(ii), you may rely on an entity other than your foreign supplier to establish the procedures to ensure that you receive food from approved suppliers as well as to implement and document use of these procedures, as long as you review and assess that entity's documentation of the procedures and activities and you document your review and assessment.

K.14 Q: What written procedures must I have for conducting foreign supplier verification activities?

A: You must establish and follow written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the dietary supplements you import (21 CFR 1.511(c)(3)). You should adopt general procedures establishing the approach you will take to determine the appropriate foreign supplier verification activities. Your procedures should address how you will consider and evaluate whether the dietary supplement was produced under conditions that provide the same level of public health protection as compliance with the dietary supplement CGMP regulation, the entities that manufacture or verify manufacturing conditions of the dietary supplement, and the factors related to the performance of the foreign supplier in deciding what verification activity or activities are appropriate and the frequency with which the activities will be conducted.

Your procedures might address, among other things, the following:

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- General principles about supplier verification activities that are appropriate for certain dietary supplements. For example, you may explain your basis for the frequency of onsite auditing or sampling and testing you will conduct as part of your supplier verification activities, or the types of food safety records you will review for supplier verification.
- Aspects of the supplier’s performance (including its procedures, processes, and practices and its compliance history (e.g., record of compliance with dietary supplement regulations; record of response to safety problems in the product it supplies)) that may affect your determination of appropriate verification activities and frequency of performance.
- Circumstances under which verification activities other than or in addition to annual onsite auditing might be appropriate when there is a SAHCODHA hazard in a dietary supplement.

K.15 Q: What requirements apply to determining appropriate foreign supplier verification activities relating to a dietary supplement that I import under section 1.511(c)?

A: For each dietary supplement you import under section 1.511(c), before importing the finished dietary supplement, you must determine and document which foreign supplier verification activities are appropriate. The verification activities must provide adequate assurance that the foreign supplier is using manufacturing processes and procedures that provide the same level of public health protection as those required under the dietary supplement CGMP regulation. You must also determine and document the frequency with which the verification activity or activities must be conducted. You must base your determination of verification activities on the evaluation for foreign supplier approval and verification that you conduct. You must retain documentation of the verification activities (21 CFR 1.511(c)(4)(i)).

K.16 Q: How do I determine whether my potential foreign supplier of a dietary supplement uses processes and procedures that provide the “same level of public health protection” as those required under the dietary supplement CGMP regulation?

A: If you are considering using a foreign supplier of a dietary supplement that uses a process or procedure that varies in some way from the processes and procedures required under the dietary supplement CGMP regulation, you will need to determine whether the potential supplier’s process or procedure provides at least the same level of public health protection as those required under that regulation. Because processes and procedures that provide the same level of protection might vary under different circumstances, you should make this determination on a case-by-case basis.

In general, to approve a foreign supplier who uses a process or procedure that differs from those required under the dietary supplement CGMP regulation, you should be able to show that the different method or approach that the foreign supplier uses adequately addresses the food safety concern that the relevant CGMP requirement is intended to address. For example, your foreign supplier might establish a master manufacturing record (MMR) for each formulation of a dietary supplement but not each batch size (as required under 21 CFR 111.205(a) and 111.210) due to seasonal variations in the plant material used as a dietary ingredient in the dietary supplement. However, you might nevertheless conclude that the supplier’s procedures and practices provide the same level of public protection as having MMRs for each batch size, provided that:

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- The foreign supplier's MMR for each formulation includes calculations for relative amounts of the other components of the dietary supplement based on the amount of constituent in the plant material used;
- The MMRs ensure uniformity in finished batches of the dietary supplement from batch to batch in accordance with 21 CFR 111.205(a); and
- The foreign supplier meets requirements for verifying that the finished batches of dietary supplements meet product specifications for identity, purity, strength, composition, and limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch.

You should have adequate scientific data or other information to enable you to conclude that your supplier's use of an alternative process or procedure provides the same level of public health protection as a dietary supplement CGMP requirement is intended to address. You can rely on your own scientific data or on data or other information available in scientific literature or developed by third parties, such as industry or trade associations or pharmacopeial or compendial organizations. (When relying on scientific literature, it is not necessary that the information be published in a peer-reviewed journal, although we encourage the use of peer-reviewed data and information to the extent it is available.) Any scientific analysis on which you rely should take into account (where appropriate) such factors as study design, sample size, weight of evidence (e.g., statistical significance), risk assessment methodology (if conducted), and range of relevant variables (e.g., animal species in which research was conducted). The conclusions on which you rely should be based on consideration of all available relevant data rather than a limited dataset selected to favor a desired outcome. In addition, any persons on whom you rely to make determinations about the same level of public health protection should have the appropriate education, training, or experience (or a combination of those characteristics) to make such decisions.

As we stated in the preamble to the FSVP final rule, you are not required to document each process or procedure of your foreign supplier that varies from those required under the dietary supplement CGMP regulation but that, in your determination, provides the same level of public health protection. However, when your supplier's use of such a process or procedure is relevant to your evaluation of the supplier's performance or the performance of supplier verification activities, you would need to include information about the supplier's alternative processes and procedures in your documentation of these FSVP requirements. We believe that a supplier's use of a process or procedure that differs from those required under the dietary supplement CGMP regulation generally would be relevant to an importer's decision to approve the supplier and to the importer's determination of appropriate supplier verification activities. As an example, alternative procedures we consider relevant to an importer's supplier evaluation and verification activities are alternative procedures that relate to ensuring the quality of the dietary supplement and procedures for ensuring the dietary supplement is packaged and labeled consistent with the master manufacturing record.

K.16 Q: What foreign supplier verification activities must I conduct if I import a dietary supplement under section 1.511(c)?

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A: If you import a dietary supplement under section 1.511(c), you must conduct one or more of the following verification activities:

- Periodic onsite auditing or documentation of an appropriate inspection.
- Sampling and testing the food.
- Review of the foreign supplier's relevant food safety records.
- Other foreign supplier verification activities procedure that you have established as being appropriate (21 CFR 1.511(c)(4)(ii)).

K.17 Q: When might onsite auditing of my foreign supplier of a dietary supplement be an appropriate verification activity?

A. Onsite auditing of your foreign supplier of a dietary supplement is always an appropriate verification activity. We recommend that you conduct or obtain the results of an onsite audit of a foreign supplier of a dietary supplement if you are working with a new supplier or if the dietary supplement has a SAHCODHA hazard (e.g., due to potential for microbial contamination, susceptibility to being adulterated with undeclared hazardous ingredients). We believe annual auditing generally provides the best verification that your supplier uses processes and procedures that provide the same level of public health protection as compliance with the dietary supplement CGMP regulation. Less frequent auditing may be appropriate in cases when your supplier has demonstrated a good compliance history and you have documented that history. In such cases, less frequent audits could also be supplemented with sampling and testing or records review in between periodic onsite audits. In addition, there may be circumstances in which you determine (and document) that you are able to provide adequate assurance that your supplier's processes and procedures provide the same level of public health protection as compliance with the dietary supplement CGMP regulation by conducting verification activities other than onsite auditing.

K.18 Q: What requirements apply if I choose to verify my foreign supplier through onsite auditing?

A: If you choose to verify your supplier through onsite auditing of the supplier, the following requirements apply:

- You must use a qualified auditor (21 CFR 1.511(c)(5)(A)(1)).
- The onsite audit must consider the applicable requirements of the dietary supplement CGMP regulation. Alternatively, when applicable, an onsite audit may consider 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 1.511(c)(5)(i)(A)(2)).
- You must retain documentation of each onsite audit, including audit procedures, audit dates, audit conclusions, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor (21 CFR 1.511(c)(5)(i)(A)(4)).

K.19 Q: Can I substitute inspection results for the results of an onsite audit of my supplier?

A: Yes, in certain circumstances. Instead of an onsite audit, you may rely on the following inspection results (provided the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted):

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- The written results of an appropriate inspection of the foreign supplier for compliance with the applicable dietary supplement CGMP provisions. The inspection may be conducted by FDA, representatives of other federal agencies (such as the USDA), or representatives of State, local, tribal or territorial agencies (21 CFR 1.511(c)(5)(A)(5)(i)) that are inspecting for compliance with the applicable dietary supplement CGMP provisions; or
- The written results of an inspection by 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 the dietary supplements are within the scope of official recognition or equivalence determination, and the foreign supplier is in and under the regulatory oversight of the country with the officially recognized or equivalent system (21 CFR 1.511(c)(5)(A)(5)(ii)).

K.20 Q: When might sampling and testing of a dietary supplement I import be an appropriate foreign supplier verification activity?

A: Periodic or lot-by-lot sampling and testing generally is not likely to be adequate, on its own, to verify that a foreign supplier's processes and procedures provide the same level of public health protection as compliance with the applicable dietary supplement CGMP provisions. Compliance with the dietary supplement CGMP regulation requires production and process controls to ensure that products are processed in a consistent manner and meet quality standards. Therefore, testing the finished product does not necessarily demonstrate that the supplier established and followed appropriate procedures for raw materials, in-process steps, and finished products through the manufacturing process. However, you might use sampling and testing of a dietary supplement to verify that the results of the most recent onsite audit of your supplier appear to provide adequate assurances, or you might combine sampling and testing with periodic review of your supplier's food safety records (see Question K.22) to verify that your supplier is producing the dietary supplement consistent with the CGMP requirements. For example, sampling and testing the dietary supplement to verify that the foreign supplier's finished product specifications for identity, purity, strength, composition, and limits on contaminants have been met could indicate if there was a problem with the foreign supplier's manufacturing processes.

K.21 Q: If my foreign supplier verification activities include periodic or lot-by-lot sampling and testing of a dietary supplement, what tests should I perform?

A: Periodic or lot-by-lot testing of a dietary supplement should provide adequate assurances that the supplier produced the dietary supplement consistent with the applicable requirements of the dietary supplement CGMP regulation. For example, you might test the finished dietary supplement to make sure it meets the foreign supplier's specifications for identity, purity, strength, composition, and limits on contaminants.

Documentation of sampling and testing must include identification of the dietary supplement tested (including lot number, as appropriate), the number of samples tested, the tests conducted (including analytical methods used), the dates on which the tests were conducted and the date of the report of the testing, the results of testing, any corrective actions taken in response to the detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual (21 CFR 1.511(c)(5)(i)(B)).

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K.22 Q: When might review of a dietary supplement manufacturer's food safety records be an appropriate foreign supplier verification activity?

A: Review of a dietary supplement manufacturer's food safety records may be adequate to verify that a foreign supplier is operating in compliance with the applicable dietary supplement CGMP provisions if the records review is sufficiently comprehensive and/or it augments a recent and well-documented history of compliance. In order for a review of a dietary supplement manufacturer's food safety records to be an appropriate foreign supplier verification activity, the records would need to provide documentation of the production and process controls needed to provide the same level of public health protection as compliance with the CGMP requirements. It might be possible in some situations for you to rely solely on periodic review of your foreign supplier's food safety records to verify that the supplier's production and process controls are consistent with the CGMP regulation. For example, this might be possible when you are able to review all relevant records. You might also be able to rely solely on a records review when your dietary supplement supplier has recently been inspected by a competent authority and that inspection showed a high level of compliance. In other situations it might be appropriate to combine review of your supplier's food safety records with periodic sampling and testing or onsite auditing to ensure adequate verification of your supplier. For example, sampling and testing might be needed to complement your review of the supplier's records if your imported dietary supplement contains ingredients susceptible to unintentional adulteration due to misidentified components.

K.23 Q: If my foreign supplier verification activities of a dietary supplement supplier include periodic review of the foreign supplier's food safety records, what records should I review and what documentation of my review must I maintain?

A: You should review records relating to whether your foreign supplier uses processes and procedures that provide the same level of public health protection as compliance with the dietary supplement CGMP regulation. Appropriate records should include batch production records for the identified products and relevant documents related to the batch production records (which include, among other things, finished product specifications and testing results, as well as manufacturing records), component testing results, records of quality control reviews, and other records the supplier used to conduct a material review and make a disposition decision regarding the dietary supplement.

Documentation of a review of a supplier's food safety records must include the dates of the review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified, and documentation that the review was conducted by a qualified individual (21 CFR 1.511(c)(5)(i)(C)).

K.24 Q: Can I rely on supplier verification activities of my dietary supplement supplier conducted by other entities?

A: Yes. You may rely on verification activities by other entities provided you review and assess the results of those activities (21 CFR 1.511(c)(5)(ii)(A)). However, you may not rely on the foreign supplier or its employees to conduct supplier verification activities, except for sampling and testing of food produced by the supplier (21 CFR 1.511(c)(5)(ii)(B)). For example, if you import dietary supplements from a foreign distributor who has obtained an audit report of the

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foreign manufacturer, you may obtain, review, and assess a copy of the audit report to determine if the manufacturer uses processes and procedures that provide the same level of public health protection as compliance with the dietary supplement CGMP regulation. Similarly, you may rely on the results of third-party laboratory analyses provided by your supplier as long as you obtain, review, and assess the results of the testing.

K.25 Q: What must I do with the results of supplier verification activities of my dietary supplement supplier?

A: You must promptly review and assess the results of supplier verification activities you conduct (or for which you obtain documentation) or that are conducted by others, and document your review and assessment (21 CFR 1.511(c)(5)(iii)). If the results show that the foreign supplier is not using processes and procedures that provide the same level of public health protection as compliance with the dietary supplement CGMP regulation, you must take appropriate corrective action in accordance with section 1.508(a). For example, if you discover that you have imported from your supplier a vitamin supplement that is contaminated with *Salmonella*, your corrective actions might include working with your supplier to identify how *Salmonella* got into the product, determining whether failure to comply with CGMP provisions was a reason for the problem, and reviewing the corrective actions the supplier implemented to prevent this from happening again. If a recall of the vitamin supplement was needed, you might assist in the recall effort. If your foreign supplier's non-compliance with CGMP requirements resulted in production of an adulterated vitamin supplement that caused a *Salmonella* outbreak, it may be appropriate to consider temporarily or permanently discontinuing use of the supplier. You are not required to retain (at your place of business) documentation of verification activities conducted by others as long as you can obtain the documentation and make it available to the Agency within 24 hours (21 CFR 1.511(c)(5)(iii)).

K.26 Q: What conflict of interest requirements apply to qualified individuals who conduct supplier verification activities of my dietary supplement supplier?

A: The person conducting a supplier verification activity cannot have a financial interest in the foreign supplier that influences the result of the verification activity and payment cannot be related to the results of the activity (21 CFR 1.511(c)(5)(iv)). Any employees of the foreign supplier would be prohibited from conducting supplier verification activities under the preceding restriction. These requirements do not prohibit the importer or one of the importer's employees from conducting the verification activity. For additional guidance on meeting conflict of interest requirements, see Question F.29.

K.27 Q: What if I import dietary supplements and I meet the eligibility criteria to be a very small importer?

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

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

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L.1 Q: When might I be eligible for the FSVP requirements applicable to a very small importer or to an importer who is obtaining certain food from a certain small foreign supplier?

A: The FSVP requirements applicable to a very small importer or to an importer obtaining certain food from a certain small foreign supplier may apply to you if:

1. You are a very small importer (see Question L.2);
2. You are importing certain food from a certain small foreign supplier, as follows:
 - a. The foreign supplier is a qualified facility as defined in the preventive controls regulations (see Question L.3);
 - b. You are importing produce from a foreign supplier that is a farm that grows produce and is not a “covered farm” under the produce safety regulation in accordance with 21 CFR 112.4(a) or in accordance with 21 CFR 112.4(b) and 112.5 (see Question L.4); or
 - c. You are importing shell eggs from a foreign supplier that is not subject to the requirements of the shell eggs regulation because it has fewer than 3,000 laying hens (a shell egg producer with fewer than 3,000 laying hens is not subject to the requirements for the production, storage, and transportation of shell eggs in 21 CFR part 118 (see 21 CFR 118.1)).

[21 CFR 1.512(a)]

L.2 Q: Who is a very small importer?

A: A very small importer is:

- 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) (21 CFR 1.500).
- 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) (21 CFR 1.500).

Regardless of whether you import human food, animal food, or both, you must consider all your food sales, not just sales of the food you import and not just sales to the United States. Also, some importers, such as certain warehouses and repacking facilities, do not sell the food they import but instead perform certain services regarding the food (e.g., storage, contract processing, contract packaging) in exchange for fees. Therefore, in determining whether you meet the definition of a very small importer, you must consider your sales of food as well as the value of the food that you manufacture, process, pack, or hold without sale (e.g., for a fee). In accounting for the food that you manufacture, process, pack, or hold without sale (e.g., for a fee), use the value of the food, not the fee for the service. You can determine this value by considering factors such as the following: (1) the cost of incoming food; (2) the amount of insurance that a warehouse holds for its products; (3) the value obtained by multiplying market price by volume of food manufactured, processed, packed, or held; and (4) assets on a balance sheet.

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For more information on methods and procedures that might be helpful in determining your potential status as a very small importer, see FDA’s draft guidance “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)” (see

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM499509.pdf>).

L.3 Q: When is a foreign supplier considered to be a qualified facility?

A: “Qualified facility” is defined in the preventive controls regulations for human food and for animal food (21 CFR 117.3 and 507.3, respectively). A qualified facility is a facility that is a “very small business” (as defined in 21 CFR 117.3 and 507.3) *or* a facility to which both of the following apply:

- During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility 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.

For human food, a “very small business” is a business (including any subsidiaries and affiliates) averaging less than \$1,000,000 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 manufactured, processed, packed, or held without sale (e.g., held for a fee) (21 CFR 117.3). For animal food, a very small business is a business (including any subsidiaries and affiliates) averaging less than \$2,500,000 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 manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale) (21 CFR 507.3).

L.4 Q: What is a “covered farm” and what farms that are not covered farms are included among the small foreign suppliers whose food is subject to the modified FSVP requirements?

A: A “covered farm” is a farm this is subject to the produce safety regulation. Certain farms that are not covered farms are considered small foreign suppliers whose food is subject to the modified FSVP requirements under section 1.512. These are:

- Farms that have an average annual monetary value of \$25,000 (on a rolling basis) or less of produce (as “produce” is defined in 21 CFR 112.3(c)), adjusted for inflation using 2011 as the baseline year for calculating the adjustment (see 21 CFR 112.4(a)); and
- Farms that are eligible for a qualified exemption from the produce safety regulation and FDA has not withdrawn the farm’s exemption (see 21 CFR 112.4(b) and 112.5). Under 21 CFR 112(b), a farm is not a covered farm if it satisfies the requirements for a qualified exemption in 21 CFR 112.5 and the Agency has not withdrawn the farm’s exemption. Under 21 CFR 112.5(a), a farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:
 - During the previous 3-year period preceding the applicable calendar year, the average monetary value of the food (as defined in 21 CFR 112.3(c)) the farm sold

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directly to qualified end-users (as defined in 21 CFR 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

- The average annual monetary value of all food (as defined in 21 CFR 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

For the purpose of determining whether 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, the baseline year for calculating the adjustment for inflation is 2011 (21 CFR 112.5(b)).

L.5 Q: What documentation of eligibility requirements apply if I am a very small importer?

A: If you are a very small importer and you choose to comply with the requirements for very small importers, you must document that you meet the definition of very small importer with respect to human food or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year (21 CFR 1.512(b)(1)(i)(A)). If you did not meet the eligibility requirements as a very small importer prior to initially importing a food, but your average sales drop below \$1 million (for human food) or \$2.5 million (for animal food) per year during a subsequent 3-year period, you must document that you meet the eligibility requirements of a very small importer based on your average sales during the applicable previous 3-year period.

For the purpose of determining whether you satisfy the definition of very small importer with respect to human food or animal food for a given calendar year, the relevant 3-year period is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. If the year in which you intend to import is 2019, the three preceding calendar years would be 2016, 2017, and 2018. The baseline year for calculating the adjustment for inflation is 2011. If you 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 (21 CFR 1.512(b)(1)(i)(B)).

You may document your annual sales using resources such as the following:

- Tax forms, such as Gross Receipts or Sales (Line 1A) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, such as Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

You may document the market value of food (human or animal) manufactured, processed, packed, or held without sale using resources such as the following:

- The cost of incoming food;
- Copies of warehouse insurance policies indicating the market value of stored food;
- Balance sheets showing assets; or
- The value obtained by multiplying market price by volume of food manufactured, processed, packed, or held.

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

A: To determine your status as a very small importer of human food, you should include all human food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of what U.S. food safety regulations the food is subject to. For example, you would include products manufactured under the preventive controls requirements for human food in part 117 as well as seafood, juice, LACF, and dietary supplements not subject to the preventive controls requirements. Likewise, you would include RACs (such as produce (including produce subject to the produce safety regulation), grains, milk, and eggs) and products subject to the jurisdiction of the USDA (e.g., meat products for human consumption).

To determine your status as a very small importer of animal food, you should include all animal food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates. This would include all animal food subject to the preventive controls requirements for animal food in part 507, as well as animal food that is not subject to those requirements. You would not include food intended for consumption by humans or other items that are not animal food.

L.7 Q: Can an affiliate or subsidiary meet the definition of “very small importer” even if the parent company does not meet the definition of very small importer?

A: No. The total annual sales apply to each entity, regardless of whether it is the parent, subsidiary, or affiliate. In other words, if the total combined sales of the parent, subsidiaries, and affiliates meet the definition of very small importer, the parent company, subsidiaries, and affiliates would all be subject to the modified requirements for very small importers. However, if the parent company, a subsidiary, or an affiliate, individually or in any combination, does not meet the definition of a very small importer, the parent company, affiliates, and subsidiaries would all be subject to the full FSVP requirements.

L.8 Q: How do I determine average annual sales plus market value of human or animal food if I do not have 3 years of financial records to use in my calculations?

A: We realize that an importer’s compliance date for complying with the very small importer provisions is the same as their compliance date for retaining records to support the importer’s status as a very small importer. Therefore, if at the time of your FSVP compliance date you do not have records covering a 3-year period of time to support your status as a very small importer, it would be reasonable for you to make the calculation based on less than 3 years. If you have records for 3 previous calendar years, you could make the calculation based on the longer time period.

If you have been in operation as an importer for less than 3 years at the time of your FSVP compliance date, it would be reasonable for you to make the very small importer calculation based on a period of less than the preceding 3 years. If you begin operations after the initial FSVP compliance dates, you can rely on a projected estimate of revenue (or market value) at the time you begin operations. We intend to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees. After you have records for 1 or 2 preceding years, you should make the calculation based on records you have (i.e., for 1 or 2

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preceding calendar years), and we intend to accept records for the preceding 1 or 2 calendar years as adequate to support your status as a very small importer in these circumstances.

L.9 Q: If I am a very small importer of human food but I have an exceptional year in human food sales that bumps my average sales above \$1 million per year during the most recent 3-year period, will I still meet the eligibility requirements as a very small importer of human food?

A: No, you would no longer meet the eligibility requirements for a very small importer of human food. The same would apply if you were a very small importer of animal food and the exceptional year bumped your 3-year average above \$2.5 million per year.

L.10 Q: What documentation of eligibility requirements apply if I am importing certain food from a small foreign supplier as specified in 21 CFR 1.512(a)(2)?

A: If you are importing food from a small foreign supplier and you choose to comply with the requirements applicable to food imported from certain small foreign suppliers, you must obtain written assurance that your foreign supplier meets the criteria for small foreign supplier status (see Question L.1) before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year (21 CFR 1.512(b)(1)(ii)).

By specifying “by December 31” for the annual written assurance that the small foreign supplier is (1) a qualified facility, (2) a farm that grows produce and is not a covered farm under the produce safety regulation, or (3) a shell egg producer that has fewer than 3,000 laying hens, the provision provides some flexibility for you to work with each applicable small foreign supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your foreign suppliers have some flexibility to approach the potential for the status of a facility to shift between “qualified facility” and “not a qualified facility,” between a covered produce farm and a produce farm that is not covered, or between a shell egg producer that is subject to the shell egg regulation or one that is exempt in a way that works best for your specific business relationship.

The requirement to obtain written assurance of “small” foreign supplier status aligns with the responsibilities of a qualified facility to submit an attestation to FDA under 21 CFR 117.201(a) or 507.7(a). In its attestation, the qualified facility attests that: (1) It meets the definition of a qualified facility; and (2) either it has established and is following certain food safety practices, or it is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. A qualified facility submits its attestation to FDA on Form FDA 3942a (for human food) or 3942b (for animal food). A foreign supplier that is a qualified facility could provide a copy of that form to its customers (including FSVP importers) to demonstrate it meets the definition of a qualified facility.

L.11 Q: What if I meet the eligibility requirements as a very small importer and I am importing a food from a foreign supplier that meets the eligibility requirements as small foreign supplier?

A: If you are a very small importer and your foreign supplier meets the criteria for a small foreign supplier (see Question L.1), you may choose to comply with either the FSVP requirements applicable to very small importers or the requirements applicable to importers of certain food from certain small foreign suppliers. However, as a very small importer you might prefer to import all of your food in accordance with the requirements applicable to very small

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importers, rather than, for some of the food you import, comply with different requirements for importers of food from small foreign suppliers. There are additional FSVP requirements (other than verification activities) that apply to importers of food from certain small suppliers but do not apply to very small importers (see Question L.19).

L.12 Q: What additional FSVP requirements apply if I meet the eligibility requirements for a very small importer or an importer who is importing certain food from a certain small foreign supplier?

A: If you meet the eligibility requirements for a very small importer or an importer who is importing certain food from a certain small foreign supplier and you choose to comply with 21 CFR 1.512:

- You must have a foreign supplier verification program as required in 21 CFR 1.502;
- 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.

[21 CFR 1.512(b)(2)]

L.13 Q: What “standard” FSVP requirements do *not* apply if I am a very small importer or I am importing certain food from a certain small foreign supplier?

A: If you are a very small importer or you are importing certain food from a certain small foreign supplier and you choose to comply with 21 CFR 1.512, you are not required to:

- Conduct a hazard analysis under 21 CFR 1.504;
- Conduct an evaluation for foreign supplier approval and verification under 21 CFR 1.505;
- Conduct foreign supplier verification and related activities under 21 CFR 1.506;
- Comply with the requirements that apply to importation of a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation under 21 CFR 1.507;
- Take corrective actions under 21 CFR 1.508; and
- Maintain FSVP records under 21 CFR 1.510.

[21 CFR 1.512(b)(2)]

L.14 Q: What foreign supplier verification activities must I conduct if I am a very small importer?

A: If you are a very small importer, 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 FD&C Act, if either is applicable, and the implementing regulations on preventive controls or produce safety, respectively, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act (21 CFR 1.512(b)(3)(i)). You should ask your foreign supplier to provide this assurance on company letterhead or in a manner that clearly identifies the supplier, the particular food addressed in the assurance, and the applicable FDA food safety requirements.

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For example, if you are a very small importer of peaches, your supplier might provide the following assurance: “I affirm that these peaches were grown and harvested in accordance with FDA’s regulation on produce safety, 21 CFR part 112, and that the peaches are not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.” If you are a very small importer of cookies, your supplier might provide the following assurance: “I affirm that these cookies were manufactured in accordance with FDA’s requirements for hazard analysis and risk-based preventive controls for human food, 21 CFR part 117, and that the cookies are not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (the Act) and not misbranded regarding labeling for major food allergens under section 403(w) of the Act.”

The assurance from your foreign supplier should be dated and include the printed name and signature of an authorizing official.

L.15 Q: What foreign supplier verification activities must I conduct if my foreign supplier is a qualified facility?

A: If your foreign supplier is a qualified facility (see Question L.3), you must obtain written assurance before importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance 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 of the following:

- A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food. For example, a foreign supplier of ground black pepper might describe its application of a steam heat treatment to destroy potential vegetative pathogens such as *Salmonella* in the pepper. As another example, a foreign supplier of honey-roasted pecans might state that it roasts the pecans at a specified temperature for a specified time to control *Salmonella* on the pecans.

- 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(c)(3)(ii)(A)-(B)]

This written assurance requirement aligns with the responsibilities of a qualified facility to submit an attestation to FDA as discussed in Response L.10. A qualified facility that submits its attestation electronically can print a copy and use this to provide its customers (including FSVP importers) with the necessary assurance. However, if a qualified facility is a foreign supplier providing a written assurance to an importer, the qualified facility will also need to either include a brief written description of the preventive controls that it is implementing to control the applicable hazard in the food or provide a statement that it is in compliance with an applicable non-Federal food safety law. For example, a qualified facility that supplies honey-roasted pecans could include a brief written description of its preventive controls to control *Salmonella* on the pecans (e.g., roasting the pecans at a specified temperature for a specified time period).

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As discussed in Section M of this document, FDA has, under our systems recognition initiative, officially recognized certain countries as having food safety systems that are comparable to the U.S. food safety system, and has determined that certain foreign food safety systems are equivalent with respect to the regulation of particular foods. If you import foods that are not intended for further manufacturing/processing, you might be subject to modified FSVP requirements under 21 CFR 1.513, provided you meet the conditions and requirements in that section. However, you might import food that is intended to be further processed (e.g., tomatoes that will be used in making salsa) from a qualified facility located in a country with an officially recognized food safety system. In that case, the modified requirements in section 1.513 would not be applicable. You could therefore follow section 1.512(c)(3)(ii) by obtaining from the foreign supplier written assurance that it is producing the tomatoes in compliance with the applicable food safety laws and regulations in that country.

L.16 Q: What foreign supplier verification activities must I conduct if I am importing produce and my foreign supplier is a not a covered farm in accordance with 21 CFR 112.4(a) or 21 CFR 112.4(b) and 112.5?

A: If your foreign supplier is a farm that grows produce and is not a covered farm under these provisions of the produce safety regulation (see Question L.4), you must obtain written assurance before importing the produce and at least every 2 years thereafter that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to 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(c)(3)(iii)). For example, if your supplier of avocados has less than \$25,000 in average annual sales of produce (as “produce” is defined in 21 CFR 112.3(c)), you would obtain written assurance from the farm that it understands that it may not export adulterated food to the United States.

L.17 Q: What foreign supplier verification activities must I conduct if my foreign supplier is a small producer of shell eggs?

A: If your foreign supplier is a shell egg producer that is not subject to the requirements of the shell eggs regulation because it has fewer than 3,000 laying hens (see 21 CFR 118.1), you must obtain written assurance before importing the shell eggs and at least every 2 years thereafter that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to 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).

L.18 Q: What corrective action must I take if I determine that a food I import from a certain small foreign supplier was not produced consistent with the written assurance provided?

A: You must promptly take appropriate corrective actions if you determine that a small foreign supplier of a food you import does not produce the food consistent with the assurance provided in accordance with section 1.512. 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 (21 CFR 1.512(b)(4)).

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L.19 Q: What additional FSVP requirements must I meet if I am importing food from a certain small foreign supplier?

A: The following additional requirements apply if you are importing food from a certain small foreign supplier (and you are not a very small importer):

- Before approving a small foreign supplier, you must evaluate the applicable FDA food safety regulations and information relevant to the small foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You should consider information on supplier compliance that is publicly available, including at FDA's Web site. You may also consider other factors relevant to the small foreign supplier's performance (21 CFR 1.512(c)(1)(i)).
- You must promptly reevaluate the small foreign supplier's compliance history when you become aware of new information about the matters addressed in your initial evaluation. Your reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier (21 CFR 1.512(c)(1)(ii)(A)).
- 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, if necessary. You must document your reevaluation and any subsequent actions you take (21 CFR 1.512(c)(1)(ii)(B)).
- If an entity other than your small foreign supplier has, using a qualified individual, performed the foreign supplier evaluation or reevaluation, you may meet the requirements for performing the supplier evaluation or reevaluation by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual (21 CFR 1.512(c)(1)(iii)).
- You must approve your small foreign suppliers on the basis of the evaluation you either conducted or reviewed and assessed. You must document your approval (21 CFR 1.512(c)(2)).
- You must establish and follow written procedures to ensure that you import foods only from small foreign suppliers you have approved based on the evaluation conducted by you or another entity in your supply chain. When necessary and appropriate, on a temporary basis you may import food from an unapproved foreign supplier if you subject the food to adequate verification activities before importing the food, such as testing lots of a food from an unapproved supplier or reviewing food safety records for such lots. You must establish and follow written procedures for use of unapproved suppliers. You must document your use of procedures for food from approved and unapproved suppliers (21 CFR 1.512(c)(3)(i)).
- You may rely on another entity 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)). You may not rely on your small foreign supplier to establish and perform these procedures.

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L.20 Q: What if I am also a receiving facility that is obtaining raw materials or other ingredients from certain small foreign suppliers?

A: If you are a receiving facility whose suppliers of raw materials or other ingredients are small foreign suppliers (i.e., qualified facilities, certain small farms that are not covered farms, or shell egg producers with fewer than 3,000 laying hens), and you are subject to and in compliance with the supply-chain program provisions of the preventive controls regulations for human or animal foods with respect to those raw materials or other ingredients (see 21 CFR 117.430(c)-(e) and 507.130(c)-(e), respectively), you will not need to obtain written assurances from your suppliers under the FSVP regulation. In that situation, you are deemed in compliance with the FSVP regulation (except for the requirement to ensure that you are identified as the FSVP importer at entry) in accordance with section 1.502(c)(3) (see Question B.10).

L.21 Q: What general requirements for records apply if I am a very small importer or I am importing a certain food from a certain small foreign supplier?

A: The following general records requirements apply if you are a very small importer or if you are importing certain food from a certain small foreign supplier:

- You must keep FSVP records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.
- You must sign and date your FSVP records upon initial completion and upon any modification of the FSVP.
- All required records must be legible and stored to prevent deterioration or loss.

[21 CFR 1.512(b)(5)(i)]

L.22 Q: May I use existing records that provide information required for FSVP?

A: Yes. If you have records that you maintain to comply with other Federal, State, or local government regulations or for your own business purposes, you do not need to duplicate those records to meet FSVP requirements if the records contain all of the information required for FSVP. If your existing records contain some, but not all, of the information required for FSVP, you may supplement your existing records as necessary to include all of the information required for FSVP (21 CFR 1.512(b)(5)(v)(A)). For example, if you have tax records or other business records that indicate your gross sales of food, you may use your existing tax records to demonstrate that you qualify as a very small importer (see Question L.5). Or, if you maintain business records documenting that you addressed a food safety problem with a foreign supplier, you may use them to help demonstrate that you took corrective actions in accordance with 21 CFR 1.512(b)(4).

You also are not required to maintain FSVP information in one set of records (21 CFR 1.512(b)(5)(v)(B)). For example, you may keep your tax records at a corporate headquarters and keep records of corrective actions at a local office. However, you must make all necessary records promptly available to an FDA representative, upon request, for inspection and copying (see Question L.24).

L.23 Q: How long must I retain my FSVP records?

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A: You must retain required FSVP records for at least 2 years after you created or obtained the records (with certain exceptions discussed below) (21 CFR 1.512(b)(5)(iii)(A)). For example, if you take a corrective action after determining that a food you import was adulterated (e.g., you work with the foreign supplier to ensure that the problem is corrected before you import additional shipments of the food), you must retain documentation of the corrective action you took for at least 2 years.

If you are subject to the requirements in 21 CFR 1.512(c) for importers of food from certain small foreign suppliers (see Question L.19), you must retain records relating to your FSVP processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure that you import food from approved foreign suppliers, for at least 2 years after you discontinue using the process or procedure (e.g., because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure importation of food from approved suppliers) (21 CFR 1.512(b)(5)(iii)(B)).

If you are a very small importer, you must retain for at least 3 years 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)).

L.24 Q: Must I store my FSVP records at my place of business?

A: You are not required to store FSVP records onsite at your place of business, provided that you can retrieve the records and provide them to FDA within 24 hours of our request for official review (21 CFR 1.512(b)(5)(ii)(B)). We recognize that some importers, particularly those that import food into the United States through multiple ports, may prefer to develop and maintain FSVP records at a single location, such as a corporate headquarters. We also recognize that some FSVP records may be maintained by other entities in your supply chain. Storing records at multiple locations is acceptable provided you can meet the requirement to make FSVP records available to FDA within 24 hours.

L.25 Q: When must I make my FSVP records available to FDA?

A: When requested, you must make all required FSVP records available promptly to an authorized FDA representative for inspection and copying (21 CFR 1.512(b)(5)(ii)(A)). When an FDA representative makes this request at your place of business, we expect you to provide the requested onsite records while FDA is at your place of business. We consider electronic records to be available onsite if they are accessible from your onsite location. You must provide records stored offsite within 24 hours of FDA's request for the records (21 CFR 1.512(b)(5)(ii)(B)).

If requested in writing by FDA, you must send your FSVP records to the Agency electronically, or by another means that delivers the records promptly, rather than making the records available for review at your place of business (21 CFR 1.512(b)(5)(ii)(C)). We will generally expect you to deliver the FSVP records within 72 hours. If there are circumstances that will cause you to need additional time, you should contact us to discuss an appropriate timeframe for delivery. We might request that you submit some or (less likely) all of your FSVP records. For information on how to submit records to FDA, see Question J.5.

L.26 Q: Do I need to maintain my records in English?

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A: You do not need to maintain your FSVP records in English. However, if you maintain records in a language other than English, you must, upon FDA request, provide an English translation of the records within a reasonable time (21 CFR 1.512(b)(5)(ii)(A)). What constitutes a “reasonable time” will vary depending on factors such as the number, length, and complexity of the records requested. For example, if we request your FSVP for one food you import, you should be able to provide an English translation of those records in less time than if we request your FSVP records for ten foods you import. We suggest you discuss with FDA the amount of time you need to obtain an English translation of the requested records when the situation arises.

L.27 Q: What requirements apply to my FSVP records maintained in electronic form?

A: An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system (21 CFR 11.3(b)(6)). Records that you establish or maintain to satisfy FSVP requirements and that meet this definition are exempt from the requirements for electronic records and signatures in 21 CFR part 11 (21 CFR 1.512(b)(5)(iv)). This exemption does not apply to electronic records that satisfy FSVP requirements but are also required under other applicable statutory provisions or regulations.

L.28 Q: Will FDA release my FSVP records to the public?

A: All FSVP records that we obtain will be subject to the disclosure requirements in 21 CFR part 20 (21 CFR 1.512(b)(5)(vi)). We expect that many FSVP records we obtain will contain confidential commercial information and trade secrets that will be exempt from public disclosure in accordance with part 20. We will keep such information confidential.

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

M.1 Q: What does it mean for a foreign country to have an “officially recognized” or “equivalent” food safety system?

A: Under FDA’s systems recognition initiative, the Agency conducts evaluations of the food safety systems of foreign countries to determine whether these systems can be recognized as “comparable” to the U.S. food safety system. The systems recognition process assesses whether:

- A country’s food safety system provides a similar, though not necessarily identical, system of protections as another food safety system (in this case, the U.S. food safety system), and
- The country’s food safety authority or authorities provide similar oversight and monitoring activities for food produced under its jurisdiction.

Systems recognition involves a comprehensive review of key elements of a country’s national food safety control system, including its relevant laws and regulations, inspection programs, response to food-related illness and outbreaks, compliance and enforcement efforts, and laboratory support. It is based on the conclusion that food safety systems with similar elements and similar levels of oversight lead to similar food safety outcomes. A systems recognition arrangement between the United States and another country might not cover all foods produced in each country but typically will cover many types of food (rather than particular commodities).

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Systems recognition is a reciprocal regulatory cooperation program. This means that FDA can rely on the oversight in an exporting country recognized as having a comparable food safety system for the purposes of assuring food safety and for follow up when a food safety problem emerges, and vice-versa. You can find additional information on FDA's systems recognition program at <http://www.fda.gov/food/internationalinteragencycoordination/ucm367400.htm>.

The term "equivalence" is used principally in the context of the international trading regime established under the World Trade Organization (WTO) and its associated agreements, including the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and in other free trade agreements, such as the North American Free Trade Agreement. Equivalence can be accepted for a specific measure or measures related to a certain product or category of products, or on a system-wide basis.

FDA has not yet undertaken equivalence determinations on a system-wide basis (covering all or virtually all foods). We have considered equivalence as most appropriately applied to the assessment of a foreign government's specific programs for certain high-risk foods. This type of assessment provides a very detailed comparison of each measure that a country applies in controlling risks associated with the particular commodity under review. To date, we have engaged in equivalence determinations with several foreign governments regarding two FDA-regulated commodities: (1) Grade A dairy and dairy products and (2) bivalve mollusks. We hope to enter into agreements with regulatory authorities in foreign countries reflecting a determination that such country's system of controls and oversight of a particular food is equivalent to that required under U.S. law. In these cases, potential equivalence determinations most likely will apply to individual foods or types of foods rather than all foods produced in a particular country.

The modified FSVP requirements in section 1.513 would apply to the foods covered under these comparability (systems recognition) and equivalency agreements because we will have determined that the systems of food safety control and oversight of the foods covered under these agreements are comparable or equivalent to that of the United States.

M.2 Q: Where can I find information on the countries FDA recognizes as having a food safety system that is comparable or equivalent to that of the United States?

A: Information on the countries FDA officially recognizes under our systems recognition initiative as having a comparable food safety system is available on FDA's website at <http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/default.htm>. The information includes systems recognition assessment reports and the texts of system recognition arrangements. In addition, we will provide updates to stakeholders as we enter into new systems recognition arrangements with additional countries. We also will maintain on our Web site a listing of equivalency agreements for which food covered under the agreements will be subject to the modified FSVP requirements in section 1.513, along with the texts of those agreements.

It is important to note that not all foods may be covered under systems recognition arrangements. For example, existing arrangements do not cover dietary supplements or food for animals.

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M.3 Q: What modified FSVP requirements apply when I import certain food from a country whose food safety system is comparable or equivalent to that of the United States?

A: If you meet the conditions and requirements for importing a food from a country whose food safety system is officially recognized as comparable or determined to be equivalent to that of the United States (see Question M.4), you must comply with the following FSVP requirements:

- Document that the foreign supplier is located in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, and the supplier is under the regulatory oversight of that country (21 CFR 1.513(b)(1)).
- Document that the food you import is within the scope of the official recognition or equivalency determination (21 CFR 1.513(b)(1)).
- Determine and document whether your foreign supplier is in good compliance standing with the food safety authority of the country in which the supplier is located (21 CFR 1.513(b)(2)). For example, you might document your supplier's good compliance standing by saving a screen shot from the Web page of a food safety authority to which FDA's Web page is linked showing your supplier's appearance on a list of food producers in good compliance standing (or your supplier's absence from a list of food producers not in good compliance standing). Alternatively, you might obtain from your foreign supplier documentation that it is in good compliance standing with the relevant food safety authority.
- Continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained (21 CFR 1.513(b)(2)). We recommend that you check FDA's Web site or contact your foreign supplier at least every 6 months to determine whether your supplier remains in good compliance standing. To meet the requirement to monitor your supplier's status, you might require your supplier to notify you if it is no longer designated as being in good compliance standing with the relevant food safety authority.
- If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action (21 CFR 1.513(b)(2)). For example, if you learn that your foreign supplier recalled a food for food safety reasons, you should determine whether any food you are importing from that foreign producer is subject to the recall or may be similarly affected. You should determine whether the foreign supplier has taken sufficient corrective actions to ensure that the identified food safety hazard is now being controlled. The appropriate corrective action you take will depend on the circumstances but could include discontinuing use of the foreign supplier (21 CFR 1.513(b)(2)).
- Document any corrective actions that you take (21 CFR 1.513(b)(2)).
- Use a qualified individual to develop and perform FSVP activities (21 CFR 1.503).
- Ensure that you are identified as the FSVP importer at entry (21 CFR 1.509).
- Maintain applicable FSVP records (21 CFR 1.510).

However, you are not required to comply with the following FSVP requirements:

- Conduct a hazard analysis of the food (21 CFR 1.504).
- Evaluate the potential foreign supplier and the risk posed by the food (21 CFR 1.505)
- Determine and conduct appropriate supplier verification activities based on the evaluation of the food and foreign supplier (21 CFR 1.506).

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- Comply with the requirements for foods that cannot be consumed without application of an appropriate control or for which the hazards are controlled after importation (21 CFR 1.507).
- Take corrective actions under 21 CFR 1.508.

M.4 Q: Do the modified FSVP requirements apply to all foods from a country with an officially recognized or equivalent food safety system?

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

M.5 Q: What does “good compliance standing with a foreign food safety authority” mean?

A: Before importing a food under the modified procedures for certain foods from a country with a comparable or equivalent food safety system, you must determine and document that 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. Good compliance standing with a foreign food safety authority means that the foreign supplier:

- 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
- Has otherwise been designated by the foreign food safety authority as being in good compliance standing (21 CFR 1.500).

A comparable or equivalent food safety authority might choose to maintain a list of producers under its oversight that are in good compliance standing under that country’s food safety laws and regulations. Alternatively, such an authority might use another means of designating producers as being in good compliance standing, such as by issuing a certificate of compliance or maintaining a list of producers who are *not* in good compliance standing (and officially designating all producers not on the list as being in good compliance standing).

M.6 Q: How do I know whether my foreign supplier is in good compliance standing with a comparable or equivalent food safety authority?

A: We intend to provide at our Web site links to information on supplier compliance status that is made available by the food safety authorities for comparable or equivalent food safety systems. Alternatively, you might be able to obtain documentation of a foreign supplier’s good compliance standing with the authority for a comparable or equivalent food safety system either directly from your supplier or from the foreign food safety authority.

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M.7 Q: What should I do if my foreign supplier is no longer in good compliance standing with a foreign food safety authority?

A: If your foreign supplier in a country with a comparable or equivalent food safety system is no longer in good compliance standing with the foreign food safety authority, you are not eligible to use the modified provisions for food from comparable or equivalent food safety systems in 21 CFR 1.513. However, a foreign supplier's lack of good compliance standing does not necessarily mean that it would be inappropriate to import food from that supplier. It may still be appropriate for you to do so, following other applicable FSVP requirements. If you wish to continue to import from that foreign supplier, you should determine the reasons why the foreign supplier is not in good compliance standing. If the foreign supplier is no longer in good compliance standing because the foreign food safety authority found significant violations of food safety regulations by the foreign supplier, you should determine whether it would be appropriate to continue to import food from the foreign supplier. If you choose to continue importing food from the foreign supplier, you would need to develop a new FSVP for the food from the supplier. Unless you could import food from the supplier under other modified provisions (e.g., the modified requirements for very small importers), you would need to comply with the standard FSVP requirements, including conducting a hazard analysis, evaluating the risk posed by the food and the foreign supplier's performance, and implementing appropriate supplier verification activities.

M.8 Q: Do I need to include in the import documentation that I submit to CBP any kind of declaration or certificate as evidence that the imported food is covered under a systems recognition arrangement or equivalency agreement?

A: No. FDA does not require a certificate or other evidence of an applicable systems recognition arrangement or equivalence agreement when you file entry with CBP. Instead, we may inspect your FSVP records to determine whether you are in compliance with the FSVP regulation, including, if applicable, the modified requirements for certain food from suppliers in countries with comparable or equivalent food safety systems.

**N. What Are Some Consequences of Failing to Comply with the FSVP Requirements?
(21 CFR 1.514)**

N.1 Q: What are some consequences if I do not comply with the applicable FSVP requirements?

A: FDA may refuse admission into the United States of a food you offer for import if it appears that you are not in compliance with the FSVP requirements with respect to that food (section 801(a)(3) of the FD&C Act; 21 CFR 1.514(a)).

In addition, importing or offering for importation a food into the United States without having an FSVP in accordance with section 805 of the FD&C Act and the FSVP regulation is a prohibited act under section 301(zz) of the FD&C Act (21 U.S.C. 331(zz)) (see also 21 CFR 1.514(b)). Under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in federal court to enjoin a person who commits a prohibited act. Under section 303 of the FD&C Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the FD&C Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. In addition, false representations

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to the U.S. government, including falsely identifying a U.S. agent or representative, may result in criminal prosecution of those involved.

It is important to note that FDA can use its additional enforcement tools (e.g., import alerts, seizures, administrative detentions) if we believe that a food poses a risk to public health. We do not need to rely solely on enforcement of the FSVP regulation.

N.2 Q: Will every violation of the FSVP regulation warrant an enforcement action by FDA?

A: No. FDA will employ a risk-based enforcement strategy focusing on violations that pose a risk to public health. We will consider your overall compliance with the FSVP regulation and any corrective actions you have taken or plan to take in determining whether a violation of FSVP requirements warrants FDA taking enforcement action. For example, if you have not developed an FSVP for a food you import or have not performed a required FSVP activity (e.g., you did not conduct a hazard analysis or you did not conduct supplier verification activities) and you do not promptly take actions to correct these violations, FDA may determine that is appropriate to take enforcement action. Types of enforcement action we may consider include listing you on an import alert that provides for detention without physical examination.

N.3 Q: How will FDA determine if I am in compliance with the FSVP requirements?

A: FDA may review your FSVP records to evaluate your compliance with the FSVP requirements. This review might be at your place of business or remotely, through an official request to send records relating to your FSVP activities to the Agency (see Question J.5). We will review required FSVP records relating to one or more of the foods you import, including the following records, when applicable:

- Hazard analysis;
- Evaluation and reevaluation of risk posed by a food and the foreign supplier's performance;
- Procedures for ensuring receipt of food from approved foreign suppliers;
- Determination and performance of appropriate foreign supplier verification activities; and
- Documentation of eligibility as a very small importer or of a foreign supplier's "small" status.

If, based on a review of records you submit to the Agency, we observe potential violations of the FSVP requirements, as necessary, we may request additional records or further review your records at your place of business. Depending on the results of our records review, FDA may take an enforcement action (see Question N.4).

N.4 Q: What are the consequences if I do not respond to an FDA request for records?

A: If you do not respond to FDA's request for records relating to your FSVP, FDA will consider that a violation of your obligations under section 805 of the FD&C Act and section 1.510. We will consider such a refusal to be a violation of FSVP requirements if the refusal is made when we request records at your place of business (21 CFR 1.510(b)(1)) or if the refusal is made in response to a written request from FDA to send records to the Agency electronically or through other prompt means (21 CFR 1.510(b)(3)). We will consider taking enforcement action if you do not respond to a request for records as required.

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N.5 Q: Must FDA evaluate my compliance with the FSVP requirements before I can import food into the United States?

A: No. An FDA evaluation of your compliance with the FSVP requirements is not a prerequisite to your importation of foods. However, at entry, you must submit the importer identification information required by the FSVP regulation (21 CFR 1.509(a)). Thus, to import food into the United States, at entry you must provide the FSVP importer's name, email address, and unique facility identifier recognized as acceptable by FDA (i.e., your DUNS number) if you are subject to FSVP (see 21 CFR 1.509(a) and Question I.1).

N.6 Q: May FDA refuse admission if I do not identify the FSVP importer at entry?

A: Yes. We may refuse admission of a food if identification of the FSVP importer is required, but not provided. Importer identification is a mandatory declaration requirement when filing entry with CBP (21 CFR 1.509(a)). In addition, we may refuse admission of a food if the foreign owner or consignee of the food at the time the food is offered for entry has not appropriately designated a U.S. agent or representative to serve as the FSVP importer (21 CFR 1.514(a)). A foreign owner or consignee must designate a U.S. agent or representative to serve as the FSVP importer when there is no U.S. owner or consignee (21 CFR 1.509(b); 21 CFR 1.500).

N.7 Q: How will FDA inform me if I am not in compliance with the FSVP requirements when FDA reviews my records?

A: If the FDA investigator observes potential violations of the FSVP requirements during a review of your records, the investigator will provide you with a written summary of the observations on an FDA Form 483a ("FSVP Observations"). FDA may also discuss the observations with you. In a discussion of the observations, you may inform the investigator or other Agency personnel of corrections you have made or that you plan to make. We will explain how you can submit your response to the FDA Form 483a, including any other corrections you may make, through the FDA/FURLS portal system, the U.S. Postal Service (e.g., certified mail), or a commercial delivery service. We will take any corrective actions into account when determining whether to take enforcement action (e.g., warning letter or FDA import alert).

N.8 Q: What is a warning letter?

A: A warning letter is a letter to an individual or firm relating to violations of FDA-enforced requirements. The Agency position is that warning letters are issued only for violations of regulatory significance. A warning letter identifies the violation or violations. The letter also makes clear that the individual or firm must correct the problem and provides directions and a timeframe to inform FDA of its plans for correction. FDA then checks to ensure that the corrections are adequate.

N.9 Q: What is an import alert?

A: An import alert provides information to FDA field staff, for instance that the Agency has sufficient evidence or other information to refuse admission of future shipments of FDA-regulated products that are imported or offered for import. If an import alert is applicable, FDA field staff may use the information in the alert, along with other information about the article being imported, to determine whether FDA should detain the article. FDA is not required to refuse admission. If we detain an article that appears violative, we will provide notice to the

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importer of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). Depending on the information submitted by the importer, the article may either be permitted or refused entry into the United States.

N.10 Q: If my FSVP violations cause me to be listed on an import alert, will this affect importation of the same food by other importers?

A: If you are on an import alert because of your FSVP violations, this will not directly affect importation of the same food by other importers. However, if our review of your FSVP records indicates that there may be a food safety issue relating to a food you import, we can follow up to determine whether enforcement action against the food and/or the foreign supplier are warranted. Although such action may be triggered by our review of your FSVP records, it is not dependent on identifying violations relating to your FSVP. For example, in the course of your FSVP supplier verification activities (e.g., onsite auditing of the foreign supplier and periodic testing of the food) you might determine that a sample of the food is positive for *Salmonella*. If we review your records and determine that you failed to take appropriate corrective actions, we might list you on import alert for FSVP violations. In this situation, we might conduct a follow-up investigation, for instance to evaluate whether circumstances warrant listing the foreign supplier, the food, and other foods from the foreign supplier on an import alert for food that appears to be adulterated due to *Salmonella* (i.e., an import alert that is not linked to FSVP violations). We might also consider whether voluntary or mandatory recall or seizure of the food in domestic commerce is appropriate. We will only take such actions if the record supports the actions.

N.11 Q: What will happen if a food I offer for entry is listed on an FSVP import alert because FDA has determined that I am not in compliance with the FSVP regulation?

A: If a food you offer for importation into the United States is listed on an FSVP import alert because you did not comply with the FSVP requirements for that food, FDA may detain the food without physical examination when you offer it for importation. FDA will then issue a Notice of FDA Action, which will state the reason for detention. The notice will also specify a place and a period of time during which you will have an opportunity to introduce testimony demonstrating that you are in compliance with FSVP with respect to the food. Such testimony may be introduced orally or in writing (21 CFR 1.94). If you do not wish to introduce testimony, you can choose to waive your right to introduce testimony and export or destroy the product. If you do respond but FDA determines that your response is inadequate, FDA may refuse entry of the food. In such a case, we will issue a Notice of FDA Action informing you that your entry has been refused. The food must then be exported or destroyed.