

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-N-0143]

RIN 0910-AG64

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt regulations on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The proposed regulations would require importers to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. We are proposing these regulations in accordance with the FDA Food Safety Modernization Act (FSMA). The proposed regulations would help ensure that imported food is produced in a manner consistent with U.S. standards.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments on this proposed rule, identified by Docket No. FDA-2011-N-0143 and/or Regulatory Information Number (RIN) 0910-AG64, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2011-N-0143, and RIN 0910-AG64 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number found in brackets in the heading of this

document into the “Search” box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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Executive Summary

Purpose of the Proposed Rule

The proposed rule would adopt regulations on FSVPs that importers must create and follow to help ensure the safety of imported food. The proposed regulations vary based on the type of food product (such as processed foods, produce, and dietary supplements) and category of importer.

Congress required importers to perform risk-based foreign supplier verification activities and directed FDA to promulgate regulations on the content of FSVPs in section 301 of FSMA, codified in section 805 of the FD&C Act. The proposed regulations would require importers to implement FSVPs that provide adequate assurances that the importer's foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that

provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the FD&C Act, as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.

Summary of Major Provisions

We are proposing a flexible, risk-based approach to foreign supplier verification. The regulations focus on foreseeable food safety risks identified through a hazard assessment process, rather than all risks covered by the adulteration provisions in section 402 of the FD&C Act. Because the principle of hazard assessment is well accepted and understood throughout the international food safety community (e.g., as a key component of hazard analysis and critical control point (HACCP) and preventive controls programs), we believe that it provides the most effective way to implement a risk-based framework in which importers can evaluate potential products and suppliers and conduct appropriate verification efforts.

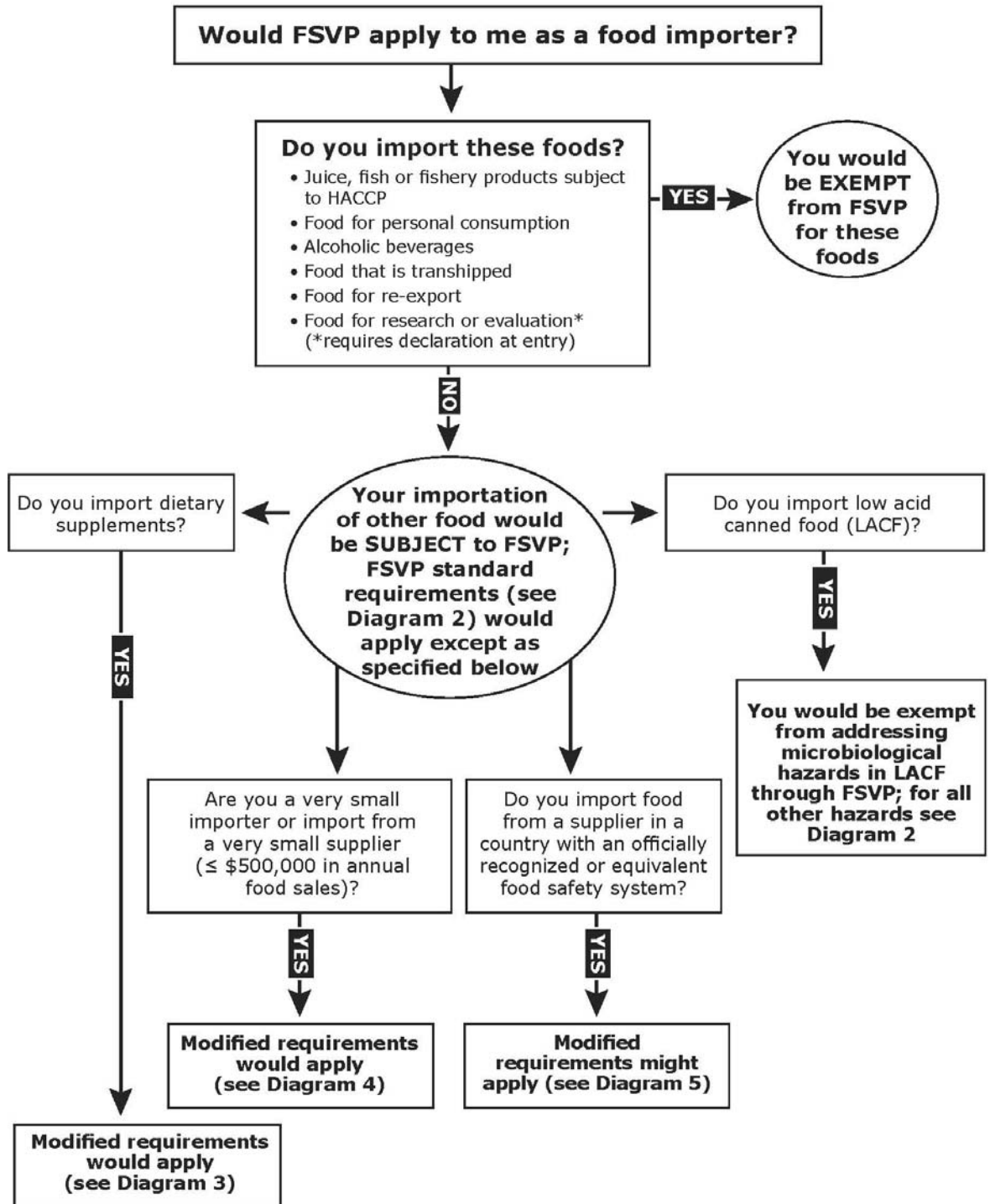
The proposed FSVP regulations also align with key components of the preventive controls programs that food manufacturers and processors should follow to ensure food safety, as discussed in FDA's recently issued proposed rule on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food. The general FSVP framework, together with the modified provisions discussed in the next section, are intended to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade.

Although the FSVP requirements would apply to most imported food under FDA's regulatory jurisdiction, certain categories of imported food would not be covered under the FSVP regulations, as shown in Diagram 1 below. (The diagrams set forth below are intended to

illustrate the FSVP requirements and do not include all aspects of the proposed regulations.)

These exemptions include certain juice, fish, and fishery products (which are already subject to verification under FDA's HACCP regulations), food for personal consumption, alcoholic beverages, food that is transshipped, food that is imported for re-export, and food for research or evaluation.

Diagram 1



The proposed FSVP regulations would require importers to:

(1) Review the compliance status of foods and potential foreign suppliers. Before importing a food from a foreign supplier, importers would be required to review the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or certification requirement relating to the safety of the food. These documents are or would be available at FDA's Web site.

(2) Determine the hazards reasonably likely to occur with each food. Importers could conduct their own analysis of the potential hazards with a food or review and evaluate the hazard analysis conducted by the food's foreign supplier.

(3) Conduct supplier verification activities. Importers would need to maintain a written list of foreign suppliers and establish written verification procedures. Importers would need to verify that hazards identified as reasonably likely to occur in a food they import are being adequately controlled. If the importer or its customer is controlling a hazard, the proposed rule would require the importer to document such control. For other hazards, the proposed rule presents two alternative proposals for requirements regarding verification activities. Under Option 1 of this co-proposal, onsite auditing of the foreign supplier would be required for hazards to be controlled by the foreign supplier when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death. Onsite auditing also would be required under Option 1 for microbiological hazards in certain raw agricultural commodities (RACs) that are fruits or vegetables. Audits could be conducted by auditors that are accredited in accordance with the accreditation system that FDA is developing to implement section 307 of FSMA, but the proposal would not require the use of accredited auditors. Also, instead of an onsite audit, an importer could rely on the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food

safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

For other hazards, including less serious hazards and hazards that the foreign supplier verifies have been controlled by its supplier, importers would have the flexibility under Option 1 to choose the verification activity or activities that will provide sufficient assurance that the hazards are adequately controlled. These activities could include onsite auditing of the foreign supplier, periodic or lot-by-lot sampling and testing, periodic review of the supplier's food safety records, and any other procedure that an importer has established as being appropriate to verify adequate control of a hazard.

Option 2 of the co-proposal would allow importers to choose from among these verification activities for all types of hazards not controlled by the importer or its customer. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the food and foreign supplier's compliance with U.S. food safety regulations.

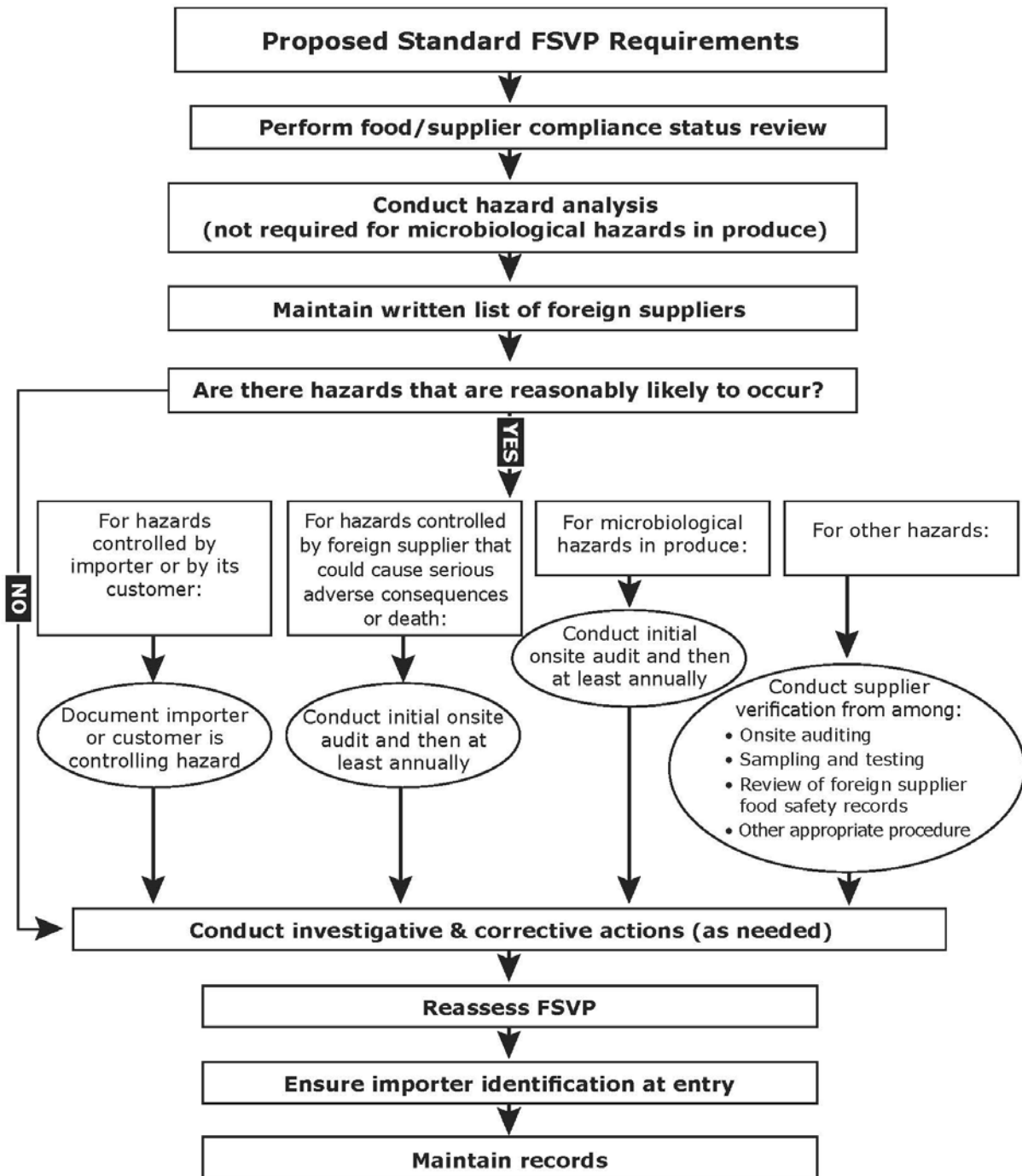
(4) Review complaints, investigate adulteration or misbranding (with respect to allergen labeling), and take corrective actions in the case of supplier noncompliance.

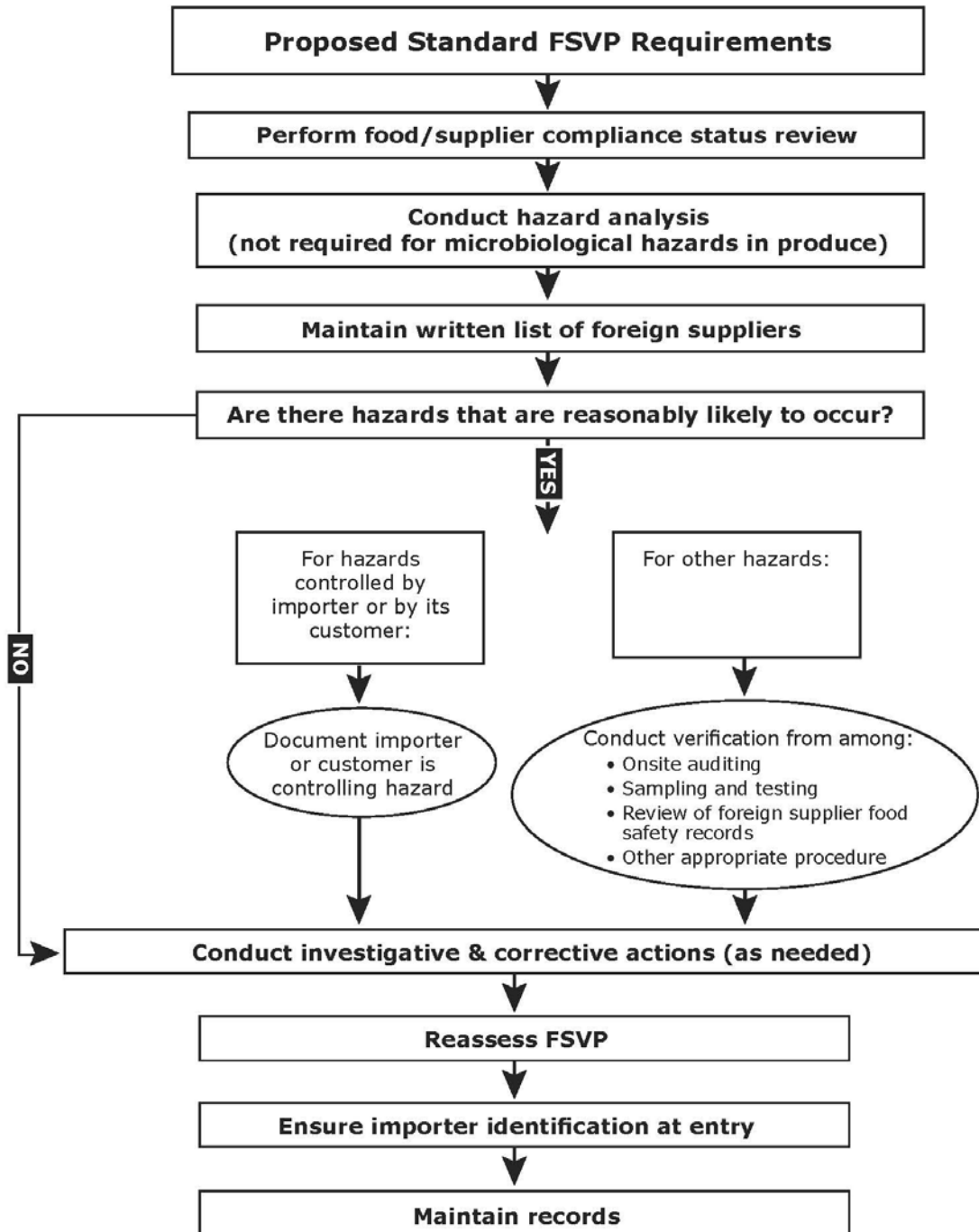
(5) Reassess the effectiveness of its FSVP when the importer becomes aware of new information about potential hazards associated with a food, or otherwise every 3 years.

(6) Ensure that the importer's name and Dun and Bradstreet Data Universal Numbering System (DUNS) number is provided for each line of entry of food.

(7) Maintain records of their FSVP activities.

These “standard” FSVP requirements are summarized in Diagram 2 (under Options 1 and 2) below:

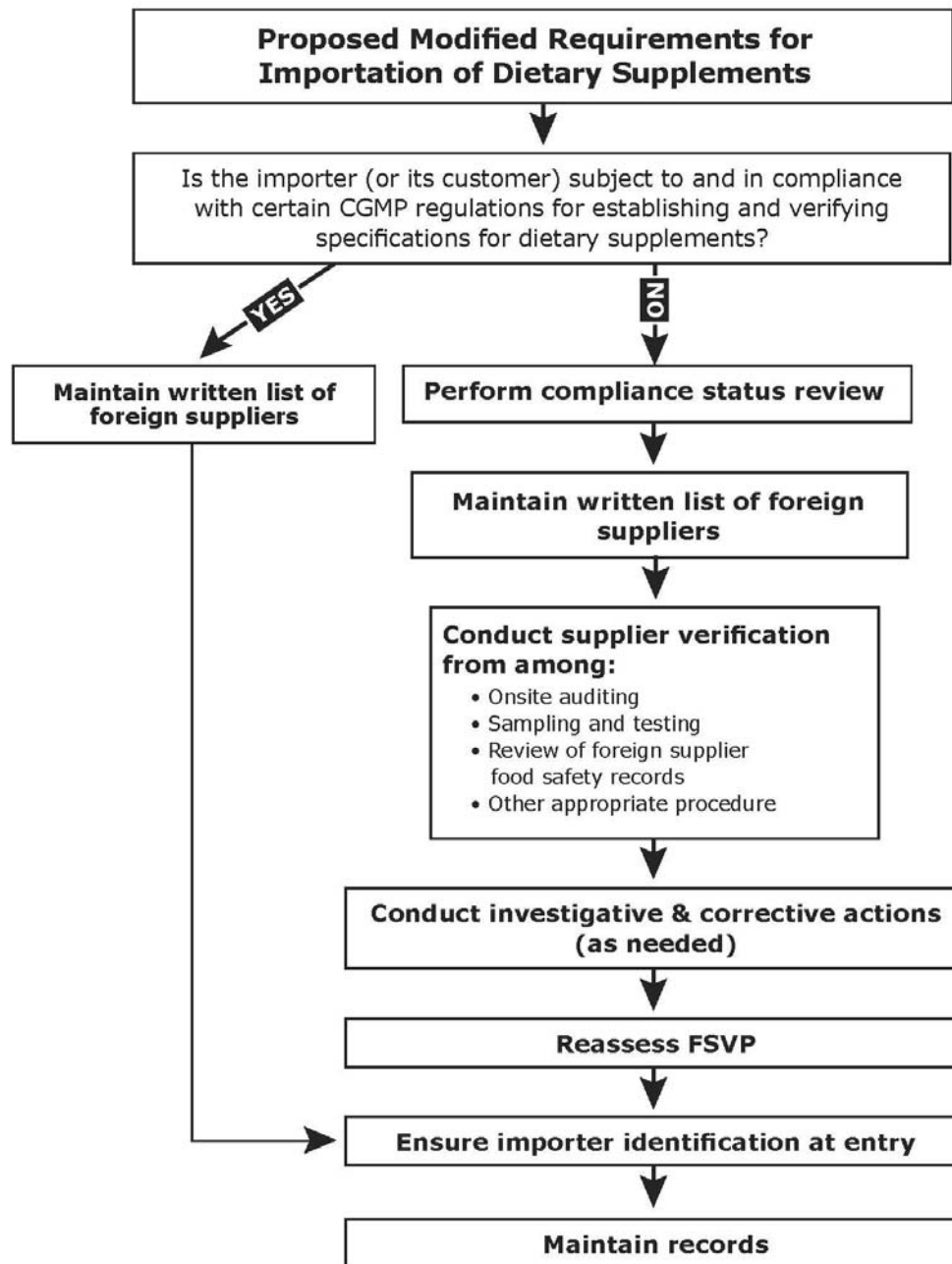
**Diagram 2
(Option 1)**


**Diagram 2
(Option 2)**


Modified Provisions for Certain Types of Importers

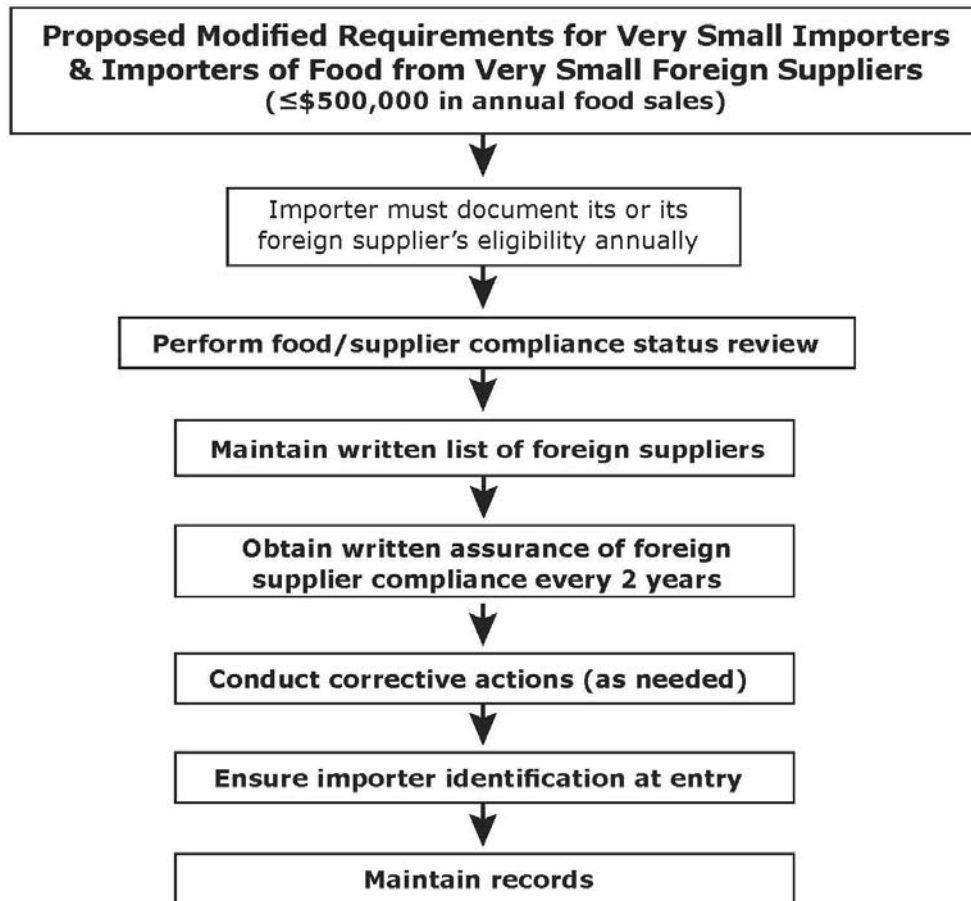
We are proposing several exceptions to the standard FSVP requirements for certain types of foods and importers. First, as shown in Diagram 3 below, for dietary supplements and dietary supplement components, importers who establish and verify compliance with certain specifications (concerning dietary supplement components, labels, packaging, and labeling) under the dietary supplement CGMP regulations would not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements. On the other hand, importers of finished dietary supplements would be required to comply with most of the standard FSVP requirements, but they would not have to conduct hazard analyses, and their supplier verification activities would focus on verifying that the supplier is in compliance with the dietary supplement CGMP regulations, rather than verifying that hazards identified as reasonably likely to occur are being adequately controlled.

Diagram 3



Second, as shown in Diagram 4 below, the proposed rule would establish modified FSVP requirements for very small food importers and importers of food from very small foreign suppliers (i.e., entities with annual food sales of no more than \$500,000). Because of the relatively small volume of food imported by and from these entities, which should reduce consumers' exposure to, and therefore potential risk from, the imported food, we are proposing that in these situations the importer would not be required to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurance that describes the processes and procedures the suppliers use to ensure the safety of the food.

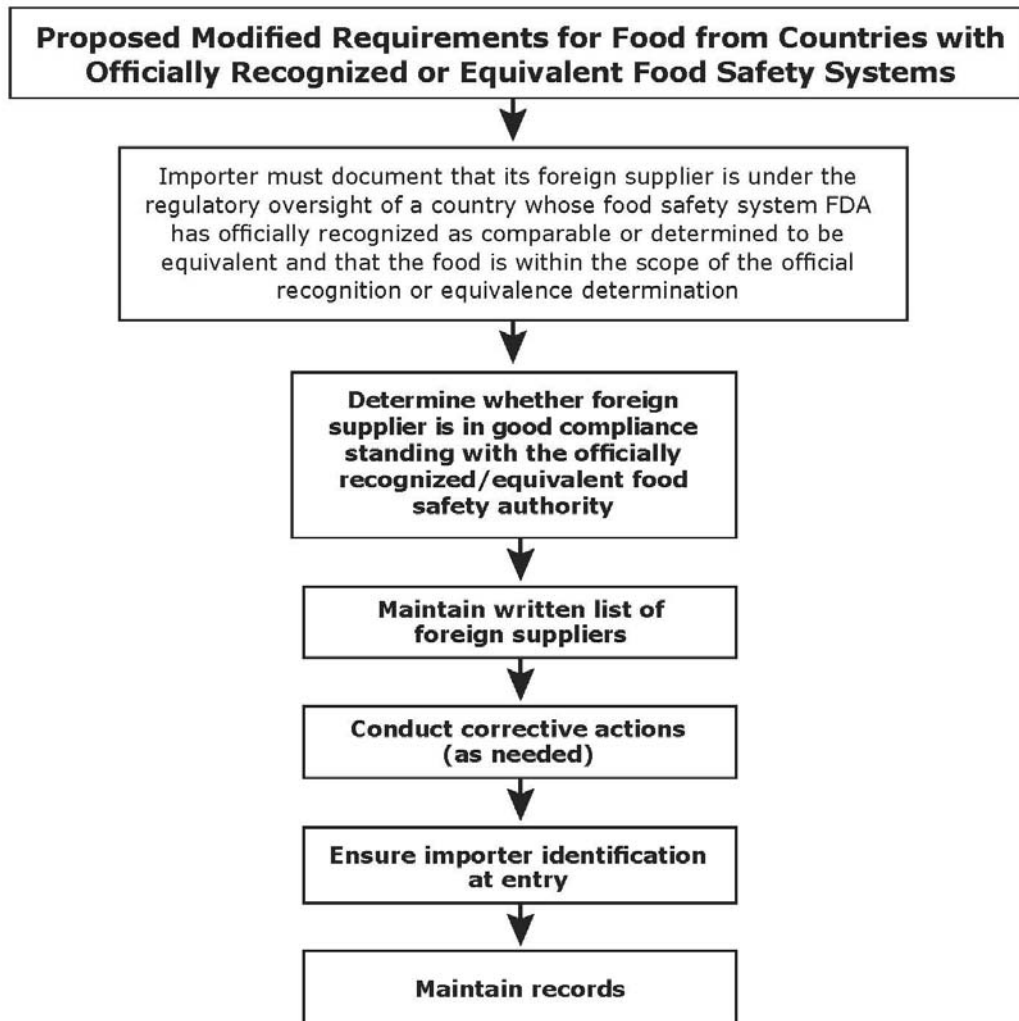
Diagram 4



Third, as shown in Diagram 5 below, the proposed rule would exclude from most of the standard FSVP requirements (including hazard analysis and verification that identified hazards are adequately controlled) food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that:

- The food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located; and
- The importer determines 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.

Diagram 5



Costs and Benefits

We summarize the annualized costs (over a 10-year time period discounted at both 3 percent and 7 percent) of the two options for the proposed rule in the table immediately below.

	3 Percent	7 Percent
Co-Proposal Option 1	\$472,971,342	\$473,380,038
Co-Proposal Option 2	\$461,407,455	\$461,821,706

Although the FSVP proposed rule would not itself establish safety requirements for food manufacturing and processing, it would benefit the public health by helping to ensure that imported food is produced in compliance with other applicable food safety regulations. The Preliminary Regulatory Impact Analyses for the proposed rules on hazard analysis and preventive controls for human food and standards for produce safety consider and analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing. The greater the compliance with those regulations, the greater the expected reduction in illnesses and deaths as well as the costs associated with them. The proposed rule on FSVPs is an important mechanism for improving and ensuring compliance with the above-noted food safety regulations as they apply to imported food. For this reason, we account for the public health benefits of the FSVP proposed rule in the preventive controls, produce safety, and other applicable food safety regulations instead of in this rule.

I. Background

A. Background and Legal Authority

In fiscal year 2011, nearly 10.5 million product lines of food (representing unique food products) were imported into the United States (Ref. 1). Human and animal food constitutes nearly 40 percent of all imported product lines regulated by FDA. About 15 percent of all food consumed in the United States is imported, including approximately 50 percent of fresh fruit and 20 percent of fresh vegetables (Ref. 2).

Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to estimates from the Centers for Disease Control and Prevention (CDC). Several foodborne disease outbreaks have been traced to imported food, including outbreaks resulting from consumption of imported fruits, vegetables, and nuts (Ref. 3).

FSMA (Public Law 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the U.S. food supply, including both domestic and imported food. FSMA enables us to focus more on preventing food safety problems rather than primarily reacting to problems after they occur. The law also provides us with new enforcement authorities to help us achieve higher rates of compliance for both domestic and imported food with prevention- and risk-based safety standards and to better respond to and contain problems when they do occur.

Section 301 of FSMA adds section 805 to the FD&C Act (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 the following: (1) 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; (2) the food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) 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 FSVPs. Section 805(c)(2)(A) states that these regulations shall require that the FSVP of each importer be adequate to provide assurances that each of the importer's foreign suppliers produces food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under sections 418 or 419 of the FD&C Act, as appropriate, and in compliance with sections 402 and 403(w) of the FD&C Act. Section 805(c)(2)(B) states that these regulations shall include such other requirements as FDA deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

Section 805(c)(3) of the FD&C Act directs FDA to, as appropriate, take into account differences among importers and types of imported food, including based on the level of risk posed by the imported food. Section 805(c)(4) states that verification activities under FSVPs may include monitoring records for shipments, lot-by-lot certification of compliance, annual onsite inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments of imported products. Section 805(g) directs FDA to publish and maintain a list of importers participating under this section on the Agency's Web site.

Section 301(b) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding section 301(zz), which designates as a prohibited act the importation or offering for importation of a food if the importer (as defined in section 805 of the FD&C Act) does not have

in place an FSVP in compliance with section 805. In addition, section 301(c) of FSMA amends section 801(a) of the FD&C Act (21 U.S.C. 381(a)) by stating that an article of food being imported or offered for import into the United States shall be refused admission if it appears from an examination of a sample of such an article or otherwise that the importer is in violation of section 805.

In addition to the authority specified in section 301 of FSMA (adding section 805 of the FD&C Act) to issue these proposed regulations, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to promulgate regulations for the efficient enforcement of the FD&C Act. Also, some aspects of the proposed FSVP regulations are being issued under section 421(b) of the FD&C Act (21 U.S.C. 350j(b)).

Section 805(b) of the FD&C Act (in section 301(a) of FSMA) directs FDA to issue guidance to assist importers in developing FSVPs. We intend to issue guidance that will provide importers with recommendations on how to comply with the various aspects of the FSVP requirements. We intend to issue a draft FSVP guidance that addresses the final, rather than proposed, regulations. We plan to issue the draft guidance concurrently with the final rule because we believe that this would facilitate more meaningful review and comment on the draft guidance. We anticipate that we will publish the finalized FSVP guidance before importers would be required to come into compliance with the FSVP regulations. We invite comment on our proposed approach to issuance of the draft and final FSVP guidances.

B. Considerations Regarding Verification of Compliance of Imported Food with U.S. Requirements

The proposed FSVP regulations would require importers of most imported food to take risk-based steps to verify that the food they import is produced in compliance with applicable

FDA regulatory requirements. The proposed FSVP regulations are intended to work in tandem with other provisions of FSMA and the FD&C Act to create a more seamless system of food safety, applicable to both domestic and imported food, that provides appropriate layers of protection for U.S. consumers. At its core, FSMA establishes a proactive and risk-based approach that assigns to the food industry the primary responsibility for food safety. The use of preventive controls, which is one of the significant elements of this approach, is not new to FDA or the industry. FDA's regulations on the processing of juice and seafood products under HACCP systems, as well as our regulations on thermally processed low-acid foods packaged in hermetically sealed containers (low-acid canned foods or LACF), are examples of preventive controls regulations that we have issued to help ensure that those sectors of the food industry meet their obligation to produce safe food.

FSMA specifies additional explicit responsibilities for the rest of the food industry by emphasizing the use of prevention-oriented standards. In particular, FSMA requires food facilities that manufacture, process, pack, and hold food to implement hazard analysis and risk-based preventive controls (in section 103 of FSMA, codified in section 418 of the FD&C Act), with certain exceptions. FSMA also requires FDA to establish science-based, minimum standards for those that grow, harvest, pack, and hold produce (i.e., RACs that are fruits or vegetables) on a farm (also with certain exceptions) (in section 105 of FSMA, codified in section 419 of the FD&C Act). The intent of these requirements is to ensure that all segments of the food industry meet their responsibility under the FD&C Act to produce safe food.

1. Regulatory Approaches to Domestic and Imported Food

Although FDA applies the same safety standards to domestic and imported food marketed in the United States, we have long taken different regulatory compliance approaches to products produced domestically and abroad.

The logistics associated with conducting foreign inspections in most countries make the kind of unannounced routine inspections of establishments that FDA conducts domestically almost impossible. The same is true of “for cause” inspections when we have evidence of a compliance problem. FDA also has to overcome very significant hurdles to conduct foreign civil and criminal investigations and prosecutions when violations occur.

These difficulties associated with foreign inspection and enforcement are compounded by the number of foreign firms. There are more foreign firms registered with FDA than domestic firms (even though fewer kinds of foreign firms are required to register).¹ In addition, FDA is able to physically examine only a small fraction of the food that is offered for import into this country. The number of food import lines has grown significantly over the past decade, reaching nearly 10.5 million lines in fiscal year 2011, and we expect this trend to continue in the coming years (Ref. 1; Ref. 2). Finally, foreign firms can be located in places with limited infrastructure where food safety regulatory mandates may lack requirements for risk-based preventive controls or other measures, such as export programs, that provide food safety assurances.

FSMA seeks to create a strong preventive system that places primary responsibility for food safety on industry, but also continues the practice, accepted by the Codex Alimentarius Commission (Codex) (see section I.B.3 of this document), of using a different compliance approach for imported food. For inspections, section 201 of FSMA requires that FDA increase the frequency of inspections at all facilities, but prescribes different rates for domestic and

¹ Unlike domestic facilities, a foreign facility is not required to register with FDA if the food undergoes further manufacturing/processing (other than de minimis) outside the United States (21 CFR 1.226).

foreign facilities. More specifically, FDA is to inspect domestic high-risk facilities at least every 3 years, after an initial inspection within the first 5 years of FSMA's enactment. For domestic non-high-risk facilities, we must inspect at least every 5 years, after an initial inspection within the first 7 years of enactment. In contrast, FSMA only requires that we conduct at least 600 foreign inspections in the first year after enactment, and then doubles that inspection requirement each year for the next 5 years. In 2016, FDA would be required to do 19,200 foreign inspections.² Because there are currently more than 250,000 foreign food facilities registered to export food to the United States (in contrast to approximately 167,000 domestic food facilities) (Ref. 1), even completing 19,200 foreign inspections in 2016 would translate to a statutory inspection rate of less than once every 10 years.

The preventive controls and produce safety regulations discussed in section I.B.2 of this document, which are cornerstones of FSMA's strong preventive system and place primary responsibility for food safety on industry, will also apply somewhat differently to domestic and foreign producers. Under FSMA, with limited exceptions, preventive controls must be adopted by firms that are required to register with FDA. For U.S. firms, that means that most domestic facilities that manufacture, process, pack, or hold food must implement preventive controls. In contrast, under section 418 of the FD&C Act, far fewer foreign firms will be subject to preventive controls requirements. The only foreign firms that will be subject to those requirements are those facilities that export to the United States without further manufacturing/processing by another facility, except for the addition of labeling or any similar activity of a de minimis nature (section 418; 21 CFR 1.225 and 1.226).

² The Agency's ability to fully meet the foreign facility inspection requirements is contingent upon having adequate resources.

Because of the different challenges to U.S. government oversight of foreign food establishments exporting to the United States, FSMA includes several provisions that focus on imported food, including the requirement that importers establish FSVPs. FSMA also states (in section 404) that the provisions of the act and any amendments to the FD&C Act may not be construed in a way that is inconsistent with the agreement establishing the World Trade Organization (WTO) or any other treaty or international agreement to which the United States is a party. The FSVP provisions in FSMA ensure that U.S. importers, who are domestic entities, share responsibility for food safety with the foreign suppliers of those foods by requiring that importers perform risk-based supplier verification activities. This requirement, in conjunction with FDA oversight of importers, is vital to ensuring a consistent level of protection for domestic and imported foods.

FSMA's FSVP provisions build on existing approaches to importer regulation. Importers of juice and certain seafood products have for more than a decade been required to comply with FDA regulations designed to help ensure that these imported products are processed in accordance with regulations on HACCP systems for juice and seafood products in parts 120 and 123 of FDA's regulations (Title 21 of the Code of Federal Regulations) (21 CFR parts 120 and 123), respectively. The regulations applicable to seafood importers in § 123.12 became effective on December 18, 1997 (see 60 FR 65096, December 18, 1995), and the regulations applicable to juice importers in § 120.14 became effective on January 22, 2002 (see 66 FR 6138, January 19, 2001). The principal components of both the juice and seafood importer requirements are as follows:

- Establish product specifications designed to ensure that each product is not adulterated.

- Implement affirmative steps to ensure that products being offered for entry into the United States were processed under controls that meet the requirements of the relevant HACCP regulations.

- Have evidence that products offered for U.S. entry have been processed under conditions that comply with the applicable HACCP regulations.

2. Proposed Rules on Preventive Controls and Produce Safety

The understanding that the principal responsibility for food safety resides with industry forms the basis of our proposed regulations implementing not only the FSVP provisions but also the preventive controls and produce safety provisions of FSMA. On January 16, 2013, FDA published, in accordance with section 418 of the FD&C Act, a proposed rule on CGMP and hazard analysis and risk-based preventive controls for human food (the “Preventive Controls Proposed Rule”) (78 FR 3646). On the same date that we published the Preventive Controls Proposed Rule, we also published, in accordance with section 419 of the FD&C Act, a proposed rule on standards for the growing, harvesting, packing, and holding of produce for human consumption (the “Produce Safety Proposed Rule”) (78 FR 3503). Although Congress did not specifically direct us to include provisions on supplier verification in the preventive controls regulations (in contrast to its directive to establish FSVP regulations), section 103(a) of FSMA (section 418(o)(3) of the FD&C Act) states that supplier verification activities that relate to the safety of food are included among the appropriate preventive controls procedures, practices, and processes that might be used by food manufacturers and processors. Approval and verification of suppliers of raw materials and ingredients is widely accepted in the domestic and international food safety community, and, as stated in the Preventive Controls Proposed Rule, we believe that such programs are an important part of an effective preventive controls approach.

Therefore, although we did not propose specific regulations on supplier verification in the Preventive Controls Proposed Rule, we requested comment on when and how approval and verification of suppliers of raw materials and ingredients are an appropriate part of preventive controls (78 FR 3646 at 3665 to 3667). We sought comment on several different aspects of supplier approval and verification programs, including whether to require that a facility consider regulatory information about the supplier, whether to specify that the type of verification conducted be linked to the seriousness of the hazard in a food, and whether to specify the frequency with which verification activities should be conducted. In addition, we stated that “FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent” to avoid imposing duplicative requirements on entities under those regulations (because they are both a registered food facility and a food importer). We also emphasized the importance of ensuring that any supplier verification provisions that are included in the preventive controls and FSVP regulations comport with U.S. international obligations, including those under the WTO’s Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (78 FR 3646 at 3767). Elsewhere in this document, we discuss particular areas where we believe it is important to coordinate the FSVP and preventive controls regulations.

3. Consistency with Relevant International Standards and Agreements

As noted previously, section 404 of FSMA states that the provisions of FSMA are not to be construed in a manner inconsistent with U.S. international obligations. As a WTO Member, the United States must act consistently with all WTO obligations, including those contained in the SPS Agreement (Ref. 4). FSMA was notified to the WTO on February 14, 2011 (G/SPS/N/USA/2156) (Ref. 5), to provide information on the act to WTO Members. The

notification included an electronic mailbox link to receive comments from Members. Several comments have been received via the mailbox. The comments note a high degree of interest in FSMA implementation, particularly with respect to how implementation will impact developing countries.

The proposed FSVP regulations recognize the relevance of the work of Codex in establishing international food safety standards, guidelines, and recommendations. Codex was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized by the WTO as the international standards organization for food safety. In describing the general characteristics of food import control systems, the Guidelines for Food Import Control Systems (CAC/GL 47–2003) (Ref. 6) developed by the Codex Committee on Food Import and Export Inspection and Certification Systems recognize a number of related concepts, including: that countries can set their own appropriate levels of protection (para. 1); that standards should be based on risk and, as far as possible, applied equally to imported and domestic food (paras. 2, 4, 5); that there is a potential need for different approaches to compliance monitoring of domestic and imported food to ensure consistent levels of protection (e.g., para. 15); and that there is utility in conducting audits, along with using other tools, in addition to assessing importer controls to ensure that imported foods are safe, including importers' use of supplier verification systems (e.g., paras. 11, 36).

4. Public Comments on FSVPs

Our development of the proposed FSVP regulations also has been informed by the comments on FSVPs provided at the public meeting on the import safety provisions of FSMA on March 29, 2011, and the public hearing on comparability of food safety systems and import

practices of foreign countries on March 30-31, 2011, as well as the comments submitted to the public dockets for these matters (i.e., the docket for this rulemaking, FDA-2011-N-0143, and docket FDA-2011-N-0135).

C. Principal Features of the Proposed Rule

Consistent with section 805 of the FD&C Act, we are proposing a flexible approach to foreign supplier verification that addresses risk-based differences among certain types of food and their importers. We have tentatively concluded that we should focus the regulations on foreseeable food safety risks rather than all risks covered by the various adulteration provisions in section 402 of the FD&C Act. We therefore are proposing that importers develop and implement FSVPs to adequately verify the control of all hazards that are reasonably likely to occur with the food being imported. We believe that this approach, which is well accepted and understood throughout the food industry as a key component of HACCP and preventive controls, also provides the most comprehensive risk-based framework in which importers can evaluate potential products and suppliers and conduct appropriate verification efforts.

We emphasize that by using this approach to determining which hazards importers should focus on, we do not intend to indirectly impose preventive controls requirements on importers or their suppliers when they are not subject to the proposed preventive controls regulations. For example, as discussed in the Produce Safety Proposed Rule, we have already identified the reasonably foreseeable microbiological hazards associated with produce and are proposing requirements designed to ensure that those hazards are adequately controlled. Therefore, the proposed rule would not require importers of RACs that are fruits or vegetables and that are subject to the regulations on produce safety in proposed part 112 (21 CFR part 112) to reanalyze these microbiological hazards. In addition, in part because section 418 of the FD&C Act

contains an exemption relating to facilities that manufacture, process, pack, or hold dietary supplements, we are proposing a modified verification approach for such products. We also are proposing modified FSVP requirements for food from very small foreign suppliers (as determined by annual food sales), and many such suppliers would be exempt from preventive controls as “qualified facilities” under section 418. The proposed rule also would establish modified requirements for food imported by very small importers (matching the requirements for food from very small foreign suppliers). Modified requirements also would apply to food from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as “comparable” to that of the United States (e.g., through a signed systems recognition arrangement or other agreement between FDA and the country establishing official recognition of the foreign food safety system) or determined to be equivalent to that of the United States, provided the importer documents that certain conditions are met.

Another principal feature of the proposed rule is that we are presenting two different alternative proposals regarding the requirements for foreign supplier verification activities. Under Option 1, for the importation of food with hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals (SAHCODHA) (e.g., many microbiological hazards), the importer would be required, at a minimum, to conduct or obtain the results of an annual onsite audit to ensure that the foreign supplier is adequately addressing the hazards. In other situations involving less serious hazards (e.g., illegal residues of pesticides or animal drugs), importers would have more flexibility to choose an appropriate supplier verification method. Under Option 2 of the co-proposal, importers would have to select a verification activity from among onsite auditing, sampling and testing, review of the supplier’s food safety records, or some other appropriate procedure, taking into account the risk presented

by the hazard in the food, the probability that exposure to the hazard will result in serious harm, and the food and supplier's status of compliance with U.S. food safety requirements.

Importers have always had the responsibility to offer for entry into the United States products that are not adulterated (60 FR 65096 at 65153). Section 301(a) of the FD&C Act makes it a prohibited act to introduce an adulterated food into interstate commerce, which means that an importer would commit a prohibited act if it offered for import a food that is adulterated under section 402 of the FD&C Act. While many food importers already conduct activities to verify the safety of the foods they import, establishing and following FSVPs will necessitate changes to the operations of many importers, especially those that have not previously conducted significant verification activities. Although many importers will need to change at least some of their business practices and incur costs to comply with the FSVP requirements, conducting foreign supplier verification activities will help these companies ensure that the products they import meet U.S. requirements and are safe for consumption.

II. Description of the Proposed Rule

We are proposing a new subpart L to part 1 of the FDA regulations (21 CFR part 1), entitled "Foreign Supplier Verification Programs for Food Importers," to specify the content of FSVPs for importers of food for humans and animals.

A. Definitions (Proposed § 1.500)

Proposed § 1.500 sets forth the meaning of several terms that we propose to use in the FSVP regulations. Some of the definitions are self-explanatory or are being used for consistency with the Preventive Controls Proposed Rule; we discuss the definitions for which additional explanation is appropriate.

1. Audit

As set forth in proposed § 1.506(g) and (h) and discussed in section II.G of this document, the proposed rule would require onsite auditing of foreign suppliers in certain circumstances (under one proposed option) and permit onsite auditing as a mechanism for supplier verification under other circumstances. Proposed § 1.500 would define audit as the systematic, independent, and documented examination (through observation, investigation, records review, and, as appropriate, sampling and laboratory analysis) to assess a foreign supplier's food safety processes and procedures.

2. Food

Proposed § 1.500 would define food as having the meaning given in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), except that it would not include pesticides as defined in 7 U.S.C. 136(u). As discussed in the preamble to the interim final rule entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Environmental Protection Agency (69 FR 58974 at 58986, October 10, 2003). For the same reason, we tentatively conclude that pesticides were not intended to be considered "food" for purposes of section 805 of the FD&C Act and the FSVP regulations. We request comment on this exclusion and on whether there should be additional exclusions from the definition of food. Comments seeking additional exclusions should provide specific justifications.

3. Foreign Supplier

Proposed § 1.500 would define foreign supplier as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for

further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

We tentatively conclude that the proposed definition of foreign supplier makes the term generally consistent with the definition of foreign facility under the preventive controls section of the FD&C Act. Section 418(o) defines “facility” as a domestic or foreign facility that is required to register with FDA under section 415 of the FD&C Act (21 U.S.C. 350d). Section 415(b)(3)(A) defines “foreign facility” as a facility that manufactures, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States. Because (as discussed in section II.B of this document) importers generally must verify that, among other things, their foreign suppliers produce food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 of the FD&C Act, we believe that it is appropriate to define foreign suppliers in a manner that is generally consistent with the scope of section 418.

However, our proposed definition of foreign supplier does not include firms that only pack or hold food even if they are required to register with FDA under section 415 of the FD&C Act. We tentatively conclude that Congress intended the importer to verify a single foreign supplier for a particular shipment of a food and, when several entities are required to register as foreign facilities with respect to that food, excluding a subsequent (and registered) packer or holder would be consistent with this intent. As stated previously in this document, the proposed rule would state that the addition of labeling or any similar activity of a de minimis nature does not constitute further processing or packaging. This proposed limitation to the definition of foreign supplier is consistent with FDA’s regulations on the registration of foreign food facilities

in § 1.226(a). Because section 805 of the FD&C Act is not limited to suppliers that are subject to section 418 of the FD&C Act, the proposed definition of foreign supplier is not limited to registered facilities. In addition to establishments that manufacture/process food, the definition also encompasses establishments that raise animals or harvest food (unless the animal or harvested food is further manufactured or processed by another establishment).

4. Hazard and Hazard Reasonably Likely to Occur

Proposed § 1.500 would define hazard as any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control. Proposed § 1.500 would define hazard reasonably likely to occur as a hazard for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls. These definitions match those that appear in the Preventive Controls Proposed Rule.

5. Importer

The term “importer” is defined in section 801(a)(2) of the FD&C Act as follows: “(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or (B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.”

Under proposed § 1.500, the importer of a food would be the U.S. owner of the food if there is one or the consignee if there is not a U.S. owner at the time of entry. Thus, importer would be defined as the person in the United States who has purchased an article of food that is

being offered for entry into the United States; if the article of food has not been sold at the time of U.S. entry, the importer would be the person in the United States to whom the article has been consigned at the time of entry; if the article of food has not been sold or consigned at the time of U.S. entry, the importer would be the U.S. agent or representative of the foreign owner or consignee at the time of entry.

Under the proposed definition, the importer of an article of food might be, but would not necessarily be, the importer of record of the article, i.e., the individual or firm responsible for making entry and payment of import duties. We agree with the majority of comments we received on how to define “importer,” which stated that the person who caused a food to be imported is the person who should be responsible for verifying that the food was produced in accordance with applicable U.S. safety requirements. This person has a direct financial interest in the food and is most likely to have knowledge and control over the product’s supply chain. This person is more likely to be the food’s U.S. owner (or consignee) than the importer of record for the food, which 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 U.S. Customs and Border Protection (CBP).

In cases in which a food has not been sold or consigned to a person in the United States at the time of entry, the foreign owner or consignee would need to have a U.S. agent or representative who would be responsible for meeting the FSVP requirements. To make this clear, proposed § 1.509(a) states (as discussed in section II.J.1 of this document) that before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the article (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer” in §

1.500. This would ensure that there is an entity in the United States who is responsible for meeting the various FSVP requirements, which would improve importer accountability and Agency oversight and enforcement.

Some importers obtain food from foreign suppliers who are part of the same corporate structure as the importer and who may, along with the importer, be subject to a single integrated, company-wide approach to food safety in which hazards are controlled and verified by a common supply chain management system. We request comment on whether importers should not be required to conduct foreign supplier verification, or should be subject to different FSVP requirements, when importing food from entities under the same corporate ownership and, if so, the specific justifications and conditions under which foreign supplier verification should not be required or should be modified.

6. Qualified Individual

Proposed § 1.500 would define qualified individual as a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart; this person may be, but is not required to be, an employee of the importer. Depending on the applicable requirements, a qualified individual would need to be capable of performing, for example, food hazard analysis and verification of foreign supplier processes and procedures to ensure that hazards are adequately controlled. Proposed § 1.500 further states that, regarding the performance of verification activities related to preventive controls implemented by the foreign supplier in accordance with section 418 of the FD&C Act, a qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and

implement a food safety system. We are proposing to define the term qualified individual in a slightly different way in the FSVP regulations than in the Preventive Controls Proposed Rule because not all of the foreign suppliers from which importers obtain their food products will be subject to the preventive controls regulations. Therefore, when an importer obtains food from a foreign supplier that is not subject to section 418 of the FD&C Act, such as a manufacturer of dietary supplements, a qualified individual performing FSVP activities for the importer would need to have appropriate education, training, and experience to conduct those activities, but would not necessarily have to be trained or have experience in the development and implementation of the particular risk-based preventive controls required under section 418. We request comment on whether the definition of qualified individual should include additional requirements regarding education, training, and experience.

As noted, the qualified individual may be, but is not required to be, an employee of the importer. The entity best suited to handling supplier verification may not fall within the definition of “importer” as proposed in this rule. The flexibility in the definition of qualified individual means that another entity may be able to conduct many of the supplier verification activities on the importer’s behalf.

Proposed § 1.500 further states that the term qualified individual includes, but is not limited to, a third-party auditor that has been accredited in accordance with section 808 of the FD&C Act. As discussed more fully in section II.G.7.a.i of this document, section 307 of FSMA (codified in section 808 of the FD&C Act (21 U.S.C. 384d)) directs us to establish a system for the recognition of accreditation bodies that can accredit third-party auditors as being qualified to conduct food safety audits of foreign suppliers, as well as to develop model accreditation standards. Elsewhere in this issue of the Federal Register (78 FR XXXXX), we are publishing a

proposed rule to establish a third-party accreditation system in accordance with section 808. We anticipate that in the future many importers will rely on onsite audits conducted at the request of foreign suppliers by third-party auditors accredited in accordance with section 808 to verify that the importers' foreign suppliers are producing food in accordance with U.S. requirements. We expect that this will reduce the costs of complying with the FSVP regulations for both importers and foreign suppliers by reducing the number of onsite audits that importers conduct themselves. However, even after FDA has implemented section 808 and importers begin using accredited third-party auditors to provide verification of their foreign suppliers in accordance with the FSVP regulations, we believe that it would be acceptable for an importer to rely on an audit conducted by a third-party auditor who is a qualified individual but is not accredited in accordance with section 808. We invite comment on whether, at some future date and/or under particular circumstances, importers should no longer be permitted to rely on third-party auditors who are not accredited in accordance with section 808 to conduct onsite audits or other FSVP activities.

In addition, proposed § 1.500 states that an employee of a foreign government may be a qualified individual. We believe that this provision is appropriate because foreign food safety authorities might conduct certain activities on which an importer might rely in complying with its FSVP requirements. For example, as part of an importer's supplier verification activities, the importer might rely on the results of an onsite audit of a foreign supplier conducted by an employee of the food safety authority in that country. Although a foreign food safety authority could be an accredited third-party auditor under section 808 of the FD&C Act, an importer's use of foreign government employees as qualified individuals would not be limited to such

accredited auditors. We request comment on ways in which importers might rely on the actions of foreign government employees in complying with FSVP requirements.

7. Raw Agricultural Commodity

As previously stated, this proposed rule includes provisions on foreign supplier verification with respect to RACs that are fruits or vegetables. Proposed § 1.500 states that raw agricultural commodity means “raw agricultural commodity” as defined in section 201(r) of the FD&C Act (21 U.S.C. 321(r)).

8. Very Small Importer and Very Small Foreign Supplier

As stated in section I.C of this document, we propose to apply modified FSVP requirements (set forth in proposed § 1.512, discussed in section II.M of this document) to very small importers of food and to food from very small foreign suppliers. Proposed § 1.500 would define very small importer as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$500,000, adjusted for inflation. Likewise, very small foreign supplier would be defined as a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$500,000, adjusted for inflation. The limitation of \$500,000 in annual food sales is consistent with the sales limitation in the definitions of “qualified facility” in the Preventive Controls Proposed Rule and “small business” in the Produce Safety Proposed Rule. As discussed more fully in section II.M of this document, we believe that it is appropriate

to establish certain modified FSVP requirements for very small importers and food from very small foreign suppliers under proposed § 1.512.

We tentatively conclude that it is appropriate to limit the scope of the definition of “very small importer” to those importers that have no more than \$500,000 in annual food sales. Because the sales value of food is related to the volume of food being brought into the United States by the importer or shipped to this country by the supplier, use of this dollar-value ceiling would help limit the total volume of food imported under these modified provisions.

Our proposed approach to the definitions of very small importer and very small foreign supplier and the FSVP requirements for these entities is discussed further in section II.M of this document. We believe that our proposed approach to defining very small importers and foreign suppliers is an appropriate as well as workable way to determine which importers and foreign suppliers would be subject to modified FSVP requirements. We request comment on this approach, including whether the limit of \$500,000 in annual food sales is appropriate. We also request comment on whether the definitions should apply only to U.S. sales of food by the importer or the foreign supplier, rather than worldwide sales by these entities.

We note that the Preventive Controls Proposed Rule includes three options for a proposed definition of “very small business,” a term that is relevant to three provisions of that proposed rule (78 FR 3646 at 3701). The proposal specifies three options for the limit on total annual food sales under the definition of very small business: \$250,000, \$500,000, or \$1,000,000. We request comment on whether the definitions of very small importer and very small foreign supplier under the FSVP regulations should take into account the definition of very small business under the preventive controls regulations and, if so, what limit on total annual food sales would be appropriate for use in these definitions.

B. Applicability and Exemptions (Proposed § 1.501)

Proposed § 1.501 answers the question, “To what foods do the regulations in this subpart apply?” Proposed § 1.501(a) states that, except as specified otherwise in § 1.501, the regulations in subpart L apply to all food imported into the United States and to the importers of such food. Proposed § 1.501(b) through (e) set forth exemptions and exceptions from subpart L for several types of foods: food from juice and seafood HACCP facilities that are in compliance with the HACCP regulations; food imported for research or evaluation purposes; food for personal consumption; alcoholic beverages; and food that is transshipped or imported for further processing and export.

1. Exemption for Food from Juice and Seafood HACCP Facilities

In accordance with section 805(e)(1) and (e)(2) of the FD&C Act, proposed § 1.501(b) would exempt products from certain juice and seafood facilities from subpart L. Section 805(e) states that the foreign supplier verification requirements “shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with,” the HACCP regulations for seafood or juice. Section 805(e) further states that the exemption applies to “a facility” that is required to comply with and is in compliance with the juice or seafood HACCP regulations. This raises the question of whether the word “facility” in this context relates to the foreign supplier or the importer.

The language of section 805(e) of the FD&C Act mirrors the language of the juice and seafood HACCP exemption in section 418 of the FD&C Act, which exempts facilities that are required to comply with and are in compliance with HACCP for juice or seafood from the hazard analysis and risk-based preventive controls required by that section. Given that many foreign suppliers are facilities subject to section 418, and given the role that importers play under section

805 in verifying foreign supplier compliance with applicable U.S. food safety regulations, we tentatively conclude that it was Congress's intent that section 805(e) apply to food being imported from foreign suppliers that are facilities subject to and in compliance with FDA requirements for juice or seafood HACCP. The importer would still be required to verify a foreign supplier's compliance with the juice or seafood HACCP provisions, but would do so under the regulations that are specific to those foods.

There are at least two other potential readings of section 805(e)'s language. One is that section 805(e) would apply to importers that are facilities subject to and in compliance with the juice or seafood HACCP regulations. This interpretation does not account for the fact that not all importers are facilities (e.g., a commodity broker that does not manufacture/process, pack, or hold food), so it would not exempt such an importer even if the juice or seafood products have been produced in compliance with the applicable HACCP requirements. The other reading is that section 805(e) would apply to importers, whether or not they are facilities, that are subject to the importer verification provisions of the juice or seafood HACCP regulations. However, this interpretation is not consistent with the language of section 805(e), which states that it applies to facilities. Thus, we tentatively conclude that the proposed reading that section 805(e) applies to food being imported from foreign suppliers that are facilities subject to and in compliance with FDA requirements for juice or seafood HACCP effectuates the purpose of the FSVP provisions more clearly than either of these other possible interpretations.

Therefore, proposed § 1.501(b) states that the regulations in subpart L do not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the regulations on juice in part 120 or the regulations on fish and fishery products in part 123. Proposed § 1.501(b) further states that

importers of juice and seafood products that are subject to the regulations in part 120 or part 123, respectively, must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12, respectively. Among other things, those provisions require importers to implement written procedures for ensuring that imported products were 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. Thus, § 1.501(b) makes clear that, in accordance with section 805(e) of the FD&C Act, importers of juice or seafood HACCP products from foreign suppliers that are facilities required to comply with and in compliance with the juice or seafood HACCP regulations are not subject to the verification requirements in the FSVP regulations.

We recognize that section 805 of the FD&C Act and the implementing regulations we are proposing set forth a more comprehensive approach to verification than the existing juice and seafood HACCP regulations. As noted in section I.B of this document, the juice and seafood importer provisions were adopted more than a decade ago. The U.S. Government Accountability Office (GAO), in its April 2011 report entitled “Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources” (Ref. 7), noted that the seafood importer regulations allow importers to obtain a copy of the foreign processor’s HACCP plan and an attestation that the foreign firm processes its seafood products in compliance with the HACCP regulations without also requiring an onsite audit. The GAO report noted some concerns that the purposes of this provision and the HACCP regulations can be defeated if a foreign processor claims to have a HACCP plan that it is not actually following and the importer does not visit the processor to determine whether the processor is implementing the plan it has

provided to the importer. In light of FSMA's increased emphasis on the safety of imported food and importers' role in ensuring food safety, as well as the proposed FSVP regulations discussed in this document, we are considering whether it would be appropriate in the future to initiate a rulemaking to revise the regulations applicable to importers of juice and seafood.

2. Food Imported for Research or Evaluation or for Personal Consumption

Section 805(f) of the FD&C Act states that FDA, by notice published in the Federal Register, shall establish an exemption from the requirements of section 805 for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public. We tentatively conclude that it is appropriate to include these section 805 exemptions in the proposed regulations implementing that section to allow interested persons to comment on how we propose to implement these exemptions.

Regarding food for research or evaluation, proposed § 1.501(c) states that the regulations in subpart L do not apply to food that is imported for research or evaluation purposes, provided that:

- Such 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."
- When filing entry for the food with CBP, the importer of record provides an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

The latter two provisions are intended to help ensure that the food is, in fact, not intended for retail sale and is not sold or distributed to the public. We tentatively conclude that they would provide an efficient and effective means of determining whether a food is exempt.

Proposed § 1.501(c) further states that food is considered to be imported for research or evaluation purposes only if it is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose and the entire quantity is used for this purpose.

Under proposed § 1.501(d), the regulations in subpart L would not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Proposed § 1.501(d) further states that food is considered to be imported for personal consumption when it is purchased or otherwise acquired by a person in a small quantity for a non-commercial purpose and is not sold or distributed to the public.

We request comment on the proposed exemptions from the FSVP requirements for food imported for research use or for personal consumption, in particular regarding whether and how to define the amount of food that constitutes a “small quantity.”

3. Exemption for Alcoholic Beverages

Section 116(a) of FSMA (21 U.S.C. 2206(a)) provides that, except as provided by certain listed sections in FSMA, nothing in FSMA, or the amendments made by FSMA, shall be construed to apply to a facility that (1) 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.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and (2) under section 415 of the FD&C Act is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages (with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages).

Section 116(b) of FSMA provides that section 116(a) shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that section 116(a) shall apply to a

facility described in section 116(a) that receives and distributes non-alcohol food, provided such food is received and distributed (1) in a prepackaged form that prevents any direct human contact with such food and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.

Section 116(c) of FSMA provides that, except as provided in section 116(a) and (b), section 116 shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of FSMA (including amendments made by FSMA).

The Preventive Controls Proposed Rule includes provisions implementing the exemptions provided in section 116 of FSMA to establish by regulation the reach of the exemptions. As discussed in the Preventive Controls Proposed Rule, FDA tentatively concludes the following regarding the reach of the exemptions for the purposes of that rule:

- The phrase “obtain a permit or register” should be interpreted broadly, to include not only facilities that must obtain what is technically named a “permit” or must “register” with Treasury, but also those facilities that must adhere to functionally similar requirements as a condition of doing business in the United States, namely, by submitting a notice or application to Treasury and obtaining Treasury approval of that notice or application.

- The exemption would apply not only to domestic facilities that are required to secure a permit, registration, or approval from Treasury under the relevant statutes, but also to foreign facilities of a type that would require such a permit, registration, or approval if they were domestic facilities.

- Activities related to alcoholic beverages (including the manufacturing, processing, packing, or holding of alcoholic beverages) at facilities within the scope of section 116(a) of

FSMA would not be subject to section 418 of the FD&C Act. Activities related to foods other than alcoholic beverages (including the receiving, manufacturing, processing, packing, holding, and distributing of such foods) would be subject to section 418 even if those activities occur at facilities that are otherwise within the scope of section 116(a) (unless they qualify for another exemption or are in prepackaged form and constitute 5 percent or less of the facility's overall sales). (For clarity, we use the term "food other than alcoholic beverages" rather than "non-alcohol food" in the Preventive Controls Proposed Rule and in this document.)

- Section 418 of the FD&C Act does not apply to the manufacturing, processing, packing, or holding of food other than alcoholic beverages to the extent that it is physically inseparable from the manufacturing, processing, packing, or holding of alcoholic beverages.

Section 116 of FSMA is premised in part upon status as a facility required to register under section 415 of the FD&C Act (section 116(a)(2) of FSMA). Under the definition in this proposed rule, an "importer" might be a registered facility but would not necessarily be one. If the alcoholic beverages exemption from the FSVP regulations was based on whether the importer of an alcoholic beverage was a registered facility, two firms might import the same product (e.g., a bottled alcoholic beverage) and one would be eligible for the alcoholic beverage exemption from the FSVP regulations because it is required to register (e.g., it packs or holds the alcoholic beverage), while the other would not be eligible for this exemption because it is not required to register (e.g., it is a commodity broker that does not manufacture, process, pack, or hold food for consumption in the United States, or it is a restaurant or retailer). The latter importer would need to conduct supplier verification under section 805 of the FD&C Act while the former would not. Under this interpretation, an importer would be exempt from the section 805 requirements if the importer is a facility required to register under section 415 of the FD&C

Act and the importer and the food in question (i.e., the alcoholic beverage or food other than alcoholic beverages) otherwise meet the requirements for exemption under section 116 of FSMA.

An alternative approach to the alcoholic beverages exemption from the FSVP regulations would focus on the foreign supplier. If an alcoholic beverage is being imported, under our proposal the foreign supplier would, by definition, be a facility that is required to register. Our proposed definition of “foreign supplier” means that the supplier would be engaged in manufacturing/processing the alcoholic beverage and that this beverage would not undergo further manufacturing/processing before being exported to the United States, except for labeling or any similar activity of a de minimis nature (see 21 CFR 1.226 regarding foreign facility registration). Under this interpretation, whether an imported food is exempt from section 805 of the FD&C Act would not depend on who the importer happens to be, but the nature of the product being imported -- whether the foreign supplier and the food in question (i.e., the alcoholic beverage or food other than alcoholic beverages) meet the requirements for exemption under section 116 of FSMA. This interpretation is consistent with our approach to the alcoholic beverages exemption in the Preventive Controls Proposed Rule. In considering the two proposals together, if a foreign supplier is exempt from section 418 of the FD&C Act by operation of section 116 of FSMA for a particular food, then the importer would not be required to conduct verification of the supplier for the food under section 805. For these reasons, we tentatively conclude that the second approach better effectuates the intent of section 805 and it is appropriate to exempt certain alcoholic beverages, under the conditions stated in proposed § 1.501(e), from the scope of the FSVP regulations.

Therefore, under proposed § 1.501(e)(1)(i) and (e)(1)(ii), the FSVP regulations would not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

- Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

- Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

Proposed § 1.501(e)(2)(i) and (e)(2)(ii) would specify that the FSVP regulations would not apply with respect to food other than alcoholic beverages that is imported from a foreign supplier described in § 1.501(e)(1), provided such food:

- Is in prepackaged form that prevents any direct human contact with such food; and
- Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

We request comment on our proposed exemption of alcoholic beverages and food other than alcoholic beverages under the conditions specified in proposed § 1.501(e).

4. Inapplicability to Food for Transshipment and Export

Some food is imported into the United States but is not distributed into the U.S. market. For example, some food is transshipped from a foreign country through the United States to a different country. In addition, food may be imported into the United States, subjected to manufacturing or processing, and exported to another country without being consumed or

distributed in U.S. commerce. Section 805 of the FD&C Act applies to “each importer” and “the food imported by the importer or agent of an importer.” This could mean that the FSVP requirements apply to all food that is brought across the U.S. border except where there is a specific exemption, such as the exemption for food imported for personal consumption. However, taking into consideration the context of section 805 of the FD&C Act, under which the importer must take affirmative steps to verify the compliance of the food with U.S. safety requirements, we tentatively conclude that section 805 is not intended to apply to food that is neither consumed nor distributed in the United States. Therefore, under proposed § 1.501(f), the regulations in subpart L would not apply to food that is:

- Transshipped through the United States to another country; or
- Imported for future export and that is neither consumed nor distributed in the United States.

C. Scope of FSVP (Proposed § 1.502)

Proposed § 1.502 answers the question, “What foreign supplier verification program (FSVP) must I have?” This section addresses the scope of FSVPs.

As noted above, section 805(c)(2) of the FD&C Act sets forth the scope of an importer’s FSVP, i.e., the program must be adequate to provide assurances that each of the importer’s foreign suppliers produces food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419, as appropriate, and with sections 402 and 403(w). We tentatively conclude that the scope of an appropriate FSVP should be as set forth below.

1. General Standard and Verification Approach

Proposed § 1.502(a) states that, except as specified in proposed § 1.502(b), for each food imported, the importer must develop, maintain, and follow an FSVP that provides adequate assurances that its 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 is producing the food in compliance with sections 402 and 403(w). Under this provision, importers would be required to develop procedures for the operation of their FSVPs, such as procedures for the following:

- Review of the compliance status of foods and foreign suppliers
- Analysis of hazards reasonably likely to occur with foods
- Determination and performance of appropriate foreign supplier verification activities for foods
- Review of complaints, investigation of adulteration or misbranding, and taking of corrective actions
- Reassessment of the FSVP
- Ensuring that required information is submitted at entry
- Maintenance of records

We tentatively conclude that by developing, maintaining, and following an FSVP that meets the requirements set forth in this proposed rule, an importer would be able to provide assurances that its foreign suppliers were producing food in a manner consistent with the preventive controls or produce safety regulations (if either were applicable) as well as provide assurances that the food is not adulterated or misbranded regarding allergen labeling.

2. Low-Acid Canned Food

In accordance with section 805(e) of the FD&C Act, proposed § 1.502(b) sets forth a standard for FSVPs regarding the importation of thermally processed low-acid canned foods packaged in hermetically sealed containers (low-acid canned foods) that differs slightly from the standard in proposed § 1.502(a). Section 805(e) states that section 805 does not apply to LACF facilities that are required to comply, and are in compliance, with the FDA standards and regulations on LACF, but only with respect to the microbiological hazards regulated under part 113 (21 CFR part 113). With respect to all other types of hazards for LACF, section 805 would apply. Therefore, under proposed § 1.502(b), with respect to those microbiological hazards that are controlled by part 113, an importer of a low-acid canned food must verify and document that the food was produced in accordance with part 113. An importer of a low-acid canned food would not know if it was importing the food from a foreign supplier whose facility was in compliance with part 113 (and thus eligible for the exemption from section 805 with respect to microbiological hazards) unless it conducted some appropriate form of verification, such as auditing. We tentatively conclude that following the FSVP provisions would be an appropriate verification approach if the importer chose to follow this for all LACF hazards, including microbiological hazards. Proposed § 1.502(b) further states that, with respect to all matters that are not controlled by part 113, an importer of a low-acid canned food must have an FSVP as specified in proposed § 1.502(a).

3. Food Imported by Facilities Subject to the Preventive Controls Requirements

Many domestic food manufacturers, both large and small companies, import food ingredients for use in the food products they manufacture or process. These facilities are (with

certain exceptions) subject to section 418, and they will be subject to the preventive controls regulations once those regulations become effective.

As stated in section I.B of this document, the Preventive Controls Proposed Rule seeks comment on when supplier approval and verification programs would be appropriate food safety requirements under the preventive controls regulations, as well as comment on what specific supplier approval and verification requirements are appropriate. As stated in that proposed rule and in section I.B of this document, we recognize the importance of coordinating the final preventive controls and FSVP regulations to avoid duplicative requirements, as well as the importance of ensuring that the food safety measures we adopt are consistent with U.S. international trade obligations, including those contained in the SPS Agreement.

We request comment on how to address foreign supplier verification by importers who could be subject to both the FSVP and preventive controls regulations to prevent the imposition of any duplicative supplier verification requirements. For example, should the FSVP regulations state that an importer that is also required to establish a supplier approval and verification program under the preventive controls regulations for a food, and is in compliance with those regulations, is deemed to be in compliance with the FSVP regulations that address the same matters?

We intend to publish in the near future a proposed rule on preventive controls for animal food that will be similar to the Preventive Controls Proposed Rule applicable to human food. We expect to issue the final rule on FSVPs concurrently with the final rules on preventive controls for human food and animal food, and we expect to adopt the same approach for animal food as we do for human food regarding importers that are in compliance with any supplier

verification provisions in those respective preventive controls regulations. We request comment on this proposed approach.

4. Food for Which Importers' Customers Are Subject to the Preventive Controls Requirements

In some cases, an importer's customer is a domestic food facility that would be subject to any supplier verification requirements that we might ultimately adopt as part of the preventive controls regulations. As with the above-described circumstances involving importers who themselves would be subject to any supplier verification requirements under the preventive controls regulations, we believe that requiring importers to conduct verification activities that their customers would have to conduct would not provide additional assurance of the safety of the imported food. Therefore, we request comment on how to coordinate the FSVP and preventive controls regulations to avoid imposing duplicative requirements on importers whose customers could be subject to any supplier verification requirements that are ultimately included in the preventive controls regulations. For example, would it be appropriate for the FSVP regulations to state that an importer whose customer is required to establish a supplier approval and verification program under the preventive controls regulations for a food is deemed to be in compliance with the FSVP regulations? We also request comment on what assurance, if any, importers should be required to obtain from their customer that the customer is in compliance with any preventive controls supplier verification requirements and the frequency with which they should obtain any such assurance.

D. Personnel (Proposed § 1.503)

Proposed § 1.503 answers the question, "Who must develop my FSVP and perform FSVP activities?" Proposed § 1.503 states that, except with respect to the requirements in proposed §§ 1.506(a) (concerning listing of foreign suppliers), 1.509 (concerning steps that an

importer must take to ensure that it is identified as the importer of a food when the food is offered for entry into the United States), 1.510 (concerning record keeping), 1.511(c)(2) (concerning listing of foreign suppliers of finished dietary supplements), and 1.512(b)(3) and (b)(6) (concerning listing of foreign suppliers and record keeping by very small importers and importers of food from very small foreign suppliers), a qualified individual must develop an importer's FSVP and perform each of the activities required under subpart L. These activities include: reviewing a food and supplier's compliance status; conducting hazard analysis and foreign supplier verification; reviewing complaints, conducting investigations, and taking corrective actions; and reassessing the FSVP and making any appropriate changes.

Education and training are important to the effective development and implementation of an FSVP, including activities such as: identifying hazards that are reasonably likely to occur in foods; evaluating controls that are intended to address those hazards; assessing the appropriateness of the use of different verification activities for different types of hazards; and determining whether investigatory and corrective actions are appropriate. In addition, the products produced by the food industry are diverse, and the hazards that are reasonably likely to occur with a particular food and in a particular facility depend on a range of factors.

Proposed § 1.503 is consistent with regulations and guidelines requiring the use of trained individuals to conduct food safety operations. The HACCP guidelines issued by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommend that experts who are knowledgeable in the food process either participate in or verify the completeness of the HACCP plan (Ref. 8). Our HACCP regulations for juice and seafood require that a trained individual be responsible for developing the hazard analysis (juice only), developing the HACCP plan, verifying and modifying the HACCP plan, and performing the record review (§§ 120.13

and 123.10, respectively). These regulations also state that job experience will qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through a standardized HACCP curriculum recognized as adequate by FDA. The U.S. Department of Agriculture's (USDA's) HACCP regulations for meat and poultry state that only an individual who has completed a training course may conduct certain activities, such as development and modification of the HACCP plan (9 CFR 417.7).

In accordance with the proposed definition of "qualified individual," proposed § 1.503 would mean that an importer would need to employ or obtain or otherwise rely on the services of a person with the necessary education, training, and experience to perform all FSVP activities except those specifically exempted from § 1.503. When these activities involve the review of food safety plans established in accordance with section 418 of the FD&C Act, the qualified individual would need to have training in the principles of hazard analysis and risk-based preventive controls as set forth in section 418.

E. Review of Food and Foreign Supplier Compliance Status (Proposed § 1.504)

Proposed § 1.504 answers the question, "What review of a food and foreign supplier's compliance status must I conduct?" We tentatively conclude that a prudent and responsible importer should review readily-available information regarding whether the Agency has identified any compliance problems with the food or the foreign supplier. Therefore, proposed § 1.504 would require an importer, before importing a food from a foreign supplier, to assess the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. (As discussed in section

II.G.7 of this document, under proposed § 1.506(g), an importer also would be required to consider the food and supplier's compliance status as assessed under § 1.504 in determining appropriate verification activities.)

FDA warning letters and import alerts are available on the Agency's Web site. Section 801(q) gives FDA the authority to require, as a condition for granting admission into the United States to an article of food, that a certification (or other assurance) that the article complies with applicable requirements of the FD&C Act be provided by either (1) an Agency or a representative of the government of the country from which the article of food originated (as designated by FDA) or (2) a person or entity accredited under section 808 of the FD&C Act to provide such certification or assurance. Other information relevant to the compliance status of a food or foreign supplier, which an importer might obtain from FDA or the foreign supplier, could include FDA Form 483s, Establishment Inspection Reports, recall notices, and documents relating to injunctions or seizures. Proposed § 1.504 also would require an importer to document this review and to continue to monitor and document the compliance status as long as the importer obtains the food from the foreign supplier.

We request comment on what compliance information about a food or foreign supplier an importer should be required to obtain and consider as part of its food/supplier compliance status review. We also request comment on whether this information should include information about a foreign supplier's compliance standing with the food safety authority of the country in which it is located.

F. Hazard Analysis (Proposed § 1.505)

Proposed § 1.505 answers the question, "What hazard analysis must I conduct?" As discussed in section I.C of this document, we believe that identification of the hazards that

commonly occur with a food is a widely accepted principle of food safety. Incorporating this principle into the proposed FSVP regulations, we tentatively conclude that it is appropriate for importers to identify the hazards that are reasonably likely to occur with the foods they import so that they can conduct verification activities to provide assurance that these hazards are being controlled. We also believe that identification of hazards that are likely to occur will be an effective, risk-based way of focusing importers' verification efforts on ensuring that the appropriate food safety risks have been addressed.

1. Hazard Analysis

Proposed § 1.505(a) would require each importer, except as permitted under proposed § 1.505(d) (discussed in section II.F.4 of this document) and (e) (discussed in section II.F.5 of this document), to determine, for each food imported, the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur. Proposed § 1.505(a) further states that the importer must document this determination and use it to determine appropriate verification activities in accordance with proposed § 1.506.

In accordance with Congress's directive to use a risk-based approach to foreign supplier verification, the proposed rule would require that the importer identify only the hazards that are reasonably likely to occur with the foods they import. Careful assessment of known or reasonably foreseeable hazards will ensure that an importer has determined whether they are reasonably likely to occur and, if they are, whether the foreign supplier of the food has the capability to produce the food in a manner that will adequately control such hazards. In turn, the importer's verification activities will focus on ensuring that its foreign supplier has adequately controlled such hazards during the food's production (or, in some cases, that an entity such as the

importer, the importer's customer, or the supplier of a raw material to the foreign supplier is controlling the hazard). Because hazard analysis is widely accepted in the industry as a fundamental principle of food safety, we tentatively conclude that it is appropriate to require that importers use this basic approach for FSVPs, unless there are applicable FDA food safety regulations intended to comprehensively address all hazards, or a specific subset of the hazards, relevant to a food (e.g., RACs that are fruits or vegetables). We also are proposing this approach to focus importers' verification efforts on those hazards that are reasonably likely to occur and thus can be addressed through routine verification. We request comment on this proposed approach.

We also tentatively conclude that it is appropriate to require importers to consider the severity of the illness or injury if a hazard determined to be reasonably likely to occur were to in fact occur. As discussed in the Preventive Controls Proposed Rule, the HACCP regulations issued by FDA and the USDA, the NACMCF HACCP guidelines (Ref. 8), and the HACCP annex to the Codex General Principles of Food Hygiene (Codex HACCP Annex) (Ref. 9) all recognize the importance of considering the severity of the effects of a hazard when conducting a hazard analysis for a food.

2. Potential Hazards

Proposed § 1.505(b) states that an importer's evaluation of the hazards that are reasonably likely to occur with each food that is imported must consider the following potential hazards that may occur naturally or may be unintentionally introduced:

- Biological hazards, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance;

- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;
- Physical hazards; and
- Radiological hazards.

These hazards are the kinds of contaminants and materials that can lead to adulteration under section 402 of the FD&C Act. The Preventive Controls Proposed Rule includes a discussion of each of these types of hazards and the circumstances under which each can pose a risk to public health (78 FR 3646 at 3734 to 3735). We tentatively conclude that it is also appropriate for food importers to examine these potential hazards as part of their FSVPs (with exceptions discussed elsewhere in this document).

We also tentatively conclude that it is appropriate to require importers to consider only those hazards that occur naturally or may be unintentionally introduced. Intentional hazards raise different issues and concerns. We plan to address the issue of certain intentionally introduced hazards as part of our rulemaking to implement section 106 of FSMA (codified in section 420 of the FD&C Act (21 U.S.C. 350i)), which directs FDA to issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. However, we also recognize that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods for which there is a widely recognized risk of economically motivated adulteration in certain circumstances. An example of this kind of hazard is the addition of melamine to certain food products apparently to enhance perceived quality and/or protein content. We request comment on whether to include potential hazards that may be

intentionally introduced for economic reasons. We also request comment on when an economically motivated adulterant can be considered reasonably likely to occur.

3. Hazard Evaluation

Proposed § 1.505(c) states that, in evaluating the hazards in § 1.505(b), the importer must consider the effect of several factors on the safety of the finished food for the intended consumer. These factors, listed in proposed § 1.505(c)(1) through (c)(9), are as follows:

- The ingredients of the food;
- The condition, function, and design of the foreign supplier's establishment and equipment;
- Transportation practices;
- Harvesting, raising, manufacturing, processing, and packing procedures;
- Packaging and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors.

We tentatively conclude that these are factors that a prudent person who imports food would consider when evaluating hazards to determine those that are reasonably likely to occur with a food. Further information regarding such factors is provided in the Preventive Controls Proposed Rule (78 FR 3646 at 3736 to 3738). We expect that importers (or the qualified individuals assisting them) will obtain information on these factors from FDA guidance, scientific and technical experts, published scientific literature, trade publications, and foreign suppliers of these foods.

Proposed § 1.505(c)(1) would require that the hazard evaluation consider the ingredients of the imported food. Examples of problems that might occur with a product's ingredients include the presence of an undeclared allergen and inadequate roasting of nuts used in a food product.

Proposed § 1.505(c)(2) would require that the hazard evaluation consider the condition, function, and design of the establishment and equipment of the foreign supplier. The condition, function, or design of an establishment or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling, and conveying equipment) may be more difficult to clean (e.g., with close-fitting components or hollow parts) and, therefore, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in such environments. Equipment designed so that there is metal-to-metal contact may generate metal fragments. An establishment that manufactures soft, fresh cheese (such as queso fresco, which is a ready-to-eat product) may have cold, moist conditions that are conducive to the development of a niche where the pathogen Listeria monocytogenes can become established and contaminate food-contact surfaces and, eventually, foods. An establishment design that has closely spaced equipment would provide more opportunities for cross-contact of allergens (such as powdered milk or soy) from one line to another (e.g., through dust) than a facility that has more spacing between equipment.

Proposed § 1.505(c)(3) would require that the hazard evaluation consider transportation practices. A food may become unsafe as a result of poor transportation practices. For example, for certain types of food, a supplier may need to take into account the method of transporting the

food in developing its preventive controls, such as for food that is temperature sensitive or susceptible to cross-contamination.

Proposed § 1.505(c)(4) would require that the hazard evaluation consider harvesting, raising, manufacturing, processing, and packing procedures. Examples of hazards that could arise during harvesting include contamination with aflatoxin or a pesticide, and the introduction of a physical hazard such as glass during mechanical harvesting. Hazards may arise from manufacturing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic spore-forming bacteria such as Clostridium perfringens and Bacillus cereus (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing processes such as acidification due to the potential for germination of spores of C. botulinum, with subsequent production of botulinum toxin, if the acidification is not done correctly and the packaging environment otherwise supports C. botulinum growth and toxin formation. Toxins can be produced by the bacteria Staphylococcus aureus or B. cereus in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth of the bacteria and S. aureus or B. cereus is present in the ingredients of the product. Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades, knives) is used to cut products during manufacturing.

Proposed § 1.505(c)(5) would require that the hazard evaluation consider packaging activities and labeling activities. For example, whether a product is packaged in glass bottles or in plastic bottles could affect what hazards are reasonably likely to occur with the product.

Proposed § 1.505(c)(6) would require that the hazard evaluation consider storage and

distribution of a food. For example, biological hazards are more likely to be reasonably likely to occur during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods, which are designed for control of biological hazards.

Proposed § 1.505(c)(7) would require that the hazard evaluation consider the intended or reasonably foreseeable use of a food. For example, if the product may either be cooked by the consumer or used in a manner that does not involve cooking, e.g., a soup mix used as a component of a dip, hazards such as Salmonella would need to be considered to determine if they are reasonably likely to occur.

Proposed § 1.505(c)(8) would require that the hazard evaluation consider sanitation, including employee hygiene. Sanitation practices can impact the likelihood of a hazard being introduced into a food. For example, inadequate worker health and hygiene can present the potential for transfer of pathogens such as Salmonella, hepatitis A, and norovirus.

Proposed § 1.505(c)(9) would require that the hazard evaluation consider any other relevant factors that might potentially affect the safety of the food for the intended consumer. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful micro-organisms or chemical residues. Following a natural disaster, environmental contaminants that could enter a facility could be hazards that are reasonably likely to occur.

Although proper evaluation of potential hazards under proposed § 1.505(c) requires the consideration of factors that may occur at various points throughout a food's production and distribution chain, an importer's responsibility to conduct verification activities in accordance with proposed § 1.506 applies only to the ability of its foreign supplier (as defined in proposed § 1.500) to control (or verify control of) these hazards (unless they are controlled by the importer

or the importer's customer). This means that an importer's verification activities would need to provide assurances regarding the actions of its foreign supplier, but the importer would not be required to conduct verification with respect to any other entities either before or after the foreign supplier in the food's production and distribution chain.

4. Review by Qualified Individual of Foreign Supplier's Hazard Analysis

Proposed § 1.505(d) would permit an importer to identify the hazards that are reasonably likely to occur for a particular food by reviewing and evaluating the hazard analysis conducted by the foreign supplier (rather than conducting an entirely separate evaluation of hazards using information that the importer itself has obtained). We tentatively conclude that this approach to hazard analysis would reduce the burden on an importer while still ensuring that the importer has an adequate understanding of the hazards that are reasonably likely to occur with a particular food.

5. Microbiological Hazards in RACs That Are Fruits or Vegetables

As stated in section I.C of this document, the proposed produce safety regulations would not require produce farms to determine the microbiological hazards that are associated with each fruit or vegetable they grow. Instead, FDA has identified the reasonably foreseeable microbiological hazards associated with fruits and vegetables and has proposed requirements for measures intended to prevent the introduction of these hazards into this food and to provide reasonable assurances that the produce is not adulterated due to these hazards. For this reason, we tentatively conclude that it would not be appropriate to require importers of RACs that are fruits or vegetables to determine whether there are any microbiological hazards that are reasonably likely to occur with this food. Therefore, proposed § 1.505(e) states that for a RAC that is a fruit or vegetable, an importer is not required to conduct a hazard analysis regarding the

microbiological hazards that might be reasonably likely to occur with this food. Instead, the importer will need to verify that this kind of food is produced in compliance with FDA's produce safety standards or equivalent standards.

However, importers of RACs that are fruits or vegetables would still be required to conduct a hazard analysis regarding all non-microbiological hazards that might be associated with the food (i.e., chemical, physical, and radiological hazards). In the case of these kinds of hazards, we anticipate that hazard analysis will not be complicated; it should consist of being aware of how the crop is produced and whether there have been non-microbiological problems associated with the crop or the producer in the past. For example, if an importer is purchasing cucumbers from a country, region, or grower with a history of pesticide residue violations for that food, we would expect the importer to address this potential adulteration. Conversely, if the cucumbers come from a country or region with no history of pesticide residue violations, we would not expect an importer to identify unsafe pesticide residues as a hazard that is reasonably likely to occur, unless new information came to light or questions about the use of pesticides or control of pesticide residues indicated an issue. We anticipate that, in addition to requesting information from foreign suppliers, importers would use public information, such as that available on FDA's Web site from FDA guidance, import alerts, warning letters, and untitled letters, to decide if a hazard was reasonably likely to occur. As we have explained, this assessment is intended to allow importers to focus on those hazards that are likely and thus can be addressed through routine verification.

G. Foreign Supplier Verification and Related Activities (Proposed § 1.506)

Proposed § 1.506 answers the question, "What foreign supplier verification and related activities must I conduct?" Requiring importers to conduct foreign supplier verification

activities is the core component of the import safety responsibilities assigned to importers under section 301 of FSMA. Verification of foreign suppliers also is consistent with the principles of verification of suppliers of raw materials and ingredients discussed in the Preventive Controls Proposed Rule (78 FR 3646 at 3765 to 3767), as well as consistent with the intent of the requirements applicable to importers of juice and seafood products under parts 120 and 123.

1. List of Foreign Suppliers

To help ensure that importers are obtaining food only from appropriate foreign suppliers, proposed § 1.506(a) would require each importer to maintain a written list of the foreign suppliers from which they are importing food. The list would also help importers to quickly and accurately identify their foreign suppliers for purposes of conducting FSVP activities such as supplier verification, investigations, and corrective actions, and help ensure consistent performance of these activities by importers' employees or other qualified individuals. The list also would assist us in monitoring importers' compliance with the FSVP requirements. We request comment on how the foreign suppliers should be identified in this list to ensure that the information is accurate and not ambiguous to the importer or FDA (e.g., identified by the foreign supplier's name and address, by their name and DUNS number, or by some other means). We would have access to this information upon request under proposed § 1.510(b). Nonetheless, we also request comment on whether the identity of the foreign supplier of the food should also be provided when the food is offered for import, along with the importer information that must be provided under proposed § 1.509(c), and, if so, how the foreign supplier should be identified to ensure that the information is accurate and not ambiguous. Under the prior notice requirements, for each line entry of imported food, we receive the identity of the foreign manufacturer/processor and, if known, the grower (see 21 CFR 1.281). Therefore, any such

comments should address how the identity of the foreign supplier could be used in conjunction with the prior notice and other relevant information we currently receive about foreign suppliers.

2. Foreign Supplier Verification Procedures

Proposed § 1.506(b) would require that importers establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods they import. These procedures will state how the importer will comply with § 1.506, including documenting when the importer itself controls hazards under § 1.506(e), documenting customer control of hazards under § 1.506(f), and conducting appropriate foreign supplier verification activities in accordance with § 1.506(g) and (h). We tentatively conclude that establishing and following written procedures on how these activities will be conducted will help ensure that importers properly and consistently verify that the hazards associated with the foods they import are adequately controlled, and will allow us to more effectively monitor compliance with section 805 of the FD&C Act.

3. Purpose of Supplier Verification

As stated in section II.F.1 of this document, the proposed rule would require importers (with some exceptions) to conduct hazard analyses as part of their FSVPs. To provide assurances of adequate control of hazards reasonably likely to occur, proposed § 1.506(c) would require the importer to conduct activities to verify that such hazards are adequately controlled. The approach of identifying hazards that are reasonably likely to occur and verifying that they are being adequately controlled is sufficiently general and flexible to apply to a variety of circumstances. We tentatively conclude, however, that it would not be appropriate to apply the supplier verification requirement in proposed § 1.506(c) -- i.e., that verification activities provide adequate assurances that the hazards identified by the importer have been adequately controlled -

- to microbiological hazards in RACs that are fruits or vegetables and that would be subject to the produce safety regulations in proposed part 112. This is because, under proposed § 1.505(e), importers of these fruits or vegetables would not be required to conduct a hazard analysis regarding the microbiological hazards for this food. Instead, as discussed below in section II.G.8 of this document, verification for these hazards should address whether foreign suppliers are producing these fruits and vegetables in accordance with the produce safety regulations. Consequently, proposed § 1.506(c) states that supplier verification activities must provide assurances that hazards identified as reasonably likely to occur are adequately controlled “[e]xcept with respect to verification activities specified in [proposed § 1.506(h)] regarding raw agricultural commodities that are fruits or vegetables that are subject to [part 112].” This exception regarding the purpose of supplier assurances would apply only to microbiological hazards for RACs that are fruits or vegetables and that are subject to the proposed produce safety regulations; such RACs that are not subject to those regulations (e.g., fruits and vegetables that are rarely consumed raw or that receive commercial processing that adequately reduces the presence of microorganisms of public health significance) are regarded as having no microbiological hazards with respect to which supplier verification would be warranted.

4. No Hazards Identified

With some foods, an importer might conduct a hazard analysis and conclude that there are no hazards that are reasonably likely to occur. Examples of foods with respect to which it is possible that, depending on the circumstances, no hazards would be reasonably likely to occur are salt and food-grade chemicals such as citric acid. In the forthcoming draft guidance on FSVPs, we intend to provide other examples of foods for which it is possible that no hazard would be reasonably likely to occur. We tentatively conclude that when an importer has

determined that no hazards are reasonably likely to occur with a particular food, there would be no public health reason to require the importer to conduct most of the activities under § 1.506. Therefore, proposed § 1.506(d) states that if an importer conducts a hazard analysis in accordance with § 1.505 and determines that there are no hazards that are reasonably likely to occur with a food, the only requirement in § 1.506 with which the importer must comply with respect to that food is to maintain a list of its suppliers of this food in accordance with § 1.506(a). However, if an importer determined that there were no hazards in a food, the importer would need to reassess this determination at least every 3 years in accordance with proposed § 1.508.

Proposed § 1.506(d) also states that this provision regarding an absence of hazards would not apply if the food is a RAC that is a fruit or vegetable and that would be subject to the produce safety regulations. This exception is appropriate because for such food the importer is not conducting a hazard analysis to identify the microbiological hazards that are reasonably likely to occur in the food. The importer would still need to conduct verification activities with respect to microbiological hazards in accordance with proposed § 1.506(h), discussed in section II.G.8 of this document.

5. Hazards Controlled by the Importer

Certain hazards associated with an imported food might be controlled through actions that the importer takes after the food is brought into the United States. Proposed § 1.506(e) states that for a hazard that the importer has identified as reasonably likely to occur with a food that the importer itself will control, the importer must document, at least annually, that it has established and is following procedures that adequately control the hazard. If the importer of a food has established validated preventive controls to ensure that a hazard is adequately controlled, there would be no need for the importer to conduct a foreign supplier verification

activity with respect to that hazard. For example, a domestic food facility might import raw peanuts for use as an ingredient in its products. If this importer identifies Salmonella as a hazard reasonably likely to occur in the peanuts, the importer would not need to conduct a verification activity with respect to the Salmonella hazard in the peanuts if the importer itself treats the peanuts using a process validated to adequately reduce Salmonella. Because, in the context of hazards controlled by an importer, process controls such as these generally are designed for the control of microbiological hazards, proposed § 1.506(e) likely would not apply to chemical hazards (such as pesticides, mycotoxins, and drug residues) or radiological hazards (such as iodine-131), although this would not necessarily always be the case.

We request comment on this proposal to require importers that control the hazards in food they import to document their control of these hazards, including on the frequency with which importers should be required to document this control.

As discussed in section II.C of this document, we are requesting comment on whether it would be appropriate to deem importers who are in compliance with any applicable supplier verification provisions that are included in the preventive controls regulations to be in compliance with the FSVP requirements, to avoid duplicative regulation of importers who are also food facilities that are required to register. We tentatively conclude that, if a provision to this effect were included in the FSVP regulations in accordance with the inclusion of any supplier verification provisions in the preventive controls regulations, proposed § 1.506(e) would be unnecessary, as importers that control hazards in foods they import would be subject to the supplier verification provisions in the preventive controls regulations. We request comment on this proposed approach to provisions on importers who control the hazards in the food they import.

Imported food that is, or appears to be, adulterated, misbranded, or manufactured, processed, or packed under insanitary conditions is subject to refusal of admission under section 801(a) of the FD&C Act. If the importer is importing food that has a hazard that is reasonably likely to occur and that has not yet been controlled (because the hazard is intended to be controlled by the importer or, as discussed in section II.G.6 of this document, by its customer), such food may be subject to refusal of admission. We request comment regarding the importation of such products and what process should be required to help ensure that food that is subject to refusal of admission is not distributed without the hazard being adequately controlled.

6. Hazards Controlled by the Importer's Customer

Some hazards associated with imported foods are controlled through procedures implemented by the importer's U.S. customer, i.e., a business that purchases the imported food for further processing or distribution. For example, imported macadamia nuts might be used as an ingredient in cookies made by a bakery operation, or imported mushrooms might be an ingredient of domestically produced canned soup. Proposed § 1.506(f) states that for a hazard that an importer has identified as reasonably likely to occur with a food that the importer's customer adequately controls, the importer must verify that its customer controls the hazard by obtaining written assurance, at least annually, from the customer that it has established and is following procedures (identified in the written assurance) that adequately control the hazard. The written assurance would need to briefly state the procedures that the customer has put in place to control the hazard and affirm that these procedures are in fact controlling the hazard.

We invite comment on how frequently an importer should be required to obtain written assurance from its customer that the customer is following procedures to adequately control the hazard. For example, we request comment on whether the importer should be required to obtain

this assurance the sooner of every 3 years or whenever there is a change in the customer's control procedures (consistent with the standard for reassessment of the importer's FSVP under proposed § 1.507(a)), or whether the importer should be required to obtain the assurance more frequently. As noted above, this food may be subject to refusal of admission when it is imported. Therefore, we request comment regarding the importation of such products and what process should be required to help ensure that food that is subject to refusal of admission is not distributed without the hazard being adequately controlled.

As with hazards to be controlled by an importer, we tentatively conclude that proposed § 1.506(f) would be unnecessary if the FSVP regulations were to include a provision stating that an importer whose customer was in compliance with any adopted preventive controls supplier verification provisions is deemed to be in compliance with the FSVP requirements. We request comment on this proposed approach to provisions on importers whose customers control hazards in the food they import.

7. Hazards Controlled or Verified by the Foreign Supplier

Proposed § 1.506(g) addresses foods with hazards that are controlled by, or for which control is verified by, the importer's foreign supplier. Requiring importers to conduct supplier verification with respect to these hazards will help to ensure, consistent with section 805(c)(2)(A) of the FD&C Act, that the foreign supplier is following processes and procedures that will provide 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 is otherwise producing food that is not adulterated under section 402 or misbranded under section 403(w) of the FD&C Act. We tentatively conclude that requiring such verification is consistent with the principles of food safety underlying current industry practice with respect to the verification of the safety of

imported food and food ingredients obtained from suppliers, as well as the principles behind the importer requirements in the juice and seafood HACCP regulations.

We are co-proposing two options for the requirements regarding supplier verification activities for hazards that are controlled, or for which control is verified, by the importer's foreign supplier. Option 1 of the co-proposal would establish certain requirements for SAHCODHA hazards to be controlled by the foreign supplier and different requirements for non-SAHCODHA hazards and SAHCODHA hazards that the foreign supplier verifies have been controlled by its raw material or ingredient supplier. Option 2 of the co-proposal would require the importer to determine the supplier verification activity it would use for all hazards that the foreign supplier controls or for which it verifies control. We are proposing alternative codified provisions to facilitate consideration of, and comment on, these two different approaches to supplier verification.

a. Option 1: Different approaches for SAHCODHA hazards controlled by the foreign supplier and other hazards.

Option 1 of the co-proposal would establish mandatory onsite auditing requirements for SAHCODHA hazards to be controlled by the foreign supplier, while for non-SAHCODHA hazards and all hazards that a foreign supplier verifies have been controlled by its raw material or ingredient supplier, the importer would choose from among certain specified verification activities, as discussed below.

i. SAHCODHA hazards to be controlled by the foreign supplier.

Under Option 1, proposed § 1.506(g)(1) sets forth the required verification activities for hazards that are to be controlled by the foreign supplier at its establishment when the hazard 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. These SAHCODHA hazards are those for which a recall of a violative product posing such a hazard is designated as “Class 1” under 21 CFR 7.3(m)(1). Proposed § 1.506(g)(1) states that for a SAHCODHA hazard that is to be controlled at the foreign supplier’s establishment, the importer must conduct and document certain onsite audits specified in § 1.506(g)(1)(i) and (ii) for the hazard.

Examples of hazards that, in some circumstances, historically have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in ready-to-eat food. Under Option 1’s § 1.506(g)(1), if such hazards are identified by the importer as hazards reasonably likely to occur in foods they receive from a foreign supplier, and the foreign supplier is to apply preventive controls to address those hazards, then onsite auditing of the foreign supplier must be conducted to verify that those controls have been properly applied. For example, if Salmonella, exposure to which creates a reasonable probability of serious adverse health consequences or death to humans or animals, is identified as a hazard reasonably likely to occur with peanuts and the foreign supplier applies a process control, e.g., oil roasting, onsite auditing must be conducted to verify that the supplier’s roasting process is adequately controlling the Salmonella.

Onsite verification is widely acknowledged in the food industry as an important component of an effective food safety management system. For example, the Grocery Manufacturers Association’s (GMA’s) Food Supply Chain Handbook (GMA Handbook) (Ref. 10) states that many food importers elect to audit a foreign supplier using an employee of the company (“second-party auditing”) or a qualified third-party auditing firm (independent auditor). In addition, onsite auditing is a major component of effective food safety schemes described in the Global Food Safety Initiative (GFSI) Guidance Document (Ref. 11).

We also believe that onsite auditing of a foreign supplier is a very effective way of verifying that the supplier understands the SAHCODHA hazard that must be addressed and has implemented appropriate controls. Through an audit conducted onsite, the auditor can observe physical conditions, interview employees, and review records to verify that preventive controls are being implemented and, if there is a written plan for controlling the hazard, that the controls are being implemented according to that plan.

We believe that, for some SAHCODHA hazards in certain situations, conducting onsite auditing alone may not be sufficient to ensure that the hazard is adequately controlled. For example, an importer who was required by Option 1's § 1.506(g)(1) to perform an onsite audit of its foreign supplier of semi-soft cheese might become aware that such cheese from that supplier's country frequently does not meet FDA's standard for the presence of L. monocytogenes. Under these circumstances, performance of annual onsite audits would not, by itself, provide sufficient assurance that the L. monocytogenes hazard has been adequately controlled; periodic sampling and testing of the cheese for the pathogen also would be needed. Similarly, an importer of acidified peppers receiving product from a foreign supplier that had experienced compliance problems because of inadequate pH controls, but that had instituted corrections to address the problem, should conclude that an annual audit to verify the adequacy of the pH controls would not provide sufficient assurances that the compliance problems did not reoccur, and that periodic pH testing of the peppers would be appropriate until confidence in the supplier has been restored. Therefore, proposed § 1.506(g)(1) under Option 1 would require that, when onsite auditing alone cannot provide adequate assurances that such a hazard is adequately controlled, the importer must conduct one or more additional verification activities to provide such assurances.

- Initial onsite audit. For SAHCODHA hazards under Option 1's § 1.506(g)(1), foreign supplier verification would require an initial onsite audit and subsequent periodic onsite audits. Proposed § 1.506(g)(1)(i) would require the importer to conduct (and document) or obtain documentation of an onsite audit before importing the food from the foreign supplier. The importer would use the results from the initial audit in determining whether any changes were warranted before obtaining food from this foreign supplier.

The importer could either conduct the onsite audit itself (if it has a qualified individual on staff), engage the services of a qualified individual who would conduct the audit, or obtain a certification or other documentation of an audit of the foreign supplier conducted by a qualified individual, including an audit conducted by a third-party auditor at the request of the foreign supplier or by an auditor working for a foreign government. We note that others have adopted a similar approach. As previously stated, the GMA Handbook (Ref. 10) acknowledges that many customers audit a supplier themselves or use a qualified third-party auditor. The NACMCF HACCP guidelines (Ref. 8) recommend that a periodic comprehensive verification of the HACCP system be conducted by an unbiased, independent authority.

It is widely recommended that persons conducting onsite audits have technical expertise in auditing. The NACMCF HACCP guidelines (Ref. 8) acknowledge that it is important that individuals performing verification have appropriate technical expertise to perform this function. GMA recommends that an auditor's competency include education/experience, advanced HACCP training, and a minimum amount of auditing expertise (Ref. 10). The GFSI Guidance Document states that an auditor's qualifications should include the following: minimum full-time work experience in food or an associated industry; formal training in auditing techniques;

initial training for each product category with which the auditor will be working; audit experience; and continuous professional development (Ref. 11).

We recognize that Option 1's proposed requirement to conduct or obtain documentation of onsite audits of foreign suppliers with respect to SAHCODHA hazards would be one of the most significant of the FSVP requirements. Many in the food industry already rely on third-party auditors to accomplish verification of food safety controls and we expect that they will continue to do so. However, we also recognize that currently there is considerable variance in the quality of auditing services and the nature of audit criteria.

Along with industry's ongoing efforts to incorporate onsite auditing into food safety operations, we anticipate that our adoption of final preventive controls and produce safety regulations will improve auditing consistency by providing clear, uniform criteria against which suppliers' processes and controls can be assessed and audited. This greater consistency in auditing should make it easier for suppliers to demonstrate their products' safety to multiple customers through a single audit, resulting in a more efficient auditing system.

We believe that this movement toward a more effective and efficient food safety auditing system will be further enhanced by FDA's adoption of regulations on the accreditation of third-party auditors. As previously stated, section 307 of FSMA (adding section 808 of the FD&C Act) requires FDA to establish a third-party accreditation system and develop model accreditation standards that will help ensure that these third parties provide high-quality auditing services. While neither the proposed FSVP regulations nor the proposed preventive controls regulations would require use of accredited third-party auditors, we expect that adoption of these regulations will increase the demand for such services. Proposed § 1.500 states that a third-party auditor accredited in accordance with section 808 of the FD&C Act would be a "qualified

individual” for purposes of the FSVP regulations. Thus, although use of accredited auditors would not be required, once FDA’s third-party accreditation system is in place, we expect that many importers will request that their suppliers obtain an accredited third-party audit that meets the requirements under section 808. Rather than have each importer and processor request individual audits of their suppliers, we anticipate that the system ultimately will evolve into one in which the foreign supplier obtains an audit by an accredited third party that will be acceptable to, and used by, most of its customers. By minimizing the number of onsite audits conducted at each foreign supplier facility, this system will more efficiently leverage the resources of importers, processors, and suppliers. The proposed FSVP regulations are designed to permit this systematic use of accredited third parties.

Regarding an importer’s obligation under Option 1’s section § 1.506(g)(1) to conduct or obtain documentation of an onsite audit of its foreign supplier, we request comment on whether it would be appropriate to allow an importer to rely on an audit conducted in accordance with section 801(q) of the FD&C Act as fulfillment of this obligation. Section 303(b) of FSMA gives FDA the authority, in section 801(q) of the FD&C Act, to require, as a condition of granting admission to an article of food imported or offered for import into the United States, that a certification or other assurance (e.g., shipment-specific certificate, listing of certified facilities) be obtained stating that a food that FDA has identified as high risk, in accordance with that provision, complies with the requirements of the FD&C Act. Such certificates or other assurances would have to be obtained from an Agency or representative of the government of the country from which the food originated, as designated by FDA, or from a third-party auditor accredited under section 808 of the FD&C Act. In deciding whether to require such certification or other assurance, FDA would consider, among other factors, known safety risks associated

with the food and with the country, territory, or region of origin of the food. We request comment on whether, if FDA required certification of a food under section 801(q), an importer should be permitted to rely on the results of the audit that led to issuance of the section 801(q) certification to meet the requirement to conduct or obtain the results of an onsite audit under proposed § 1.506(g)(1). If you believe that an importer should be permitted to rely on the results of the audit that led to issuance of the section 801(q) certification, we request comment on the circumstances and conditions under which this would be appropriate.

We also request comment on whether an importer should be permitted to meet its onsite auditing requirements under the FSVP regulations by relying on the results of an audit conducted to obtain facility certification required for participation in the voluntary qualified importer program (VQIP), which Congress directed FDA to establish in section 302 of FSMA (codified in section 806 of the FD&C Act (21 U.S.C. 384b)). As with audits for section 801(q) certification, we request comment on the particular circumstances and conditions under which reliance on audits conducted for facility certification under VQIP would be appropriate for meeting FSVP requirements.

- Subsequent periodic onsite audits. For ongoing verification with respect to SAHCODHA hazards controlled by a foreign supplier of a food, Option 1's proposed § 1.506(g)(1)(ii) would require the importer to conduct (and document) or obtain documentation of an onsite audit of the foreign supplier at least annually, unless more frequent onsite audits were necessary to adequately verify adequate control of the hazard. We tentatively conclude that conducting audits annually for SAHCODHA hazards is often adequate for verifying that these hazards are appropriately controlled. The requirement for annual onsite audits is consistent with the recommendations on the frequency of third-party auditing issued by the GFSI (Ref. 11),

although GFSI recommends annual auditing regardless of the potential severity of the hazard. However, if more frequent onsite audits were necessary to verify adequate control of the hazard, the importer would be required to conduct or obtain documentation of audits more frequently. GFSI states that the frequency of audits may be influenced by a number of factors, such as previous audit history, concerns about compliance with an audit scheme's standard, and changes in product technology (Ref. 11). We request comment on the proposed annual onsite audit frequency as well as comment on what criteria, if any, should be specified for determining whether more frequent audits are appropriate. We are aware that there are circumstances in which suppliers are audited multiple times each year due to multiple customer requests (in addition to, in some cases, the company's internal audit). It is not our intent to increase the number of audits of each foreign supplier; rather, we anticipate there will be consolidation of audits. We request comment on this approach.

ii. Supplier verification activities for other hazards under Option 1.

Option 1's proposed § 1.506(g)(2) sets forth the foreign supplier verification requirements for hazards not specified in proposed § 1.506(g)(1), i.e., non-SAHCODHA hazards to be controlled by the foreign supplier of a food and any hazard which the foreign supplier verifies has been controlled by its supplier.

We tentatively conclude that onsite auditing is not necessarily warranted to verify adequate control of a non-SAHCODHA hazard. Examples of hazards that historically have not resulted in serious adverse health consequences or death to humans or animals include drug residues and some foreign objects. We tentatively conclude that a verification activity other than onsite auditing may be adequate for such hazards.

Also included in the hazards subject to Option 1's proposed § 1.506(g)(2) are hazards for which a foreign supplier, upon receipt of an ingredient from another entity, takes steps to verify that the hazards have been adequately controlled before the foreign supplier processes the received ingredient. For example, an importer might identify Salmonella as a hazard reasonably likely to occur in a seasoning mix made by blending milk powder and spices. The foreign supplier of the seasoning mix does not apply a control for Salmonella in its blending operation but instead conducts verification to ensure that the suppliers of milk powder and spice have used proper controls. Another example is when a foreign supplier conducts testing to verify that its raw material supplier has applied a procedure that removes a hazard posed by the potential presence of a pesticide in the raw material. For such hazards, a foreign supplier is not applying a process control during the manufacturing/processing of a raw material or ingredient to adequately reduce the hazard but is instead relying on testing the incoming raw material or ingredient or conducting some other activity to verify that the hazard is appropriately controlled by its supplier, thereby making in-plant audits of conditions and practices less important.

To address these types of hazards and any others not subject to Option 1's proposed § 1.506(g)(1), Option 1's proposed § 1.506(g)(2) would require that the importer conduct one or more of the verification activities specified in proposed § 1.506(g)(2)(i) through (g)(2)(iv) before using or distributing the food and periodically thereafter as specified for the relevant activity. Proposed § 1.506(g)(2) also would require that the importer determine and document the frequency with which the activity or activities must be conducted. Finally, proposed § 1.506(g)(2) states that, in determining the appropriate verification activities and how frequently they should be conducted, the importer must consider the risk presented by the hazard and the food and foreign supplier's compliance status as reviewed under § 1.504.

As set forth in Option 1's proposed § 1.506(g)(2)(i) through (g)(2)(iv), the foreign supplier verification activities that importers may choose to conduct, if they are appropriate for the hazard, are as follows:

- Periodic onsite auditing.
- Periodic or lot-by-lot sampling and testing of the food.
- Periodic review of the foreign supplier's food safety records.
- Any other procedure established to be appropriate.

These verification procedures, and examples of types of foods/hazards for which they may be appropriate, are discussed below.

- Periodic onsite auditing. Under Option 1's proposed § 1.506(g)(2)(i), an importer could choose to conduct or obtain documentation of an onsite audit of its foreign supplier to verify control of a hazard subject to § 1.506(g)(2). Using the example provided above involving imported seasoning mix, the importer might choose to conduct an audit or use a third-party auditor to conduct an audit of the foreign supplier's receiving and blending operations to verify that the foreign supplier tests incoming lots of powdered milk and spices to verify that they have been controlled for Salmonella.

Because the frequency of onsite auditing must be risk-based under § 1.506(g)(2), the frequency of audits may be affected by factors such as previous audit history, compliance history, seasonality of the product, significant capacity increases, structural changes, and changes in product technology. For example, audits might be conducted annually until a positive compliance history is developed with the foreign supplier.

- Periodic or lot-by-lot sampling and testing of the food. Under Option 1's proposed § 1.506(g)(2)(ii), an importer could determine that it is appropriate to conduct and document

periodic or lot-by-lot sampling and testing of an imported food before the importer uses or distributes the food. For example, an importer of the above-described seasoning mix might conduct its own periodic Salmonella testing or use a contracted laboratory to test samples of 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 the importer might determine it would be appropriate to test less frequently, such as quarterly.

Alternatively, an importer could choose to obtain documentation (such as a certificate of analysis (COA)) of lot-by-lot or periodic testing of the food that is conducted before the food is distributed by the foreign supplier. This supplier verification method is consistent with the recommendation in the GMA Handbook that customers ask suppliers to provide COAs documenting that major analytical parameters for the specific foods, or lots, contained in a specific shipment have been met (Ref. 10). GMA also recommends the use of recognized analytical methods and statistically valid sampling plans, as well as, in some cases, approval of the use of outside laboratories.

Although requirements for a COA or other documentation of testing will depend on factors such as the food involved, information included in a COA might include the following: a full description of the food; the name of the supplier; lot number(s) for products in the shipment; the date of production; whether the testing was done in-house or by an outside laboratory; the date the food was shipped; the quantity of product covered by the COA (e.g., 40 cases at 70 pounds each); results of chemical, physical, microbiological, or other analyses; methods of analysis; descriptions of sampling plans used to generate results contained in the COA; and the signature of the person issuing the certificate (Ref. 9). To ensure the accuracy and validity of testing, importers should verify that the testing has been performed using proper techniques.

As with the other verification activities, Option 1's proposed § 1.506(g)(2) would require that the frequency of supplier testing be based on the risk presented by the hazard in the food. For example, an importer might initially ask its new foreign supplier of roasted peanuts and tree nuts to provide lot-by-lot COAs for aflatoxin in accordance with a designated sample size and method. The importer might base its decision on the need for lot-by-lot certification on the following factors: the lack of a performance history for the new foreign supplier; the fact that the country in which the supplier is located has a history of aflatoxin occurrence; and the fact that the foreign supplier does not apply a preventive control for aflatoxin in its roasting facility. Until a performance baseline is established with the foreign supplier, the importer might even conduct its own periodic sampling and testing in addition to reviewing the COAs from the foreign supplier. Once the foreign supplier has established a history of no aflatoxin in the roasted peanuts and tree nuts, the importer might be assured that it is appropriate to have the foreign supplier provide COAs at some lesser frequency, such as every tenth delivery.

Although we would expect that sampling and testing of food under Option 1's § 1.506(g)(2)(ii) would be conducted in accordance with any applicable regulations or widely accepted industry standards, because of the diversity of hazards and foods that could potentially be tested, we tentatively conclude that it is not appropriate to specify standards of testing in the regulation. However, we request comment on whether the regulation should specify testing standards and, if so, what those standards should be.

- Periodic review of the foreign supplier's food safety records. Under Option 1's proposed § 1.506(g)(2)(iii), an importer could choose to periodically review (and document) or obtain documentation of a review of a foreign supplier's food safety records. Food safety records are records documenting that the food safety procedures that the supplier has established

to control hazards reasonably likely to occur are being followed and are adequately controlling the hazards. Such records might include records of a foreign supplier's audit of its supplier's hazard control activities or records of environmental monitoring or product testing. Record review might be an appropriate verification activity when, for example, a foreign supplier of venison performs onsite audits of the deer farms that supply the venison to verify that the farms are not using unapproved drugs. The foreign supplier of venison could provide the importer with copies of the reports of these audits.

- Other appropriate verification procedure. Under Option 1's proposed § 1.506(g)(2)(iv), an importer could choose to follow any other procedure that it has established and documented as being appropriate, based on the risk associated with the hazard, for verifying that a foreign supplier is adequately controlling (or verifying control of) the hazard. We tentatively conclude that it is appropriate to allow an importer to use any other procedure that it can develop, as long as the importer can document that the procedure can effectively verify whether a foreign supplier is adequately controlling a hazard. We are aware that importers currently use onsite audits, product testing, and record review to verify the safety of the food they import; we request comment on other foreign supplier verification methods that may be appropriate.

As stated in section I.A of this document, section 805(c)(4) of the FD&C Act states that verification activities under an FSVP may include monitoring records for shipment, lot-by-lot certification of compliance, annual onsite inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments of imported products. The potential methods for foreign supplier verification specified in Option 1's proposed § 1.506(g)(2) include each of the verification activities stated in

section 805(c)(4) (we tentatively conclude that, by “monitoring records for shipment,” Congress meant review of the foreign supplier’s food safety records).

b. Option 2: Same approach for all hazards.

Although we are aware that it is an industry best practice to conduct onsite audits to verify supplier control of SAHCODHA hazards and that audits are an effective and efficient means of verification, we are co-proposing an alternative approach to verification that is similar to the approach described above for non-SAHCODHA hazards. Option 2 of the co-proposal for supplier verification activities would require the importer to choose whatever verification activity would enable the importer to adequately verify that a hazard has been adequately controlled, whether it is a SAHCODHA hazard or a non-SAHCODHA hazard.

Under Option 2 for supplier verification activities, proposed § 1.506(g)(1) would require, for any hazard that the importer has identified as reasonably likely to occur with a food that is to be controlled by the foreign supplier or for which the foreign supplier verifies control by its supplier, that the importer conduct one or more of the verification activities listed in § 1.506(g)(1)(i) through (g)(1)(iv) before using or distributing the food and periodically thereafter. Proposed § 1.506(g)(1) also would require the importer to determine and document which verification activity or activities are appropriate to adequately verify that the hazard is adequately controlled, as well as to determine and document how frequently the verification activities must be conducted. In addition, Option 2’s proposed § 1.506(g)(1) would require the importer, in determining the appropriate verification activities and how frequently they should be conducted, to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier’s compliance status as reviewed under § 1.504.

As set forth in Option 2's proposed § 1.506(g)(2)(i) through (g)(2)(iv), the foreign supplier verification activities that importers may choose to conduct, if they are appropriate for the hazard, are as follows:

- Periodic onsite auditing: The importer would conduct (and document) or obtain documentation of a periodic onsite audit of its foreign supplier.
- Periodic or lot-by-lot sampling and testing of the food: The importer would conduct (and document) or obtain documentation (such as a COA containing the results of the testing) from its foreign supplier of lot-by-lot or periodic sampling and testing of the food for the hazard.
- Periodic review of the foreign supplier's food safety records: The importer would periodically review (and document) or obtain documentation of a review of its foreign supplier's food safety records (such as records of the foreign supplier's audit of its supplier's hazard control activities).
- Other appropriate procedure: The importer would use any other procedure that it had established as being appropriate based on the risk associated with the hazard, and the importer would document its use of any such procedure.

As stated, Option 2 would require importers to consider certain factors in determining which verification activity or activities are appropriate and how frequently they must be conducted. First, the importer would need to consider the risk presented by the hazard and what activity could provide adequate verification of hazard control given the nature of this risk. In making this assessment, an importer would need to consider which verification activities might be needed to adequately assess the foreign supplier's operations to determine if the supplier is adequately and consistently applying its hazard controls (or verifying the controls applied by its raw material or ingredient suppliers). For example, product testing may not, by itself, provide

adequate verification when a hazard is not likely to be uniformly distributed or present in a food, e.g., pathogens in untreated spices.

Second, the importer would need to consider the probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. Generally, we believe that conducting onsite auditing would provide adequate assurance of SAHCODHA hazard control. We request comment on whether there are circumstances under which other mechanisms might be effective and, if so, what these circumstances might be.

Third, the importer would need to consider the food and foreign supplier's compliance status as reviewed under § 1.504. For example, review of the supplier's food safety records might not provide adequate assurance of supplier compliance with applicable food safety regulations if the supplier had recently been found to be non-compliant with significant requirements.

Section II.G.7.a of this document, which addresses the use of different verification activities for non-SAHCODHA hazards (and hazards to be controlled by the supplier to the foreign supplier) under Option 1 of the co-proposal, offers further examples of circumstances in which particular verification activities might be appropriate under Option 2 of the co-proposal.

We request comment on Options 1 and 2 of the co-proposal regarding supplier verification activities. One advantage of Option 1 is that it would establish a clear verification requirement, i.e., onsite auditing, for the most serious hazards that are controlled during supplier processing, circumstances in which other verification methods (such as records review) might not provide adequate assurance that the foreign supplier has implemented appropriate controls. On the other hand, if verification mechanisms other than onsite auditing could provide adequate assurance of control of serious hazards, Option 2 would give importers somewhat greater

flexibility in selecting effective verification activities without adversely affecting food safety. If you recommend either Option 1 or Option 2 concerning verification requirements, provide your rationale and examples of the use of particular supplier verification activities for particular types of hazards that support your preferred approach.

Regardless of the particular requirements for supplier verification activity that we adopt in the final rule, as stated in section I.B.2 of this document, we intend to align these provisions with any supplier verification provisions in the final rule on preventive controls.

c. Requirements of onsite auditing. Proposed § 1.506(g)(3) (under Option 1; this is § 1.506(g)(2) under Option 2) sets forth the basic requirements for an onsite audit conducted under § 1.506(g) or (h) (the latter of which concerns auditing related to microbiological hazards in certain RACs). We tentatively conclude that, to provide adequate assurance that the hazard reasonably likely to occur with the food is adequately controlled, the onsite audit must:

- Consider any relevant FDA food safety regulations, such as those on preventive controls, produce safety, acidified foods (part 114 (21 CFR part 114)), shell eggs (part 118 (21 CFR part 118)), and bottled drinking water (part 129 (21 CFR part 129)), and
- Include a review of the foreign supplier's written food safety plan, if any, for the hazard being audited and the supplier's implementation of such plan.

Because different foods are subject to different food safety regulations, we believe it is appropriate that an onsite audit of the foreign supplier of a food should include consideration of the standards and requirements of the applicable FDA food safety regulations to which the supplier is subject in assessing whether the supplier is adequately controlling the hazard.

Because these regulations vary in scope and detail, the parameters and key components of an

onsite audit conducted under § 1.506(g) or (h) would necessarily vary depending on what regulations applied to the foreign supplier.

We also tentatively conclude that review of the foreign supplier's written food safety plan, if any, and the supplier's implementation of such plan should be a required part of an effective onsite audit. If the supplier is required by section 418 of the FD&C Act 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 hazards that the importer has identified as reasonably likely to occur. Preventive controls might include process controls, food allergen controls, sanitation controls, and other controls for biological, chemical, physical, or radiological hazards identified as reasonably likely to occur.

For example, before an importer obtained roasted peanuts for which the importer had identified Salmonella as a hazard from a foreign supplier that was subject to the preventive controls regulations, the importer 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 the Salmonella. Because the supplier was subject to the preventive controls regulations, the audit would include a review of the supplier's food safety plan. For example, 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).

Reviewing the food safety plan during the audit is consistent with GMA's recommendation that all supplier food safety and quality programs be substantiated and documented (Ref. 10). For foreign suppliers that are not required to have a food safety plan

under section 418 of the FD&C Act but are required to have one under another FDA food safety regulation, or that have opted to have a plan even though not required to do so, the onsite audit would also be required to include a review of the foreign supplier's written plan, and its implementation of the plan, to assure that hazards identified by the importer are being adequately controlled.

For these reasons, proposed § 1.506(g)(3) (or § 1.506(g)(2) if Option 2 were adopted) states that an onsite audit conducted under § 1.506 must consider the relevant FDA food safety regulations and must include a review of the foreign supplier's written plan, if any, including its implementation, for the hazard being audited. We believe that an onsite audit concerning such a food should, at a minimum, include these actions. We request comment on these proposed requirements as well as on whether any other requirements regarding the scope and content of onsite audits are appropriate.

d. Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.

We tentatively conclude that, instead of an onsite audit conducted under § 1.506(g), (concerning hazards controlled or verified by a foreign supplier) or (h) (concerning microbiological hazards associated with certain RACs that are fruits or vegetables), an importer may rely on the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable to that of the United States (e.g., through a signed systems recognition arrangement between FDA and the country establishing official recognition of the foreign food safety system) or determined to be equivalent to that of the United States. Proposed § 1.506(g)(4) (under Option 1; this is § 1.506(g)(3) under Option 2) states that, to be valid for this purpose, the

inspection would have to have been conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by an officially recognized or equivalent food safety authority, proposed § 1.506(g)(4) states that the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in such country and under the regulatory oversight of the country's food safety authority.

As already noted, FSMA directs FDA to increase the number of inspections of foreign food manufacturing/processing facilities. We believe that it would be appropriate to allow an importer to use an FDA inspection in lieu of an audit by a qualified person to fulfill a supplier verification requirement under proposed § 1.506(g) or (h). Similarly, we also believe that it would be appropriate to allow an importer to use the results of an inspection of its foreign supplier that was conducted by the food safety authority of a country whose food safety system FDA has officially recognized or determined to be equivalent to that of the United States. Such inspections would provide an importer with information on the foreign supplier's control of hazards that is sufficiently similar to information that can be obtained from an onsite audit to be relied upon instead of such an audit. In addition, use of such inspection results could lessen the burden of conducting supplier verification activities by eliminating the need for an onsite audit.

We request comment on whether importers should be permitted to rely on an inspection of a foreign supplier by FDA or an officially recognized or equivalent food safety authority in substitution of an onsite audit. We request comment on whether the use of an FDA or foreign food safety authority inspection should be limited to the specific products/activities covered in the inspection, products/activities that concern the same hazard(s) as the food for which the onsite audit would have been required, or any other limitation in scope. We also request

comment on the likelihood that importers would choose to rely on such inspections to meet the requirements for supplier verification under proposed § 1.506, rather than seek to import a food under the modified requirements in proposed § 1.513 (discussed in section II.N of this document) applicable to food imported from a foreign supplier in a country with an officially recognized or equivalent food safety system as described above. In addition, we request comment on whether there are other kinds of intergovernmental arrangements that might assist importers in meeting their foreign supplier verification requirements.

We propose to require that inspections of foreign suppliers by FDA or foreign food safety authorities be conducted within 1 year of the date that the onsite audit would have been required to be conducted to help ensure that such an inspection can provide information about the supplier's control of a food's hazards that is similar to the information that could be obtained from an onsite audit. If commenters believe that importers should be permitted to use such inspections as an alternative to onsite audits, we request comment on the appropriateness of the proposed 1-year time limitation for use of such inspection.

e. Review of results of verification activities. Importers' foreign supplier verification activities would not provide adequate assurance that suppliers are controlling hazards if importers did not review the results of their verification activities and take corrective action if the results indicated that hazards were not adequately controlled. Therefore, proposed § 1.506(g)(5) (under Option 1; this is § 1.506(g)(4) under Option 2) would require that an importer promptly review the results of the verification activities that it conducts or for which it obtains documentation.

Proposed § 1.506(g)(5) further states that if the results of verification activities show that hazards identified as reasonably likely to occur with a food are not adequately controlled, the

importer must take appropriate corrective action in accordance with proposed § 1.507(c). As discussed in section II.H.3 of this document, § 1.507(c) would require that an importer promptly take appropriate corrective actions if it determines that its foreign supplier does not produce a 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, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act. The appropriate corrective actions would depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes have been adequately addressed. Thus, under proposed § 1.506(g)(5), if, for example, the sampling and testing conducted by an importer in accordance with § 1.506(g)(2)(ii) (under Option 1) showed that a supplier was not adequately controlling a hazard reasonably likely to occur with a food, the importer likely would need to notify the supplier of the failing results so that the supplier could take appropriate corrective action, which could include changes to its processes and procedures or sources of ingredients. If the foreign supplier did not make changes necessary to ensure that it adequately controlled the hazard, the importer would need to cease obtaining the food from the supplier.

f. Independence of qualified individuals. Proposed § 1.506(g)(6) (under Option 1; this is § 1.506(g)(5) under Option 2) addresses the issue of financial conflicts of interests that might arise in the performance of verification activities by qualified individuals (as defined in proposed § 1.500). We recognize the possibility that a conflict of interest might arise when there is a financial relationship between a qualified individual who is conducting a verification activity (such as an onsite audit or lot-by-lot testing) and the foreign supplier whose procedures the qualified individual is reviewing. For example, the owner of an auditing firm might own

substantial shares of stock in a foreign supplier that has requested an audit by the firm. On the other hand, § 1.506(g) and (h) permits the importer itself to conduct onsite audits of foreign suppliers and other verification activities under these regulations. In such cases, there would obviously be a financial relationship between the qualified individual, as an employee of the importer, and the importer itself, but this relationship should not pose a conflict of interest concern.

To address concerns about conflict of interest in the performance of FSVP activities, proposed § 1.506(g)(6) (§ 1.506(g)(5) under Option 2) specifies that a qualified individual who conducts any of the verification activities in § 1.505(g)(1), (g)(2), and (h) (§ 1.506(g)(1) and (h) under Option 2) must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity conducted. Proposed § 1.506(g)(6) further states that this provision would not prohibit the importer or one of its employees from conducting the verification activity.

We invite comment on whether this prohibition reflects the appropriate approach to concerns about conflicts of interest in the performance of foreign supplier verification activities and, if not, what changes would be appropriate. We also request comment on whether and, if so, how, the regulations should specify what constitutes a financial interest.

8. Microbiological Hazards in RACs That Are Fruits or Vegetables and That Would Be Subject to the Produce Safety Regulations

As discussed in section II.G.3 of this document, because importers of produce RACs that are subject to the proposed regulations on produce safety would not be required to conduct a hazard analysis regarding microbiological hazards in these products, we are not proposing that importers of such produce conduct verification activities on a hazard-by-hazard basis in the

manner described in section II.H.7 of this document. Instead, for such microbiological hazards we tentatively conclude that supplier verification with respect to these products should provide adequate assurances that the foreign supplier is producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112, the produce safety regulations.

Because we have presented two options in our co-proposal concerning supplier verification activities, we are presenting a co-proposal regarding supplier verification activities for RACs that are fruits or vegetables. Under Option 1 of the co-proposal, we tentatively conclude that, because all microbiological hazards associated with produce RACs that are subject to the proposed produce safety regulations have the potential to result in serious adverse health consequences or death to humans or animals, it would be appropriate to require importers of this food to conduct onsite auditing to verify that the food is being produced in a manner that is consistent with part 112. We also believe that such audits should be subject to the requirements concerning the scope of auditing, substitution of certain inspection results, review of results of verification activities, and independence of qualified individuals conducting verification activities discussed in sections II.G.7.c through II.G.7.f of this document (proposed § 1.506(g)(3) through (g)(6)). Finally, because onsite auditing might also be required to verify control of any non-microbiological hazards associated with produce RACs that are subject to the proposed produce safety regulations, we propose to specify that an audit conducted to address microbiological hazards associated with such a food may be conducted in conjunction with an audit that is required under proposed § 1.506(g). For these reasons, under Option 1, proposed § 1.506(h) states that, for a RAC that is a fruit or vegetable and that is subject to part 112, in addition to the other requirements of § 1.506, before importing the fruit or vegetable from the

foreign supplier and at least annually thereafter, the importer must conduct or obtain documentation of an onsite audit to provide adequate assurances that the foreign supplier is producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112; that such audits are subject to § 1.506(g)(3) through (g)(6); and that an audit conducted under § 1.506(h) may be conducted in conjunction with an audit, if any, that is required under § 1.506(g).

Under Option 2 of the co-proposal on supplier verification activities, importers would choose, from among several possible verification activities, an activity that would enable the importer to adequately verify that a hazard has been adequately controlled. Consistent with this approach, under Option 2, for a RAC that is a fruit or vegetable and that is subject to part 112, proposed § 1.506(h) would require the importer, in addition to meeting the other requirements of § 1.506, to conduct one or more of the verification activities listed in § 1.506(g)(1)(i) through (g)(1)(iv), before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, to provide adequate assurances that the foreign supplier was producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112. Option 2's proposed § 1.506(h) further states that any audits conducted under this paragraph would be subject to § 1.506(g)(2) through (g)(5) (as numbered in Option 2 of the co-proposal) and that an importer may conduct an activity under § 1.506(h) in conjunction with an activity conducted in accordance with § 1.506(g)(1)(i) through (g)(1)(iv).

We request comment on Options 1 and 2 of our co-proposal with respect to supplier verification of microbiological hazards in RACs that are fruits or vegetables that are subject to the produce safety regulations.

9. Hazards That Emerge Long After Foreign Supplier Processing But Before U.S. Entry

Some foods are manufactured by a foreign supplier and then stored for a relatively long time before being exported to the United States. For example, some dried, packaged foods are stored before being exported. It is even conceivable that the entity that produced the food might no longer be in existence at the time the food is imported into the United States. When there is an extended delay between the production and export of a food, a verification activity such as onsite auditing might not be possible or might provide little assurance that the food was produced under procedures that controlled the hazards. We request comment on what foreign supplier verification activities are appropriate for foods that are exported to the United States long after they are produced.

H. Complaints, Investigations, and Corrective Actions (Proposed § 1.507)

Proposed § 1.507 answers the question, “What investigations and corrective actions must I conduct under my FSVP?” We tentatively conclude that, as part of the FSVP, it is appropriate to require importers to review complaints concerning the foods they import, investigate possible adulteration or misbranding, take certain corrective actions when the foods they import do not meet applicable U.S. requirements, and revise their FSVPs when appropriate. These requirements would be generally consistent with the requirements applicable to juice and seafood processors under the HACCP regulations as well as those that would apply to food facilities under the Preventive Controls Proposed Rule. The proposal would direct the importer to use available information to determine whether its FSVP is inadequate and, if so, to appropriately revise its program so it meets the statutory requirement to provide adequate assurances that the food is compliant with applicable standards. Similarly, we believe that the proposed corrective action requirements are among those that, consistent with section 805(c)(2)(B) of the FD&C Act,

are necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

Proposed § 1.507(a) states that an importer must promptly conduct a review of any customer, consumer, or other complaint that the importer receives to determine whether the complaint relates to the adequacy of the importer's FSVP. Examples of such complaints might include a consumer complaint of illness following consumption of food imported by the importer and a customer complaint regarding a positive test for a pathogen in food received from the importer. Not all complaints that an importer might receive will concern its FSVP. However, complaints that might raise questions about how well an importer's FSVP is functioning could have a significant impact on food safety. For example, review of consumer complaints of illness linked to consumption of a product could result in an investigation revealing that a particular supplier is not adequately controlling a hazard, which could prompt the importer to reconsider whether the verification approach it uses with this product and supplier is appropriate. Therefore, we propose that importers be required to review all complaints to determine whether they relate to the FSVP.

Proposed § 1.507(b) states that if an importer becomes aware that an article of imported food is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act, either through review of a complaint or by other means, the importer must promptly investigate the cause or causes of such adulteration or misbranding and document any such investigation. An importer might learn that a food it imported is adulterated or misbranded as a result of investigating a complaint (such as a consumer reporting becoming ill after eating an imported food), being notified by FDA (such as during an Agency investigation of possible contamination), through media reports, or by other means. Regardless of how the importer

becomes aware of adulteration or misbranding, the importer would be required to promptly investigate what might have caused the problem with the food. The investigation would seek to determine the source of the adulteration or misbranding, such as contamination of a food with Salmonella due to the use of improperly cleaned machinery or the introduction of metal fragments generated during the manufacture of a food. In many cases, the investigation might require the importer to coordinate with the foreign supplier to evaluate the information on adulteration or misbranding and review relevant factors and processes (e.g., source of raw materials, procedures for harvesting, manufacturing, processing, packing, labeling, and transportation) to identify the source of the problem and take steps to correct it.

Proposed § 1.507(c) would require an importer to take appropriate corrective actions if it determines that one of its foreign suppliers did not produce the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produced food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act.

Proposed § 1.507(c) states that this determination regarding the need for corrective action could be based on an investigation conducted under § 1.507(b), the verification activities the importer conducts under § 1.506 or § 1.511(c) (the latter of which concerns verification requirements for importers of finished dietary supplements, discussed in section II.L.2 of this document), the FSVP reassessment that the importer conducts under proposed § 1.508 (discussed in section II.I of this document), or otherwise. Regardless of how an importer obtains the information that forms the basis of the importer's determination that its foreign supplier did not produce the imported food in accordance with the applicable requirements, the importer must take action in response to this noncompliance.

Proposed § 1.507(c) further states that the appropriate corrective actions by the importer 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. Finally, proposed § 1.507(c) would require the importer to document any corrective actions it takes in accordance with this provision.

Under proposed § 1.507(d), if an importer determines, by means other than its verification activities conducted under § 1.506 or § 1.511(c) or its FSVP reassessment conducted under § 1.508, that one of its foreign suppliers does not produce an imported food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w), the importer must promptly investigate to determine whether its FSVP is adequate and, when appropriate, modify the program. For example, FDA might inform an importer that the Agency has determined that one of the importer's foreign suppliers does not have an adequate food safety plan as required under section 418. Upon investigating, the importer might conclude that it should modify its supplier verification procedures to increase the likelihood that the importer will be able to detect future supplier noncompliance. Proposed § 1.507(d) further states that an importer must document any investigation, corrective actions, and FSVP changes it makes under this provision.

Proposed § 1.507(e) states that § 1.507 would not limit an importer's obligations with respect to other laws enforced by the Agency, such as those relating to product recalls. In addition to recall provisions, these laws might include, for example, the provisions on the Reportable Food Registry in section 417 of the FD&C Act (21 U.S.C. 350f).

I. Reassessment of FSVP (Proposed § 1.508)

Proposed § 1.508 answers the question, “How must I reassess the effectiveness of my FSVP?” Unless an importer periodically assesses how its FSVP is functioning, a once-effective program could become ineffective over time, due to changes to the foods that are imported, the processing methods of foreign suppliers, or other factors affecting safety. As with corrective actions, we believe that requiring importers to periodically reassess their FSVPs will help ensure that the FSVP is adequate to provide assurances that the food is compliant with applicable standards, within the meaning of section 805(c)(2)(A) of the FD&C Act. We also tentatively conclude that it is necessary and appropriate in accordance with section 805(c)(2)(B).

Proposed § 1.508(a) sets forth requirements concerning the timing of reassessments. Proposed § 1.508(a)(1) states that, except as specified in proposed § 1.508(a)(2), for each food imported, the importer must conduct a reassessment of its FSVP for the food, as described in proposed § 1.508(b), within 3 years of establishing the FSVP and within 3 years of the last reassessment. This requirement parallels the required frequency for periodic reanalysis of food safety plans in the Preventive Controls Proposed Rule. For the reasons stated in that proposed rule, we tentatively conclude that reevaluation is also necessary to ensure the continued validity of an FSVP.

Under proposed § 1.508(a)(2), however, an importer might be required to reassess its FSVP sooner than every 3 years. Proposed § 1.508(a)(2) would require an importer to reassess the effectiveness of its FSVP for a food it imports when the importer becomes aware of new information about potential hazards associated with the food. Examples of such information might include information on changes to raw materials or the source of raw materials, product formulation (e.g., a change that results in higher moisture in a processed cheese could lead to C.

botulinum), processing methods or systems (e.g., the foreign supplier switches from dedicated production lines for chocolate with nuts and chocolate without nuts to using combined production lines), finished product distribution systems, or the intended use or consumers of the food.

We tentatively conclude that effective reassessment of an importer's FSVP should begin with a reanalysis of the hazards that might be reasonably likely to occur with a food. Therefore, proposed § 1.508(b) would require an importer, in conducting a reassessment of its FSVP, to update its hazard analysis for the food in accordance with § 1.505. For example, if, subsequent to an importer's hazard analysis for a food, the food became linked to the outbreak of a disease with which the food was not previously associated, this could result in identification of a new hazard reasonably likely to occur with the food. Proposed § 1.508(b) further states that if the hazards the importer had previously identified as reasonably likely to occur change as a result of the reassessment, the importer must promptly determine whether the verification activities the importer conducts under § 1.506 need to be changed to comply with that section and, if so, promptly implement any such changes. For example, identification of a new hazard associated with a food could, depending on the type of hazard, necessitate a change in supplier verification activity in accordance with § 1.506.

J. Identification of Importer at Entry (Proposed § 1.509)

Proposed § 1.509 answers the question, "How must the importer be identified at entry?" Section 1.509 is intended to ensure that the importer of each food imported or offered for import into the United States is accurately identified so that the Agency can effectively implement and monitor compliance with the FSVP regulations.

1. Designation of U.S. Agent or Representative

Proposed § 1.509(a) would require, before an article of food is imported or offered for import into the United States, that the foreign owner or consignee of the food (if there is no U.S. owner or consignee) designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer” in § 1.500. This would ensure that, when there is no U.S. owner or consignee of the food at the time of U.S. entry, there will be an entity in the United States--the U.S. agent or representative of the foreign owner or consignee of the food--who will be responsible for meeting the FSVP requirements with respect to that food. We also note that, under the proposed regulations, the U.S. agent or representative may rely on qualified individuals to perform FSVP activities on its behalf.

2. Identification of the Importer

Proposed § 1.509(b) would require importers to obtain a DUNS number (if the importer does not already have one). Proposed § 1.509(c) would require an importer to ensure that, for each line entry of food product offered for importation into the United States, the importer’s name and DUNS number are provided electronically when filing entry with CBP to identify the importer of the product. Our reasons for proposing these requirements are twofold, although they both concern our ability to accurately identify importers who are subject to the FSVP regulations.

First, knowing the identity of the importer for a particular food being imported would help us carry out section 421(b) of the FD&C Act. This provision, also added by FSMA, requires FDA to allocate its resources for examining imported products based on certain risk factors, including the rigor and effectiveness of the importer’s FSVP. To effectively implement this, we need to know, at the time of importation, who the importer is. While we currently

receive information identifying the “importer” as part of entry and as part of prior notice under section 801(m) of the FD&C Act, the entities identified under those procedures are not necessarily the “importer” for the purposes of FSVP.

In addition, accurate information identifying importers will enable us to effectively implement, monitor compliance with, and enforce the FSVP requirements. This information would help the Agency create a comprehensive and up-to-date database that will enable us to efficiently and effectively monitor compliance with and enforce the FSVP regulations.

Obtaining the identity of the importer at entry could also help us meet the requirement, stated in section 805(g) of the FD&C Act, to “publish and maintain on [our] Internet Web site . . . a current list that includes the name and location of, and other important information deemed necessary by [FDA] about, importers participating under this section [i.e., section 805].” The meaning of the phrase “importers participating under this section” is ambiguous. Among other things, it could mean that the list must include all importers subject to section 805 or only those subject to section 805 and in compliance with that provision. If so, FDA must have a means of identifying these importers. One way to do this would be to obtain information about importers at the time they are shipping products for entry into the United States. We request comment on the meaning of the phrase and the purpose of section 805(g).

We considered requiring food importers to register with FDA to develop a database of importers. Some, but not all, importers currently register with FDA as food facilities and are assigned registration numbers under 21 CFR part 1, subpart H (§§ 1.225 through 1.243). Because not all importers are required to register, the current food facility registration system would not be sufficient for FSVP purposes. Moreover, obtaining the identity of the importer at the time of entry would enable us to both carry out section 421(b) of the FD&C Act and develop

a database of importers without creating a new or revised registration system. By collecting this information with each entry, we would know the firm's last importation date and would receive "fresh" information with each importation (as opposed to, with a registration system, when the firm updates its registration or periodically re-registers). With the information gathered at the time of entry, our database would be able to include the types of food the firm is importing, which would better enable the Agency to assess and allocate its compliance and enforcement resources. For example, this information would help us target for inspection firms that import high-risk products more often than other firms and enable us to identify importers who should participate in the recall of an adulterated food product.

To identify the importer, proposed § 1.509(b) would require each importer to obtain a DUNS number and proposed § 1.509(c) would require each importer to ensure that, for each line of entry of food product offered for importation, the importer's name and DUNS number are provided. DUNS is an international business entity listing system under which a company can obtain, at no charge, a unique identification number for a business entity. Dun and Bradstreet continuously updates the business entity information (e.g., name, address, contact numbers) based on automated searches of publicly available information and regular follow-up with each business entity. We believe that, using the DUNS numbers that would be submitted at entry for each importer of food, we could develop a database of information about importers (including their location and the foods they import) that would be comparable to the information that we could obtain through an importer registration system and also enable us to effectively monitor importers' compliance with the FSVP requirements. The importer's name and DUNS number would enable FDA to accurately identify the importer. The use of DUNS, as a unique numerical ID, is less prone to mistake or ambiguity than the use of the firm's name and address. Obtaining

both the importer's name and DUNS number would guard against inadvertent mistakes in providing just the latter. With respect to section 805(g) of the FD&C Act, depending on how we interpret this provision, the use of the unique DUNS number would help ensure that we have an accurate list of "importers participating under this section."

We are currently conducting the study, required under section 110(i) of FSMA, regarding the need for, and challenges associated with, development and implementation of a program that requires the use of a unique identification number for each registered food facility and, as appropriate, "each broker that imports food into the United States." We intend to take the results of this study into consideration in finalizing the requirements in proposed § 1.509 concerning identification of the importer at entry. We request comment on the proposed use of DUNS numbers to identify importers under the FSVP regulations and, if you recommend use of a different identifier, what that identifier should be.

3. Electronic Submission of Information

Proposed § 1.509(c) would require that the information identifying the importer of each line of entry of food product be provided electronically when filing entry with CBP. We tentatively conclude that this information must be submitted electronically to enable the Agency to effectively monitor and enforce compliance with the FSVP regulations. With several million product lines of food being imported into the United States each year, monitoring the safety of imported food imposes huge demands on FDA resources. In addition, the Agency has begun implementing the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) electronic import screening system to target higher-risk products for examination and sampling and minimize delays for shipments of lower-risk products. Requiring the electronic submission of importer information would improve the accuracy and therefore the

efficiency of PREDICT for the purposes of section 421(b) of the FD&C Act by allowing fast and accurate identification of importers not in compliance with the FSVP regulations. The CBP generally receives information about imports at entry in electronic form, so requiring electronic submission of importer information should require little change to import entry procedures. In addition, if section 805(g) of the FD&C Act is interpreted to mean that the list of participating importers must include all importers subject to section 805, or all importers subject to section 805 and in compliance with that provision, then it will be much more efficient to build such a database using information submitted electronically. For these reasons, we tentatively conclude that requiring the electronic submission of importer identifying information for a food when filing entry with CBP will help us effectively monitor and enforce compliance with the FSVP regulations and carry out section 421(b), and is therefore authorized under sections 805 (including section 805(c)(2)(B)), 421(b), and 701(a) of the FD&C Act.

K. Records (Proposed § 1.510)

Proposed § 1.510 answers the question, “How must I maintain records of my FSVP?”

Proposed § 1.510(a) would require importers to sign and date records concerning their FSVPs upon initial completion and upon any modification of the FSVP.

Proposed § 1.510(b) would require importers to maintain records required under the FSVP regulations in English and make these records available promptly to an authorized FDA representative, upon request, for inspection and copying. Section 805(d) of the FD&C Act states that records related to a foreign supplier verification program “shall be made available promptly to a duly authorized representative [of FDA] upon request.” Proposed § 1.510(b) therefore states that an importer must maintain records at its place of business or at a reasonably accessible location; records would be considered to be at a reasonably accessible location if they could be

immediately retrieved from another location by computer or other electronic means. Proposed § 1.510(b) further states that if requested in writing by FDA, an importer must send records to the Agency electronically rather than making the records available for Agency review at the importer's place of business. We tentatively conclude that requiring prompt delivery to FDA will better enable us to efficiently and effectively monitor importers' compliance with the FSVP regulations and is therefore also authorized by sections 805 and 701(a) of the FD&C Act. We also believe that such access would reduce the burden on importers posed by a visit by Agency representatives to an importer's place of business.

Proposed § 1.510(c) would require that all records be legible and stored to prevent deterioration or loss.

Proposed § 1.510(d) sets forth requirements for the retention of FSVP records. Consistent with section 805(d) of the FD&C Act, proposed § 1.510(d) would require importers to maintain all records for a period of at least 2 years, but the start of the 2-year period would differ depending on the type of record. We tentatively conclude that it is appropriate that importers maintain certain records, such as hazard analysis determinations, documentation of hazard control by an importer or its customer, and determinations that use of a particular foreign supplier verification activity is appropriate under § 1.506(g), for as long as the records remain in use and are not revised or replaced. Therefore, under proposed § 1.510(d)(1), except as specified in § 1.510(c)(2), importers must maintain records referenced in subpart L until at least 2 years after their use is discontinued (e.g., because the importer no longer imports a particular food, no longer uses a particular foreign supplier, or has changed its FSVP procedures).

Records that concern the actual performance of supplier verification activities, relate to complaints, investigations, and corrective actions associated with particular foods, or involve the

documentation of FSVP reassessments are not records that remain in use until revised; consequently, we tentatively conclude that the retention period for these records should begin at the time that the records are created or obtained. Therefore, proposed § 1.510(d)(2) would require importers to maintain records required under §§ 1.506(g)(1), (g)(2), and (h) (certain verification activities) (these would be the applicable provisions under Option 1 of the co-proposal regarding supplier verification activities; under Option 2, the relevant provisions would be § 1.506(g)(1) and (h)), 1.507 (investigations and corrective actions), 1.508 (FSVP reassessments), 1.511 (requirements for food subject to certain dietary supplement CGMP regulations), and 1.513(b) (conditions and requirements for food imported from a country whose food safety system FDA had officially recognized as comparable or determined to be equivalent) for a period of at least 2 years after the records were created or obtained, except that the importer must maintain records of any changes to its FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.

L. Dietary Supplements and Dietary Supplement Components (Proposed § 1.511)

Proposed § 1.511 answers the question, “What FSVP must I have if I am importing a food subject to certain dietary supplement good manufacturing practice regulations?” Under section 103(g) of FSMA, facilities that manufacture, process, pack, or hold dietary supplements, and that are in compliance with section 402(g)(2) (concerning CGMP regulations for dietary supplements) and 761 (concerning adverse event reporting for dietary supplements) of the FD&C Act (21 U.S.C. 342(g)(2) and 379aa-1, respectively), are exempt from the preventive controls requirements set forth in section 418 of the FD&C Act. We are proposing FSVP requirements for dietary supplements and dietary supplement components that reflect the food safety regulations applicable to those products (i.e., the dietary supplement CGMP regulations) rather

than the general approach of verifying that hazards identified as reasonably likely to occur are being adequately controlled.

The modified requirements would vary depending on whether the importer is bringing in the following:

- Dietary supplement components or dietary supplements that will be subjected to further processing (including packaging or labeling); or
- “Finished” dietary supplements.

The FSVP requirements applicable to the importation of these products are set forth below.

1. Dietary Supplements for Further Processing

The dietary supplement CGMP regulations in § 111.70 (21 CFR 111.70) include provisions requiring firms that manufacture, package, or label dietary supplements to establish specifications for, among other things, components and packaging, as follows:

- Specifications for each component used in manufacturing a dietary supplement (§ 111.70(b)).
- Specifications for dietary supplement packaging that may come in contact with dietary supplements (§ 111.70(d)).
- Specifications to provide assurance that products from a supplier for packaging and labeling as a dietary supplement (for distribution rather than return to the supplier) are adequately identified and consistent with the purchase order (§ 111.70(f)).

Part 111 (e.g., §§ 111.73 and 111.75) requires these firms to verify that the specifications established under § 111.70 are met. This applies regardless of whether the components are imported or sourced domestically.

We believe that these specification and verification provisions in the dietary supplement CGMP regulations provide adequate assurances, in light of the nature of the product being imported, that the supplier produces the food in compliance with sections 402 and 403(w) of the FD&C Act. For this reason, we are proposing, in § 1.511(a), that importers who are required to establish specifications under § 111.70(b), (d), or (f) with respect to a food they import, and who are in compliance with the requirements of part 111 applicable to determining whether those specifications are met, would not be required to comply with the requirements of §§ 1.503 through 1.508 (except § 1.506(a)). This would mean that such importers of dietary supplements and dietary supplement components complying with part 111 would not be required to comply with most of the generally applicable FSVP requirements, including those on review of food and supplier compliance status, hazard analysis, supplier verification (except for listing of suppliers), investigative and corrective actions, and FSVP reassessment. Instead, proposed § 1.511(a) would require such importers to comply with the requirements in part 111 applicable to determining whether the specifications they established are met for such food and with the requirements in §§ 1.506(a) (listing of foreign suppliers), 1.509 (identification of the importer at entry), and 1.510 (records). Proposed § 1.511(a) further states that this requirement would not limit these importers' obligations with respect to part 111 or any other laws enforced by FDA.

We note that if an importer who was required to establish specifications under § 111.70(b), (d), or (f) with respect to a food they imported was not in compliance with the requirements for determining whether those specifications were met, we could refuse admission of the food on the ground that it was adulterated because it was not in compliance with CGMP (under section 801(a)(1) of the FD&C Act) and, provided that an alternative FSVP was not in place, on the ground that the importer was in violation of section 805 of the FD&C Act

(concerning FSVPs) (under section 801(a)(3)). We anticipate that such an importer typically would seek to come into compliance with the relevant specification provisions of part 111, and thereby bring itself into compliance with proposed § 1.511(a), rather than elect to revise its approach to foreign supplier verification by complying with the “standard” FSVP requirements (e.g., regarding compliance status review, hazard analysis, and supplier verification).

We are proposing, in § 1.511(b), to establish similar requirements for importers who are not subject to these specification and verification requirements under part 111, but whose customers are subject to those requirements. The only difference from the requirements we are proposing for importers who are themselves subject to those specification provisions is that the importer also would have to obtain written assurance that its customer was in compliance with those provisions. Thus, proposed § 1.511(b) would provide that if an importer’s customer is required to establish specifications under § 111.70(b), (d), or (f) with respect to an imported food, the customer is in compliance with the requirements of part 111 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that it is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.506(a), 1.509, and 1.510, but is not required to comply with the requirements of §§ 1.503 through 1.508 (except § 1.506(a)).

We request comment on whether it is appropriate to establish modified FSVP requirements for importers of dietary supplements and dietary supplement components when the importer or its customer will be subject to the above-noted specification provisions in the dietary supplement CGMP regulations. If you believe that modified requirements are appropriate, we request comment on the appropriateness of the specific requirements that we have proposed.

2. Finished Dietary Supplements

We also are proposing modified FSVP requirements for importers of “finished” dietary supplements, by which we mean, for purposes of this proposal, packaged and labeled dietary supplements that are not subject to further processing. Foreign suppliers of these products are subject to the very detailed and comprehensive dietary supplement CGMP regulations. Suppliers that are in compliance with these regulations, and with section 761 of the FD&C Act (relating to serious adverse event reporting), are exempt from section 418 of the FD&C Act (preventive controls) with regard to the manufacturing, processing, packing, and holding of a dietary supplement. Therefore, we tentatively conclude that the verification conducted by importers of these products should be specific to these CGMP regulations.

One key difference in the FSVP requirements for importers of finished dietary supplements is that the importer would not have to evaluate the hazards reasonably likely to occur. This is appropriate because the dietary supplement CGMP regulations effectively address the control of relevant hazards by including provisions encompassing all aspects of dietary supplement production. Therefore, we tentatively conclude that the importer should verify its supplier’s compliance with part 111 and not conduct a separate hazard evaluation to use as a means to determine what to verify. Another potential key difference is that we are not proposing that importers of finished dietary supplements always be required to conduct onsite auditing for SAHCODHA hazards, as would be required under Option 1 of proposed § 1.506(g)(1), because we are not requiring these importers to conduct hazard analyses for the dietary supplements they import under § 1.511(c) and the relevant hazards are not necessarily SAHCODHA hazards. However, this potential difference would not exist under Option 2 of proposed § 1.506(g)(1).

For these reasons, we are proposing, under § 1.511(c)(1), that if a dietary supplement is being imported and neither § 1.511(a) nor (b) is applicable, the importer must comply with

§ 1.511(c) and the requirements in §§ 1.502 through 1.504 and §§ 1.507 through 1.510, but it is not required to comply with the requirements of §§ 1.505 and 1.506. Proposed § 1.511(c)(1) further states that this requirement does not limit the importer's obligations with respect to part 111 or any other laws enforced by FDA.

As part of their verification requirements, importers of finished dietary supplements also would be subject to the following supplier verification requirements (some of which mirror the standard requirements in proposed § 1.506), as follows:

- List of foreign suppliers: The importer must maintain a written list of foreign suppliers (proposed § 1.511(c)(2)).
- Foreign supplier verification procedures: The importer must establish and follow adequate written procedures for conducting foreign supplier verification activities (proposed § 1.511(c)(3)).
- Purpose of supplier verification: The importer's foreign supplier verification activities must provide adequate assurances that the supplier is producing the dietary supplement in accordance with the requirements of part 111 (i.e., the dietary supplement CGMP regulations) (proposed § 1.511(c)(4)).
- Supplier verification activities: For each dietary supplement imported, the importer must conduct one or more of the verification activities listed in proposed § 1.511(c)(5)(i) through (c)(5)(iv) before using or distributing the dietary supplement and periodically thereafter (proposed § 1.511(c)(5)). These are the same verification activities in proposed § 1.506(g)(2)(i) through (g)(2)(iv) under Option 1 and proposed § 1.506(g)(1)(i) through (g)(1)(iv) under Option 2 for supplier verification, i.e., periodic onsite auditing, periodic or lot-by-lot sampling and testing, periodic review of the foreign supplier's food safety records, and any other procedure

that the importer has established as being appropriate. The importer of the dietary supplement must determine and document which verification activity or activities are appropriate to adequately verify that the foreign supplier is in compliance with the requirements of part 111, and determine and document how frequently the verification activities must be conducted. As under proposed § 1.506(g)(2)(i) through (g)(2)(iv) (under Option 1), the importer would have to document, or obtain documentation of, any performance of these activities.

- Requirements of onsite auditing: Any onsite audit conducted under § 1.511(c)(5)(i) must consider the requirements of part 111 (proposed § 1.511(c)(6)). The audit also must include a review of the foreign supplier's written food safety plan, if any, and the supplier's implementation of such plan.

- Substitution of inspection for onsite audit: Instead of an onsite audit conducted under § 1.511(c)(5)(i), an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted (proposed § 1.511(c)(7)). For inspections conducted by an officially recognized or equivalent food safety authority, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in such country and under the regulatory oversight of the country's food safety authority.

- Review of results of verification activities: The importer must promptly review the results of the verification activities that it conducts or obtains documentation of under § 1.511(c)(5) (proposed § 1.511(c)(8)). If the results show that the foreign supplier does not

meet the standard in § 1.511(c)(4), the importer must take appropriate action in accordance with § 1.507(c).

- Independence of qualified individuals conducting verification activities: A qualified individual who conducts any of the verification activities set forth in § 1.511(c)(5) must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity (proposed § 1.511(c)(9)). This would not prohibit the importer or one of its employees from conducting the verification activity.

We request comment on whether establishing modified FSVP requirements for importers of finished dietary supplement is appropriate and, if so, whether the requirements we have proposed are appropriate.

We also request comment on whether it would be more appropriate to add the proposed FSVP requirements applicable to dietary supplements to the regulations on dietary supplement CGMP in part 111, instead of to the FSVP regulations in proposed subpart L of part 1. Such an approach would parallel the inclusion of importer requirements in the HACCP regulations on juice and seafood in parts 120 and 123 and might facilitate compliance by dietary supplement importers and suppliers with the applicable regulations.

3. Other Foods

We request comment on whether there are any other types of food, in addition to dietary supplements, for which we should establish modified foreign supplier verification requirements and, if so, what these requirements should be. For example, should they include an evaluation of the hazards reasonably likely to occur with the type of food or, as with finished dietary supplements, should there be no requirement to conduct a hazard analysis? Similarly, what verification activities would be appropriate for the type of food? Your comments should include

the rationale for any modified requirements, including whether, such as with dietary supplements, they are based on the nature of any existing regulations governing the manufacturing/processing, raising, or harvesting of the type of food. With respect to any such foods for which there are existing regulations establishing safety-related requirements (e.g., part 114 regarding acidified foods), part 118 regarding shell eggs), we also request comment on whether modified supplier verification requirements for importers of these foods should be added to the regulations concerning the production of these foods or to the FSVP regulations being proposed under this proposed rule (i.e., proposed subpart L of part 1).

M. Very Small Importers and Very Small Foreign Suppliers (Proposed § 1.512)

Proposed § 1.512 answers the question, “What FSVP may I have if I am a very small importer or I am importing from a very small foreign supplier?” As stated in sections I.C and II.A.8 of this document, we are proposing to adopt modified FSVP requirements for very small importers and food from very small foreign suppliers. Section 805(c)(3) of the FD&C Act directs FDA to, as appropriate, take into account differences among importers and types of imported food, including based on the level of risk posed by the imported food. The modified requirements we are proposing are for situations that involve a relatively low volume of imported food, which should reduce consumers’ exposure to, and thus potential risk from, the food.

As stated in proposed § 1.500, the proposed definitions of very small importer and very small foreign supplier would include a maximum annual sales volume of \$500,000 in annual food sales. This is a conservative measure of the volume of food imported into the United States because a supplier may ship food to other countries and an importer may sell both domestically sourced and imported food. Using annual sales of food, we believe, would be a workable approach for importers, suppliers, and FDA to determine who is subject to the modified

requirements applicable to very small importers and food from very small foreign suppliers. Other measures for the volume of imported food, while perhaps more precise, would be more complex. We request comment on our proposed measure.

In sections 418(l) and 419(f) of the FD&C Act, “qualified facilities” and certain farms are subject to qualified exemptions with modified requirements. Eligible establishments are defined, in part, based on the relatively limited value of their annual food sales, which for those provisions is also capped at \$500,000. The proposed modified FSVP requirements for very small importers and food from very small foreign suppliers are designed to specify verification activities that take into account the risk to overall public health posed by such food. In the context of the nature of their imports, we tentatively conclude that the modified requirements described below would be adequate to provide assurances that the foreign suppliers to these importers produce food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, as applicable, and sections 402 and 403(w) of the FD&C Act.

1. Eligibility

Proposed § 1.512(a) states that § 1.512 applies only when the importer is a very small importer or when the food it is importing is from a very small foreign supplier.

2. Applicable Requirements

Importers who meet the definition of very small importer may follow proposed § 1.512, but they could instead choose to follow the standard FSVP requirements (or the FSVP requirements under proposed § 1.513 for food from countries with officially recognized or equivalent food safety systems). Similarly, importers of food from very small foreign suppliers may follow proposed § 1.512, but they are not required to do so. Therefore, proposed §

1.512(b)(1) states that if § 1.512 applies and the importer chooses to comply with the requirements in this section, the importer must document, at the end of each calendar year, that it meets the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. Proposed § 1.512(b)(1) further states that, for the purpose of determining whether the definition of very small importer or very small foreign supplier is satisfied, the baseline year for calculating the adjustment for inflation is 2012. Proposed § 1.512(b)(1) adds that if the importer or the foreign supplier conducts any food sales in currency other than U.S. dollars, the importer 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.

Proposed § 1.512(b)(2) would require that if an importer is eligible to import a food under this section and chooses to comply with the requirements in § 1.512(b), it also must comply with the requirements in §§ 1.502 through 1.504 (concerning the “scope” of an FSVP, the use of qualified individuals, and review of food and foreign supplier compliance status, respectively) and § 1.509 (concerning identification of the importer at entry), but it is not required to comply with the requirements in §§ 1.505 through 1.508 or § 1.510. This means that very small importers and importers bringing in food from very small foreign suppliers would not have to meet many of the standard FSVP requirements, including those for hazard analysis and supplier verification.

3. List of Foreign Suppliers

Proposed § 1.512(b)(3) would require a very small importer and an importer who obtains food from very small foreign suppliers to maintain a written list of foreign suppliers from which it is importing food.

4. Supplier Verification

Under proposed § 1.512, very small importers and importers of food from very small foreign suppliers would not be required to conduct hazard analyses for each food they import. The other most significant modification of FSVP requirements for these entities involves supplier verification. Very small importers and importers of food from very small foreign suppliers would be required to obtain from their foreign suppliers, before importing a food and at least every 2 years thereafter, a written assurance that the 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 in compliance with sections 402 and 403(w) of the FD&C Act. We believe that it would be appropriate for importers to obtain this written assurance at least every 2 years so that the assurance that the importer obtains will more accurately reflect the current operations of the foreign supplier than would relying on assurance that was not updated.

To provide adequate assurance of the safety of the food obtained by very small importers and from very small foreign suppliers, we tentatively conclude that the written assurance from the foreign supplier must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food. Thus, the supplier would need to provide the importer with enough information about its processes and procedures to enable the importer to understand what the supplier is doing to ensure the safety of the imported food.

For these reasons, proposed § 1.512(b)(4) would require, for each food imported, that the very small importer or importer of food from a very small foreign supplier obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in compliance with processes and procedures that provide at least the same

level of public health protection as that required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. Proposed § 1.512(b)(4) further states that the written assurance must include a brief description of the processes and procedures that the foreign supplier is following to ensure the safety of the food.

Although we do not believe that merely checking the food safety plan of a supplier is an appropriate stand-alone verification activity under the standard supplier verification requirements in proposed § 1.506, we believe that obtaining written assurance of supplier compliance, including a description of the processes and procedures used to ensure safety, is an appropriate verification activity for importers of such food under proposed § 1.512. We request comment on whether these proposed verification activities are appropriate for very small importers and importers of food from very small foreign suppliers and, if not, what verification activities these importers should instead be required to conduct.

5. Corrective Actions

We tentatively conclude that it is appropriate that very small importers and importers of food from very small foreign suppliers not be required to comply with the provisions on complaint review and investigation of adulteration or misbranding in proposed § 1.507(a) and (b). Similarly, because these importers would be subject to the modified FSVP requirements set forth in § 1.512, we conclude that it is not appropriate to require these importers to comply with the requirements to investigate to determine the adequacy of, and make appropriate changes to, their FSVPs under proposed § 1.507(d).

However, we tentatively conclude that, as part of adequately verifying and ensuring the safety of imported food, very small importers and importers of food from very small foreign

suppliers should be required to take corrective actions if they determine that a foreign supplier is not producing a food in compliance with applicable requirements. Therefore, proposed § 1.512(b)(5) would require these importers to promptly take appropriate corrective actions if they determine that a foreign supplier 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, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act, and to document any such corrective actions. A need for corrective action could be based, for example, on the foreign supplier compliance status review conducted by the importer. Proposed § 1.512(b)(5) further states that 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. Proposed § 1.512(b)(5) also notes that this provision does not limit the importer's obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

6. Records

Because of the modified nature of the FSVP requirements for very small importers and importers of food from very small foreign suppliers, we are proposing to tailor the record keeping requirements in proposed § 1.510 for these importers as discussed below.

Proposed § 1.512(b)(6)(i) would require that a very small importer or importer of food from a very small foreign supplier maintain required FSVP records, in English, and make them available promptly to an authorized FDA representative, upon request, for inspection and copying. Further, proposed § 1.512(b)(6)(i) would require such an importer to maintain records at its place of business or at a reasonably accessible location; records would be considered to be

at a reasonably accessible location if they could be immediately retrieved from another location by computer or other electronic means. Finally, proposed § 1.512(b)(6)(i) would require a very small importer or importer of food from a very small foreign supplier, when requested in writing by FDA, to send records to the Agency electronically or by mail rather than making the records available for review at its place of business. We propose to allow these importers to provide records by mail instead of electronically in the event that providing records electronically might be significantly burdensome to some of these entities (e.g., due to increased computer-related expenses).

Proposed § 1.512(b)(6)(ii) would require that all records maintained by very small importers and importers of food from very small foreign suppliers be legible and stored to prevent deterioration or loss.

Because they are subject to different FSVP requirements, very small importers and importers of food from very small foreign suppliers, unlike other importers, will not be creating records that need to be maintained for as long as the records remain in use, such as records of hazard analysis determinations and determinations as to appropriate verification activities. Consequently, proposed § 1.512(b)(6)(iii) would require these importers to maintain required FSVP records for a period of at least 2 years after the records were created or obtained. Such records would include documentation of eligibility as a very small importer or importer of food from a very small foreign supplier, food and foreign supplier compliance status reviews, written assurances from foreign suppliers, and documentation of corrective actions.

N. Food from Countries with Officially Recognized or Equivalent Food Safety Systems
(Proposed § 1.513)

Proposed § 1.513 answers the question, “What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?” Proposed § 1.513 addresses the circumstances under which importers would be subject to modified FSVP requirements for food from a country whose food safety system we have officially recognized as comparable to that of the United States (e.g., through a signed systems recognition arrangement or other agreement between FDA and the country officially recognizing the foreign food safety system) or that we have determined to be equivalent to that of the United States, for foods under FDA’s jurisdiction. We are developing an approach for systems recognition involving assessing the food safety system of a foreign country and determining whether the system may be deemed comparable to that of the United States.

1. Bilateral and International Efforts to Enhance FDA’s Food Safety Capability

FDA is developing several complementary tools to assess countries’ food safety systems (or parts of these systems) that are specific to countries’ particular interests and the maturity of their regulatory systems. Food safety authorities in other countries may wish to have FDA assess their food safety systems in their entirety through systems recognition (discussed in section II.N.2 of this document), or they may pursue assessments of their food safety controls and oversight for particular export products through FDA’s future third-party accreditation program (see the proposed rule published elsewhere in this issue of the Federal Register). Additionally, we will continue our longstanding practice of entering into commodity-specific arrangements and agreements with regulatory authorities in other countries to help ensure that specific commodities imported to the United States are safe.

An example of FDA’s ongoing efforts involving commodity-specific arrangements is the establishment of memoranda of understanding (MOUs) covering molluscan shellfish. Countries

with which FDA has signed molluscan shellfish MOUs include Canada, Mexico, South Korea, and New Zealand. Shellfish processors certified by competent authorities in these countries are listed on the Interstate Certified Shellfish Shippers List (ICSSL). U.S. importers may use the ICSSL to meet their requirements under FDA's seafood HACCP regulations.² FDA's Systems Recognition Assessment Program

FDA is developing a program for conducting food safety systems recognition assessments to, among other things, assist us with setting our food safety regulatory priorities. Systems recognition is one tool that FDA can use to incorporate the efforts of foreign food safety systems into our risk-based decision making regarding inspections, monitoring, admissibility, and outbreak response. Another tool is accreditation of foreign governments to audit and certify foreign food facilities and foods offered for import into the United States. Because the national food safety control systems in place in different countries are unique, have varying outcomes, and differ in their approaches to providing assurances of the safety of exported food, we plan to work with competent authorities in different countries to determine which tools might be most appropriate for different systems and/or commodities. Our use of systems recognition will not preclude the use of other tools to help ensure the safety of imported food; rather, to the extent possible, we will use a variety of tools to leverage the work done by foreign food safety authorities to facilitate this effort.

We envision a systems recognition assessment as a process for determining that (1) a country's food safety system provides a similar, though not identical, system of protections as the U.S. food safety system, and (2) the country's food safety authority provides similar oversight and monitoring activities for food produced under its jurisdiction. Systems recognition

is based on the conclusion that food safety systems with similar elements and similar levels of oversight lead to similar food safety outcomes.

A public hearing on systems recognition, which at the time was termed “comparability,” was held in March 2011, and a transcript of the hearing is posted on FDA’s Web site at

<http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm243781.htm>. We

conducted a systems recognition assessment pilot project with New Zealand and signed a systems recognition arrangement with that country in December 2012. Information regarding this pilot project and outcomes can be found on FDA’s Web site at

<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm331276.htm>. Neither the

FD&C Act nor FSMA explicitly mentions systems recognition. While the concept of systems recognition, the development of assessment tools, and the launching of the systems recognition pilot were initiated before the enactment of FSMA, systems recognition is consistent with several of the principles of FSMA, including a preventive approach to food safety, leveraging of resources to help ensure the safety of domestic and imported foods, and the development of enhanced regulatory partnerships.

The systems recognition initiative supports FDA strategies to accomplish Agency goals in our global approach to food safety regulation, as outlined in the Commissioner’s June 2011 report on the “Pathway to Global Product Safety and Quality” (Ref. 2). The systems recognition initiative focuses on creating global coalitions of regulators, building global data-information systems and networks, expanding capabilities in intelligence gathering and use (through the use of risk analytics and modernized information technology), and leveraging efforts of government authorities. In an era when the amount of food traded internationally increases annually, systems

recognition will serve as a key tool for FDA to build partnerships, leverage resources, and strengthen international food safety.

As currently structured, FDA's systems recognition assessment process involves a review of a country's food safety system by a team of FDA scientists, auditors, and investigators. The process includes a review of the elements of the country's food safety programs, including any export-specific programs. We are developing processes and procedures for conducting systems recognition assessments. The draft International Comparability Assessment Tool (ICAT) is a self-assessment tool that, along with analyses of compliance information, in-country assessments, and other information, will help us determine whether a country has a food safety system that is comparable to that of the United States. The ICAT provides an objective framework in which to assess certain factors affecting the effectiveness of a country's food safety system. These factors are a country's regulatory foundation, training program, inspection program, program assessment and audit program, control of food-related illness and outbreaks (including trace-back and emergency preparedness systems), compliance and enforcement, industry and community relations, program resources, international communication and harmonization, and laboratory support. Using lessons learned in the New Zealand pilot, we have revised and updated the ICAT (including by adding a reference guide for countries to use as they complete the self-assessment), and we have initiated a second pilot assessment project with Canada.

A systems recognition assessment consists of two principal stages. After satisfactory completion of a documentation review of a country's ICAT submission, audit teams from FDA, including persons specializing in particular high-risk commodities, will perform an in-country assessment to verify the implementation of programs and measures as outlined in the ICAT

submission. The assessments provide an objective and comprehensive means of assessing the level of assurance that the foreign food safety authority can provide that food produced in that country is as safe as food produced in the United States. An assessment also will incorporate data from the country's food safety system (e.g., review of the regulatory performance of the food safety authority and hazard monitoring databases) as well as data collected by FDA (e.g., through border examinations, notifications/recalls, and foreign audits and inspections). After successful completion of documentation and in-country reviews, FDA may determine that a country's food safety system is "comparable." If so, we intend to officially recognize the country's food safety system through a formal mechanism, such as establishing a systems recognition arrangement with the relevant food safety authority of the country. We expect to determine whether a country's food safety system continues to be comparable through open bilateral communications and periodic review. The specific process for periodic review is still in development as we establish the operational details of this new program.

We intend to leverage the work being done by food safety authorities in countries whose food safety systems we have officially recognized to enhance our capabilities in ensuring the safety of imported foods. Systems recognition arrangements and other agreements establishing official recognition will not be static, but rather will serve as the basis for ongoing exchange and partnership, and will be reviewed and updated as appropriate. These arrangements are likely to also involve provisions for enhanced information exchange (e.g., inspection findings) and emergency response partnerships.

3. Equivalency

In addition to food imported from foreign suppliers in countries with officially recognized food safety systems, proposed § 1.513 addresses food imported from suppliers in

countries whose food safety systems are determined to be “equivalent.” In 1998, the United States and the European Union (EU) signed the Agreement between the European Community and the United States of America on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products, known as the Veterinary Equivalency Agreement (VEA) (Ref. 12). Due to the complexity of determining equivalence, FDA and its EU counterpart thus far have been unable to conclude that there is full equivalence with respect to the FDA-regulated products that fall within the scope of the VEA.

FDA has found equivalence determinations, under the VEA and otherwise, to be technically difficult and resource intensive. Equivalence determinations have involved a review of each measure (e.g., laws, regulations, requirements, procedures, processes, production methods) in place in each country to determine whether the exporting country meets the importing country’s level of protection associated with each measure. In an effort to achieve efficiencies in the review of food safety systems, we are considering how to achieve similar objectives using the systems recognition approach.

4. Proposed Provisions on Importation of Food from Countries with Officially Recognized or Equivalent Food Safety Systems

Under proposed § 1.513, the importation of food from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable to that of the United States (e.g., when FDA and the other country have signed a systems recognition arrangement or other agreement establishing official recognition of the foreign food safety system) or that FDA has determined to be equivalent to that of the United States would be subject to modified FSVP requirements when certain conditions are met and documented. These conditions are that (1) the foreign supplier must be in, and under the

regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, and (2) the food must be within the scope of the relevant official recognition or equivalency determination.

When these conditions are met, the importer would be required to determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located.

Proposed § 1.513(a) states that if an importer meets the conditions and requirements of § 1.513(b) for a food that it is importing, the importer is not required to comply with the requirements in §§ 1.503 through 1.508 (except § 1.506(a) (concerning listing of foreign suppliers)). As such, the importer would not be required to, for example, conduct a hazard analysis (§ 1.505) or the standard supplier verification (§ 1.506). Proposed § 1.513(a) further states that the importer would still be required to comply with the requirements in §§ 1.506(a), 1.509 (concerning identification of the importer at entry), and 1.510 (concerning records).

Proposed § 1.513(b)(1) would require an importer, before importing a food from the foreign supplier and annually thereafter, to document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States and that the food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located. For example, if we completed an equivalence determination for grade A dairy products with country "X", proposed § 1.513 would not apply to the importation of other products from that country.

Proposed § 1.513(b)(2) would require an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier is in good compliance

standing, as defined in proposed § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer would be required to continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicated that food safety hazards associated with the food were not being adequately controlled, the importer would be required to take prompt corrective action. The appropriate corrective action would depend on the circumstances but could include discontinuing use of the foreign supplier. Proposed § 1.513(b)(2) also would require the importer to document any corrective actions that it undertakes.

As defined in proposed § 1.500, good compliance standing with a foreign food safety authority would mean that the foreign supplier (1) appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of establishments that are in good compliance standing with the food safety authority, or (2) has otherwise been designated by such food safety authority as being in good compliance standing. Because it is possible that not all countries whose food safety systems we have officially recognized as comparable or determined to be equivalent may choose to maintain a list of food manufacturers that are in good compliance standing, we believe it is appropriate to provide for the possibility that countries may use other methods to designate food manufacturers as being in good compliance standing. We request comment on what should constitute good compliance standing under proposed § 1.513, as well as what documents or other information issued by a food safety authority should be acceptable to demonstrate that a foreign supplier of a food is in good compliance standing with that food safety authority.

We request comment on the appropriateness of our proposed modified FSVP requirements for food imported from a foreign supplier in, and under the regulatory oversight of,

a country whose food safety system we have officially recognized as comparable or determined to be equivalent to that of the United States, including the proposed conditions and modified FSVP requirements that would be applicable to such imported food.

As described in section II.N.1 of this document, the establishment of commodity-specific arrangements and agreements provides FDA and foreign governments with an important tool, in addition to systems recognition and the use of accredited third-party auditors, for leveraging work done by food safety authorities in those countries. The selection of the most appropriate tool for a particular country and/or a particular commodity will be made by FDA in consultation with the food safety authority of the particular country. Important factors affecting this decision include the volume of food and types of commodities that a country exports to the United States and the regulatory structure of the foreign country. We request comment on what FSVP requirements might be appropriate for food imported from countries whose food safety authorities have entered into commodity-specific arrangements or agreements with FDA.

As discussed elsewhere in this document, the Preventive Controls Proposed Rule seeks comment on what requirements might be appropriate with respect to supplier approval and verification programs for raw materials and ingredients. Any such requirements would likely apply regardless of whether the supplier is located in the United States or in another country and, therefore, would apply regardless of the level of government oversight. In light of this, we request comment on whether it would be appropriate for the modified requirements in proposed § 1.513 of the FSVP regulations to be applicable to the importation of raw materials and ingredients.

O. Consequences of Failure to Comply (Proposed § 1.514)

Proposed § 1.514 answers the question, “What are some consequences of failing to comply with the requirements of this subpart?” This section addresses certain circumstances related to noncompliance with the FSVP regulations under which we may refuse admission of certain foods. In addition, this section codifies the provision in FSMA designating as a prohibited act the importation of a food without an appropriate FSVP.

Proposed § 1.514(a) states that an article of food is subject to refusal of admission under section 801(a)(3) of the FD&C Act if it appears that the importer of that food fails to comply with subpart L with respect to that food. This provision incorporates into the regulations section 301(c) of FSMA, which amended section 801(a) of the FD&C Act.

Proposed § 1.514(a) further states that if an article of food has not been sold or consigned to a person in the United States at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has designated a U.S. agent or representative as the importer for the purposes of the definition of “importer” in § 1.500. We tentatively conclude that when no designation has been made under section 805(a)(2)(B) of the FD&C Act, the “importer” for the purposes of refusal of admission in accordance with section 301(c) of FSMA is the foreign owner or consignee.

Proposed § 1.514(b) states that the importation or offering for importation into the United States of an article of food by an importer without having an FSVP that meets the requirements of section 805 of the FD&C Act, including the requirements of subpart L, is prohibited under section 301(zz) of the FD&C Act. This provision incorporates into the regulations section 301(b) of FSMA, which amended section 301 of the FD&C Act.

Regardless of whether an importer is in compliance with the FSVP requirements, the food or the importer might still be in violation of other applicable requirements. For example, if the food was nonetheless adulterated or misbranded, it could not be introduced or delivered for introduction into interstate commerce under section 301(a) of the FD&C Act and it would be subject to refusal of admission under section 801(a) of the FD&C Act. The FSVP regulations would not limit FDA's ability to take action to ensure that noncompliant food does not reach consumers.

III. Preliminary Regulatory Impact Analysis

A. Overview

We have examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (along with the benefits and costs of the proposed rule on "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," Docket No. FDA-2011-N-0146) (Ref. 13). We believe that the proposed rule is a significant regulatory action as defined by Executive Order 12866. We request comment on the PRIA.

The summary analysis of benefits and costs included in the Executive Summary of this document is drawn from the detailed PRIA, which is available at <http://www.regulations.gov>

(enter Docket No. FDA-2011-N-0143), and is also available on FDA's Web site at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to adopt FSVPs or conduct additional verification activities, we acknowledge that the final rule resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of

\$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. We expect that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the proposed rule have been submitted to OMB for review under section 3507(d) of the Paperwork Reduction Act. We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.”

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for

review. These requirements will not be effective until FDA obtains OMB approval. We will publish a notice concerning OMB approval of these requirements in the Federal Register.

F. Public Access to the Analyses

The analyses that FDA has performed to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act of 1995, and the Paperwork Reduction Act of 1995 are available to the public in the docket for this proposed rule (Ref. 13).

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we tentatively conclude that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Proposed Effective and Compliance Dates

We propose that any final rule on FSVPs become effective 60 days after the date on which it is published in the Federal Register. Section 301(d) of FSMA states that the amendments to the FD&C Act made by section 301-- i.e., section 805 of the FD&C Act

concerning FSVPs -- shall take effect 2 years after the date of the enactment of FSMA, i.e., on January 4, 2013. Although section 805 took effect on January 4, 2013, we intend to require importers to comply with section 805 in accordance with the effective and compliance dates that will be established when we finalize the rule implementing section 805.

Although we are proposing that the FSVP final rule become effective 60 days after the date of publication in the Federal Register, we are proposing to provide additional time before importers would be required to come into compliance. In general, the compliance date would be 18 months after the publication date of the final FSVP regulations. We believe this would give importers enough time to make changes to their business practices that would be needed to come into compliance with the various requirements we are proposing.

We are proposing exceptions to this approach that would provide different compliance dates applicable to the importation of food that is the subject of certain regulations that are currently in development -- specifically, the proposed regulations on preventive controls for human food (as well as the future proposed regulations on preventive controls for animal food) and the proposed regulations on produce safety. In the Preventive Controls Proposed Rule, we proposed a compliance date for the preventive controls regulations of 1 year after the date of publication of the final rule, with an additional 1 year for small businesses and an additional 2 years for very small businesses (78 FR 3646 at 3674). (We anticipate that we will issue the final rules on preventive controls for human food and preventive controls for animal food on the same date, and that these regulations will share the same effective and compliance dates.) Regarding the FSVP provisions, we are proposing that, with respect to a particular food, the importer be required to comply with the FSVP regulations 6 months after the foreign supplier of the food is required to comply with the preventive controls regulations (i.e., 6 months after the applicable

compliance date for the supplier under those regulations). Our goal is to avoid a situation in which an importer would be required to develop an FSVP for a food from a particular supplier and then be required to revise this FSVP shortly thereafter once the supplier is subject to the preventive controls regulations. Because different foreign suppliers will be required to comply with those regulations at different times (e.g., based on the size of the firm), our proposed compliance dates for FSVP would be staggered depending on who the importer's supplier or suppliers are.

Some foreign suppliers that are farms would be subject to the new standards for produce safety that we have proposed to establish in part 112. Importers will not be certain which farm suppliers are covered by the produce safety standards or when a foreign supplier will be required to comply with the standards until a final produce safety rule is issued. If importers are required to conduct verification activities before a farm is subject to the produce rule, some importers could be required to change their verification activities for the supplier after the produce rule is in effect because, for example, the produce rule will establish food safety regulations that must be considered in any audit. RACs that are not fruits or vegetables would not be covered by the produce rule. Nonetheless, waiting to implement the FSVP requirements for all RACs from farms until after the produce safety rule is effective will facilitate implementation.

In light of these circumstances, we believe that it is reasonable to stagger the compliance dates for FSVP activities for RACs from farms as follows:

- The compliance date for an importer to comply with the FSVP regulations with respect to a RAC from a farm would be 18 months after the publication date of the final rule or 6 months after the date on which the supplier must be in compliance with the produce safety regulations, whichever is later.

- If the foreign supplier is not subject to the produce safety regulations, the compliance date for an importer to comply with the FSVP regulations with respect to a RAC received from a farm would be 18 months after the publication date of the final rule or 6 months after the effective date of the produce final rule, whichever is later. This approach would ensure that the receiving facility would be able to know whether the farm supplier is subject to the produce safety regulations before choosing any appropriate verification activities.

We request comment on our proposed approach to compliance dates.

VII. Comments

We invite public comment on the matters specified in this document as well as any other matters concerning the proposed FSVP regulations that are of interest. As previously stated, we issued the Preventive Controls Proposed Rule and the Produce Safety Proposed Rule on January 14, 2013. We understand that many persons who are directly affected by, or otherwise interested in, those proposed regulations also are affected by, or interested in, the proposed FSVP regulations, and that aspects of the FSVP proposed rule might affect views regarding the previously issued rules. To address these concerns, on April 26, 2013, we issued documents in the Federal Register (78 FR 24691 and 24692) extending the comment periods on the preventive controls and produce safety proposed rules to September 16, 2013, to allow additional time for interested persons to consider the potential impact of the proposed FSVP regulations on those rules.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the heading of this document.

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (We have verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. U.S. Food and Drug Administration, “Annual Report to Congress on Food Facilities, Food Imports, and FDA Foreign Offices Provisions of the FDA Food Safety and Modernization Act,” August 2012 (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>)

2. U.S. Food and Drug Administration, “Pathway to Global Product Safety and Quality,” July 2011 (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/GlobalProductPathway/default.htm>).

3. Centers for Disease Control and Prevention, Multistate Foodborne Outbreaks (<http://www.cdc.gov/outbreaknet/outbreaks.html>). 4. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm).

5. Notification to World Trade Organization, Committee on Sanitary and Phytosanitary Measures, G/SPS/N/USA/2156, February 14, 2011 (<https://docs.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/SPS/NUSA2156.DOC>)

).

6. Codex Committee on Food Import and Export Inspection and Certification Systems; Guidelines for Food Import Control Systems (CAC/GL 47-2003)

(http://www.codexalimentarius.net/download/standards/10075/CXG_047e.pdf)

7. U.S. Government Accountability Office (GAO), “Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources” (GAO-11-286), April 2011 (<http://www.gao.gov/new.items/d11286.pdf>).

8. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998, Hazard Analysis and Critical Control Point Principles and Application Guidelines, Journal of Food Protection, 61:1246-1259

(<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm>).

9. Codex Alimentarius Committee (CAC), 2003, General Principles of Food Hygiene (CAC/RCP 1-1969) (rev. 4-2003)

(http://www.codexalimentarius.net/download/standards/23/CXP_001e.pdf).

10. Grocery Manufacturers Association (GMA), Food Supply Chain Handbook, April 18, 2008 (http://gmaonline.org/downloads/technical-guidance-and-tools/GMA_SupplyChain2.pdf).

11. The Global Food Safety Initiative (GFSI), GFSI Guidance Document, Version 6.2 (http://www.mygfsi.com/gfsifiles/Overview_GFSI_Guidance_Document_Sixth_Edition_Version_6.2.pdf).

12. Agreement between the European Community and the United States of America on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal

Products

(<http://ec.europa.eu/world/agreements/downloadFile.do?fullText=yes&treatyTransId=751>).

13. U.S. Food and Drug Administration, 2013, “Preliminary Regulatory Impact Analysis,” Docket Nos. FDA-2011-N-0143, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, and FDA-2011-N-0146, Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.

(<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>)

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 384a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Add subpart L, consisting of §§ 1.500 through 1.514 to read as follows:

Subpart L--Foreign Supplier Verification Programs for Food Importers

Sec.

1.500 What definitions apply to this subpart?

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

- 1.502 What foreign supplier verification program (FSVP) must I have?
- 1.503 Who must develop my FSVP and perform FSVP activities?
- 1.504 What review of a food and foreign supplier's compliance status must I conduct?
- 1.505 What hazard analysis must I conduct?
- 1.506 What foreign supplier verification and related activities must I conduct?
- 1.507 What investigations and corrective actions must I conduct under my FSVP?
- 1.508 How must I reassess the effectiveness of my FSVP?
- 1.509 How must the importer be identified at entry?
- 1.510 How must I maintain records of my FSVP?
- 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?
- 1.512 What FSVP may I have if I am a very small importer or I am importing from a very small foreign supplier?
- 1.513 What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?
- 1.514 What are some consequences of failing to comply with the requirements of this subpart?

Subpart L--Foreign Supplier Verification Programs for Food Importers

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart.

Other definitions of these terms may apply when they are used in other subparts of this part.

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

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

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

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) and other ingredients.

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

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

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

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

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

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

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

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

Importer means the person in the United States who has purchased an article of food that is being offered for import into the United States. If the article of food has not been sold to a person in the United States at the time of U.S. entry, the importer is the person in the United States to whom the article has been consigned at the time of entry. If the article of food has not been sold or consigned to a person in the United States at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry.

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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

Qualified individual means a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart. This person may be, but is not required to be, an employee of the importer. Regarding the performance of verification activities related to preventive controls implemented by the foreign supplier in accordance with section 418 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g), a qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a

standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety system. A qualified individual includes, but is not limited to, a third-party auditor that has been accredited in accordance with section 808 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384d). A foreign government employee could be a qualified individual.

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

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

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

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

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

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

(b) Exemption for certain juice and seafood products. The regulations in this subpart do not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the regulations on juice in

part 120 of this chapter or the regulations on fish and fishery products in part 123 of this chapter. If you import juice or fish and fishery products that are subject to the regulations in part 120 or part 123 of this chapter, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

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

(d) Exemption for food imported for personal consumption. The regulations in this subpart do not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

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

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

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

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

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

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

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

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

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

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

(a) General. Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that

provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w)).

(b) Low-acid canned foods. With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid canned food packaged in a hermetically sealed container, you must verify and document that the food was produced in accordance with part 113 of this chapter. With respect to all matters that are not controlled by part 113 of this chapter, you must have an FSVP as specified in paragraph (a) of this section.

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

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

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

Before importing a food from a foreign supplier, you must review the compliance status of the food and the foreign supplier, including whether they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. You must

document this review. You must continue to monitor and document the compliance status as long as you import the food from the foreign supplier.

§ 1.505 What hazard analysis must I conduct?

(a) Requirement of a hazard analysis. Except as permitted under paragraphs (d) and (e) of this section, for each food you import, you must determine the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur. You must document this determination and use it to determine appropriate verification activities in accordance with § 1.506.

(b) Potential hazards. Your evaluation of the hazards that are reasonably likely to occur with each food you import must consider hazards that may occur naturally or may be unintentionally introduced, including the following:

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

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

(3) Physical hazards; and

(4) Radiological hazards.

(c) Hazard evaluation. In evaluating the hazards set forth in paragraph (b) of this section, you must consider the effect of the following on the safety of the finished food for the intended consumer:

(1) The ingredients of the food;

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

- (3) Transportation practices;
- (4) Harvesting, raising, manufacturing, processing, and packing procedures;
- (5) Packaging and labeling activities;
- (6) Storage and distribution;
- (7) Intended or reasonably foreseeable use;
- (8) Sanitation, including employee hygiene; and
- (9) Any other relevant factors.

(d) Review of hazard analysis developed by foreign supplier. If your foreign supplier has conducted a hazard analysis for the food, you may identify the hazards that are reasonably likely to occur for a particular food by reviewing and evaluating the hazard analysis conducted by the foreign supplier. You must document the determination you make based on this review and evaluation.

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

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

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

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

(c) Purpose of supplier verification. Except with respect to verification activities specified in paragraph (h) of this section concerning raw agricultural commodities that are fruits or vegetables and that are subject to part 112 of this chapter, your foreign supplier verification activities must provide adequate assurances that the hazards you have identified as reasonably likely to occur are adequately controlled.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 1 for Importers of Certain Produce

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

Option 2 for Importers of Certain Produce

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

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

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

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

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

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

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

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

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

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

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

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

§ 1.509 How must the importer be identified at entry?

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

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

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

§ 1.510 How must I maintain records of my FSVP?

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

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

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

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

Option 1

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

Option 2

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

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

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

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

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

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

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

(4) Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that your supplier is producing the dietary supplement in accordance with the requirements of part 111 of this chapter.

(5) Supplier verification activities. For each dietary supplement you import under paragraph (c) of this section, you must conduct one or more of the verification activities listed in paragraphs (c)(5)(i) through (iv) of this section before using or distributing the dietary supplement and periodically thereafter. You must determine and document which verification activity or activities are appropriate to adequately verify that the foreign supplier is in compliance with the requirements of part 111 of this chapter. You must determine and document how frequently the verification activities must be conducted.

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

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

(iii) Periodic review of the foreign supplier's food safety records. You periodically review (and document) or obtain documentation of a review of your foreign supplier's food safety records.

(iv) Other appropriate procedure. You use any other procedure that you have established as being appropriate. You must document your use of any such procedure.

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

(7) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. Instead of an onsite audit conducted under paragraph (c)(5)(i) of this section, an importer may rely on the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(8) Review of results of verification activities. You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5) of

this section. If the results show that the foreign supplier does not meet the standard in paragraph (c)(4) of this section, you must take appropriate action in accordance with § 1.507(c).

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

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

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

(b) Applicable requirements. (1) Documentation. If this section applies and you choose to comply with the requirements in this section, you must document, at the end of each calendar year, that you meet the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. For the purpose of determining whether you satisfy the definition of very small importer or the foreign supplier satisfies the definition of very small foreign supplier, the baseline year for calculating the adjustment for inflation is 2012. If you or the foreign supplier conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(2) Additional requirements. If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the

requirements in §§ 1.502 through 1.504 and § 1.509, but you are not required to comply with the requirements in §§ 1.505 through 1.508 or § 1.510.

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

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

(5) Corrective actions. You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph. This

paragraph does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

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

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

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

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

(a) General. If you meet the conditions and requirements of paragraph (b) of this section for a food you are importing, then you are not required to comply with the requirements in §§ 1.503 through 1.508 (except § 1.506(a)). You would still be required to comply with the requirements in §§ 1.506(a), 1.509, and 1.510.

(b) Conditions and requirements. (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is

within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located.

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

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

(a) Refusal of admission. An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)(3)) if it appears that the importer of that food fails to comply with this subpart with respect to that food. If an article of food has not been sold or consigned to a person in the United States at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has designated a U.S. agent or representative as the importer for the purposes of the definition of "importer" in § 1.500.

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

of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(zz)).

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Leslie Kux,

Assistant Commissioner for Policy.

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